

**Recovery from extra capsular hip fracture.
A longitudinal qualitative study of
patients' experiences.**

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Abstract

Introduction: Evaluating recovery from hip fracture is important to ensure optimum care and the best outcomes for patients. Measuring outcomes is difficult due to heterogeneity in the hip fracture population and confounders such as ageing and co-morbidities. Current consensus recommends measuring mortality, pain, mobility, activities of daily living and quality of life using the EuroQol 5 Dimension score (EQ-5D) after hip fracture. However there is currently a lack of understanding of the longitudinal experience of recovery from hip fracture and the implications that this might have for outcome measurement.

Objectives: To explore patient experiences of recovery in the year following hip fracture.

Methods: Longitudinal qualitative semi-structured interviews were conducted with eleven extracapsular hip fracture patients (six men, age 69-92 years) in three phases over twelve months. Using thematic analysis methods, the data were coded and grouped into themes cross-sectionally within each phase and longitudinally across the phases.

Findings: The findings suggested there was a sequential experience in recovery. Early priorities focused on a theme of 'physical and functional recovery'. Later, participants focused on recovering the 'effect on lifestyle' and 'emotional response' from the fracture. This supported participants to regain their sense of identity - adapting to and accepting the injury, in the context of their individual health and age - essential for a feeling of having recovered. Successful recovery was described as having achieved a satisfactory 'new normal'.

Conclusions: This study highlighted a breadth of experience not currently included in consensus recommendations for health measurement, and that experiences continue to change across the 12 months. Findings from this study suggested that measuring outcomes with the EQ5D up to four months post injury may oversimplify the patient's experience of, and priorities for, recovery following a hip fracture.

Keywords: hip fracture, experience, recovery, longitudinal, qualitative

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Abbreviations

ACR	American College of Rheumatology
ADL	Activities of Daily Living
AMED	Allied and Complementary Medicine Database
BGS	British Geriatric Society
BNI	British Nursing Index
BOA	British Orthopaedic Association
BOAST	British Orthopaedic Association Standards for Trauma
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COMET	Core Outcome Measurement in Evaluative Trials
COPM	Canadian Occupational Performance Measure
COSMIN	Consensus-based Standards for the selection of health Measurement INstruments
CPN	Community Psychiatric Nurse
CSP	Chartered Society of Physiotherapy
CtIMP	Clinical trial of an Investigational Medicinal Product
EQ-5D	EuroQol 5 dimension score
EQ-5D-3L	EuroQol 5 dimension score 3 level
EQ-5D-5L	EuroQol 5 dimension score 5 level
GAS	Goal Attainment Scaling
HQIP	Healthcare Quality Improvement Partnership
ICF	International Classification of Functioning, Disability and Health
IPA	Interpretative Phenomenological Analysis
LQR	Longitudinal Qualitative Research
MPhil	Master of Philosophy
MYMOP	Measure Your Own Medical Outcomes Profile
NHFD	National Hip Fracture Database
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OMERACT	Outcome Measures in Rheumatoid Arthritis Clinical Trials
PIS	Participant Information Sheet
PROM	Patient Reported Outcome Measure
QoL	Quality of Life

RA	Rheumatoid Arthritis
RAPP-PI	Rheumatoid Arthritis Patient Priorities for Pharmacologic Interventions
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
SF36	Short Form 36 questionnaire
SIGN	Scottish Intercollegiate Guidelines Network
SPPB	Short Physical Performance Battery
UK	United Kingdom
UWE	University of the West of England
VAS	Visual Analogue Scale
WHiTE	Warwick Hip Trauma Evaluation study
WHO	World Health Organisation

Chapter 1: Introduction

1.1 Background

In the United Kingdom an estimated 70 000 – 75 000 people are admitted to hospital each year with a fractured neck of femur (broken hip) with associated annual medical and social care costs of approximately £2 billion (National Institute for Health and Care Excellence [NICE], 2011). The number of hip fractures is estimated to rise to over 100 000 by 2020 due to the ageing population (British Orthopaedic Association [BOA], 2007). A hip fracture is the most common fragility fracture, defined as a fracture that occurs from low energy trauma equivalent to a fall from standing height or less where the mechanical forces would not normally result in a fracture (NICE, 2012). Fragility fractures occur in patients with or at risk of osteoporosis; a disease affecting the structure of the bone resulting in reduced bone mass. Older adults, particularly women, are especially susceptible to these fractures due to increased bone loss with age and after menopause (NICE, 2012). Recovery from a hip fracture, both in terms of outcome for the patient and time taken, places great demands on health and social services and has great implications for quality of life [QoL] and social support requirements for the individual despite the current treatment options available (Melton, 2003). Patients in this population rarely recover their pre injury mobility and independence (Magaziner et al, 2003; Cree et al, 2001).

In response to the difficulties and poor recovery people experience after a hip fracture, over the last decade there has been a drive to improve the clinical outcomes for this patient group through audit, research and evaluation of current and developing clinical practices. Hip fracture is a burgeoning area of evaluation with developments such as the publication of 'The Blue Book' by the BOA and British Geriatric Society [BGS] and the creation of a National Hip Fracture Database [NHFD] in 2007. The Blue Book was a collaboration between surgeons and geriatricians to summarise the best evidence for the care of fragility fracture. The NHFD is a web-based audit which aimed to promote best practice in the care and secondary prevention of hip fractures. Six standards for best practice were laid out in the Blue Book, and compliance with these standards could be continuously monitored by participation in the NHFD. These joint ventures were followed by the development of the NICE clinical guidelines for Hip Fracture in 2011 and the first major multicentre surgical randomised controls trials [RCTs] in hip fracture care in the United Kingdom [UK] (Griffin et al, 2012). Importantly, this collection of

RCTs includes patient reported outcome measures [PROMs], patient-centred data previously omitted from national initiatives such as the NHFD. Assessing the impact on the person and their perception of outcome is important to establish which interventions are successfully able to reduce that impact.

Initially conceived in 2008, the current study has been ongoing throughout these national developments. Audits such as the NHFD measure successful completion of aspects of the care pathway but focus on evaluating the process of provision of hip fracture care in the National Health Service [NHS]. By not including patient reported outcomes, the NHFD misses the opportunity to examine the patients' perspective of their treatment in addition to the clinical outcomes it currently measures (for example time to surgery and length of stay). Progressively more importance is being placed on measuring PROMs but only recently has a PROM been included in any standardised data collection for hip fracture in the UK. Health related quality of life measured by the EuroQoL score (EQ-5D) is now being collected as part of the NHFD data collection for the Warwick Hip Trauma Evaluation [WHiTE study] (Griffin et al, 2012). However the extent to which scores such as the EQ-5D reflect meaningful recovery for these patients has only recently been examined in the literature (Parsons et al, 2014). The EQ-5D was found to be responsive to change at multiple time points and for proxy reporting, strongly correlated with a hip specific score (the Oxford Hip Score), and moderately good at predicting mortality at 12 months following fracture. The EQ-5D has been suggested as a useful measure of outcome in hip fracture patients by multiple authors (Haywood et al, 2014; Parsons et al, 2014; Liem et al, 2013; Hutchings, Fox and Chessier, 2011). The EQ-5D has been proposed as the basis for a core outcome set which will be discussed in more detail in Chapter Two. Although the core set is a useful starting point, there remains minimal input from patients in its development, therefore the content validity would benefit from further evidence. Also the timing for when outcome assessment is most appropriate after hip fracture remains unclear. If outcome measures do not represent the outcomes important to the individual, there is a risk the clinical care pathways and treatments recommended may not reflect the aims and rehabilitation priorities of the patients. Identifying how to measure recovery that is meaningful to the patient, to later inform evaluation of interventions, guided the design and pursuit of this MPhil.

This thesis consists of five chapters. This first chapter further expands on the clinical picture for hip fracture care in the UK and gives an overview of outcomes assessment in this patient

group. The context of this study within the parent study in which it was conceived is also presented. Chapter Two reviews the importance of including patient perception and consultation in outcome measurement design and choice, along with what is currently known about the patient experience of recovering from hip fracture. The research question and aims for this study are then summarised. Chapter Three explains the methodology drawn upon and the methods used in the study. Chapter Four presents the findings. The thesis concludes with Chapter Five with further discussion of the findings, the limitations of the study, how the findings relate to existing literature, and how they might inform future evaluation of outcomes for patients with hip fracture.

1.2 Hip Fracture

The average age of patients with a hip fracture is 83 years for women and 84 years for men, with 76% occurring in women (NICE, 2011). Hip fractures predominantly result from a fall. The injury often occurs due to a combination of factors such as reduced bone density, reduced reflexes and an increased tendency to fall. Those in care homes are three times more likely to fall than those living in their own homes (Parker and Johansen, 2006). Mortality following hip fracture has been shown to be 7.5% at 30 days and up to one third at one year (Royal College Physicians [RCP], 2016). Despite hip fracture being more common in women, Penrod et al (2008) found mortality rates at six months to be higher in men (19.2%) than women (9.7%). However at six months post fracture they found no difference in ability to walk between the surviving men and women. Comorbidities are common in this population. Penrod et al (2008) found a mean of 1.6 comorbidities per patient, with conditions such as arrhythmia, stroke, parkinsons disease and particularly dementia affecting functional outcome at six months. Seitz et al (2011) reported the incidence of cognitive impairment as 42% and of dementia as 19% of hip fracture patients. Cree et al (2001) found age, number of comorbidities and hip pain were the most important predictors of functional dependence at three months following a hip fracture. 145 of their 367 participants were reported to have signs of cognitive impairment (a Mini Mental State Exam Score of 22 or less). Of those 145, 90% were reported as low function or dependent prior to their hip fracture increasing to 95% following their fracture.

The patient with a hip fracture typically presents with a painful hip and unable to walk following a fall. The leg may be shortened and externally rotated. The fracture will be visible on a radiograph (x-ray) in most cases; occasionally further scans are required. Most hip fractures

are surgically managed to enable the patient to mobilise again rapidly in order to avoid or minimise the potentially devastating ramifications of prolonged bed rest in this frail elderly population (Parker and Johansen, 2006). The type of surgery undertaken depends on location and displacement of the fracture. The orthopaedic surgical team will assess the injury to determine whether to replace the head of the femur or to internally fix the fracture with a plate, screws or nail. For the purposes of this thesis the classification of fractures has been simplified to whether or not a fracture is displaced and whether it is intracapsular or extracapsular (Figure 1).

Intracapsular fractures, where the fracture is within the joint capsule, carry a risk of disruption of the blood supply to the head of the femur when the fracture is displaced and therefore a hemiarthroplasty (replacement of the head of the femur) is usually undertaken (Parker and Gurusamy, 2005). Following recent guidelines (NICE 2011) it is becoming more common for younger, more functionally able, patients to undergo a total hip replacement as it has been shown to have better outcomes in terms of pain and function in this group. Extracapsular fractures, where the fracture lies outside the joint capsule and the blood supply is not at risk, are predominantly stabilised with surgical fixation using a plate and screws on the surface of the bone or a nail within the central cavity of the bone (Parker and Gurusamy, 2005). Fox et al (1999) found a slightly higher proportion of extracapsular (53.7%) to intracapsular fractures (46.3%). There was no difference in distribution of gender between extracapsular and intracapsular fractures. Those with extracapsular fractures were slightly older on average but there was no difference in other demographics or social characteristics. People with extracapsular fractures were more likely to have four or more comorbid conditions but the proportion of the specific conditions was not different. Fox et al (1999) found that people with extracapsular fracture tended to have a longer acute inpatient stay and were more likely to be discharged to a nursing home than those with intracapsular fracture. Mortality was slightly higher for people with extracapsular fracture at two and six months but this had equalised at one year. At two months those with extracapsular fracture were less functional able but they had caught up with their counterparts with intracapsular fracture by six months. As will be described later in Section 1.5 (Context of study) and Chapter Three (Methodology and Methods), the current study included only those with extracapsular fractures.

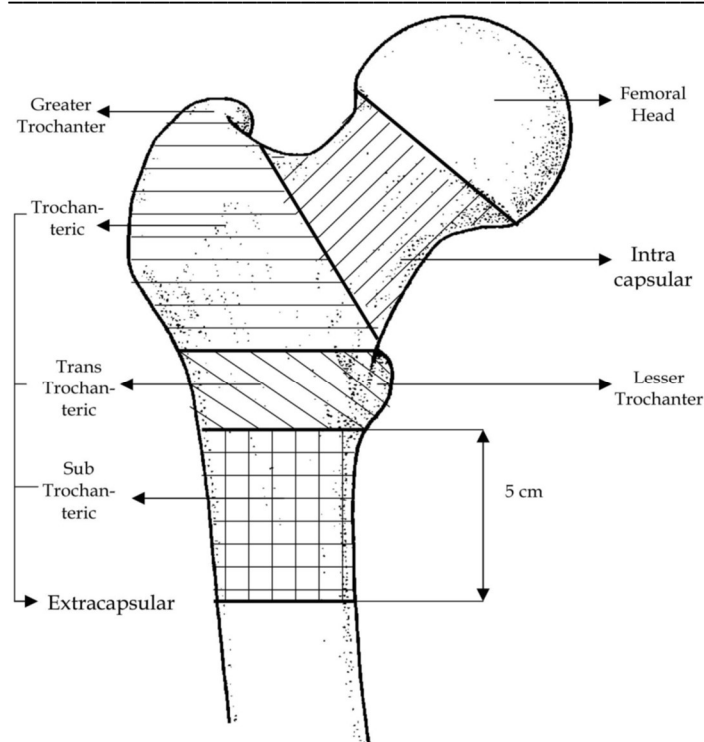


Figure 1 Classification of hip fractures (reproduced with permission from Parker and Gurusamy, 2005)

In 2007 the BOA and BGS published *The Blue Book for care of patients with fragility fracture* (BOA, 2007) to improve the standards of clinical care across the UK for patients with a hip fracture. Subsequently the BOA Standards for Trauma 1: Hip fracture in the Older Adult (BOAST 1) were developed in 2008 and updated in 2012 to facilitate audit of practice (BOA, 2012; BOA, 2008). These publications, in conjunction with the Scottish Intercollegiate Guidelines Network [SIGN] guideline 111 Management of hip fracture in older people (SIGN, 2009), provided the momentum to prioritise care for these older trauma patients in recognition of their previously unacknowledged complexity and the potential for better outcomes.

The NICE guidelines for best practice in hip fracture care included recommendations for the patient pathway from admission and diagnosis through to discharge from hospital and rehabilitation. In the acute phase of the patient pathway the best practice recommendations include effective early analgesia, early review by a senior physician, and, once the patient is medically stable, surgery on the next available trauma operating list supervised by a senior orthopaedic surgeon (NICE, 2011). The guidelines identify comorbidities that should be addressed to prevent any delays to surgery and supports selection of the surgical implant to be used. The requirement for timely care, led by senior professionals, reflects the complex nature of the patients and the multidisciplinary care required.

After management of the acute phase of the patient pathway, guidelines for rehabilitation are less specific. Mobilising from the bed at least once a day is recommended from the day after surgery, with regular physiotherapy reviews. Goals for multidisciplinary rehabilitation should be identified to recover mobility and promote independence and to facilitate patients to return to their previous residence and long-term well being (NICE 2011). Handoll et al (2009) defined multidisciplinary rehabilitation as services provided with the goal of reducing disability by improving task-orientated behaviour (examples being walking and dressing). In their Cochrane review (Handoll et al, 2009) they highlighted considerable variation of formats in which multidisciplinary rehabilitation was provided. There was some favourable evidence for provision of multidisciplinary rehabilitation measured against their primary outcome of 'poor outcome' which was defined as mortality or deterioration of functional status. However this finding was from trials with heterogeneity of interventions and the outcomes measured, making it difficult to draw conclusions regarding specific interventions. The best support for multidisciplinary rehabilitation was from one of their secondary outcomes of reduced morbidity, where a reduced incidence of medical complications was reported for the intervention groups. Handoll et al (2009) reported that making any recommendations was difficult because the other secondary outcomes considered, such as functional status, carer burden and costs, were again poorly and diversely measured.

Crotty et al (2010) reviewed the rehabilitation interventions for improving physical and psychosocial functioning after hip fracture. This Cochrane review found that a variety of interventions, administered by a range of professional groups at different time periods in the recovery journey, had been evaluated using a range of different outcomes. They were therefore unable to recommend any change in practice due to the lack of comparable study methods. A further Cochrane review in 2011 by Handoll, Sherrington and Mak found that the trials of interventions to improve mobility after a hip fracture were small and evaluated different interventions, precluding the option to combine data. The studies reviewed included specific interventions such as quadriceps strengthening and treadmill-based gait reeducation; more intensive physiotherapy packages; and different timing of interventions (for example early and additional late physiotherapy). The review concluded that there was insufficient evidence to establish which were the best strategies to regain mobility after hip fracture.

Despite developments in knowledge and a drive to provide good quality care few patients recover their pre-fracture levels of function and independence. Hommel and Baath (2016) reviewed QoL data from the Swedish national quality register for hip fractures from 2011 to 2013 and Griffin et al (2015) presented the recovery of health related QoL for a UK population in a prospective cohort between 2012 and 2014. Both studies found that QoL (as measured by the EQ-5D) did not return to the pre-injury baseline at four months. Ability to walk outdoors was also significantly reduced. Hommel and Baath (2016) show the proportion of the population reporting no problems with walking, self-care, usual activities and no pain or discomfort was substantially reduced at four months. At 12 months for the UK population EQ-5D scores demonstrated minimal improvement from the four month review (Griffin et al, 2015).

In summary, although typically an injury experienced by the older woman with multiple comorbidities, the hip fracture population is diverse, with both men and women affected. It affects those who were previously active and those who were functionally dependent, and people with and without cognitive impairment. Initially managed operatively in most cases, as stipulated by evidence based guidelines, the acute management of a hip fracture requires multidisciplinary care led by senior professionals (NICE, 2011). The evidence base for longer term rehabilitation to promote optimal recovery is less well defined. Currently few patients regain their pre-fracture QoL.

1.3 Evaluating care and measuring outcome in hip fracture

The outcomes from hip fracture can be life-changing and due to the high demands on the health and social care system it is becoming an active area for research. Every aspect of the patient's pathway is open to evaluation; from the anaesthetic used for the operation, the surgical technique used, the pain management, the medical care for their co-morbidities and prevention of associated conditions (such as respiratory infections, embolisms or pressure sores), through to the planning for discharge from the hospital setting and rehabilitation. In general studies seek to improve the process and experience for the patient, or reduce cost and resource use whilst at least maintaining patients' outcomes.

The NHFD is a clinical audit project started as a voluntary process in 2007 using the standards compiled in the Blue Book (BOA, 2007). NICE Clinical Guideline 124 the Management of Hip Fracture in Adults was published in 2011 which updated the quality standards currently

monitored by the NHFD, now centrally funded by the Healthcare Quality Improvement Partnership (HQIP) as part of the Falls and Fragility Fracture Audit Programme (Gray and Chesser, 2014). The Department of Health's first objective in the report from the national audit of falls and bone health in older people in 2010 was to improve patient outcome and improve efficiency of care after hip fractures (RCP, 2011), demonstrating the importance of improving the care of this patient group. The NHFD is a continuous audit of the performance of hospitals across England, incentivising change and investment in good practice using the key findings from the NICE clinical guidelines as standards (NICE, 2011). Participation in the NHFD has increased from the initial few enthusiastic hospitals with pioneering clinicians to all hospitals in England. Information regarding 63 102 people presenting to 180 hospitals in England with a hip fracture in 2014 is available on the database and is reported in the 2015 audit report (RCP, 2015). The report indicates continued improvements in all the audit standards, including improved rates of early surgery and pre-operative senior medical review, and outcomes such as 30 day mortality, length of stay and discharge destination, with an increased proportion of community dwelling patients previously living in their own homes able to return there. However there remains minimal information regarding the post-acute phase of the patient's pathway and no input from community services into the database. The longer-term outcomes recorded in the NHFD to date have included residential status, 'super-spell' (i.e. full length of stay including rehabilitation hospitals), mobility and whether they are taking bone protection medications at 30, 120 days and one year following their hip fracture. Although these clinical outcomes provide basic information about the patient's recovery and their return to previous functional levels, there is minimal patient involvement or insight into their perception of their recovery.

1.3.1 Outcome measurement instruments

Outcome measurement instruments seek to evaluate a characteristic or attribute of a patient through the systematic application of a test, measure or score to allow comparison to normal levels or monitor change over time. Outcome measurement instruments may combine multiple factors and can be completed by a clinician or increasingly the patient. In clinical care the use of standardised outcome measures is encouraged to evaluate an individual's response to treatment, the quality of the care and service delivery being provided. In research outcome measurement instruments should correspond to the research question and aim to measure the hypothesised treatment effect. Patient reported outcome measures (PROMS) place emphasis on the patient's perspective of the impact of the health care intervention and have

become increasingly popular in evaluation in clinical care and research. Measurement instruments can be specific to a condition or population or can give a wider view of a person's health or health related quality of life. The choice of which would pertain to what outcomes are under evaluation. To ensure the data obtained from outcome measurements is robust and opportunities for bias are minimised, efforts should be made to ensure the quality of measures used. The quality of outcome measures can be established through assessment of validity, reliability, responsiveness, interpretability and practicality. Groups such as the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) study group (Mokkink et al, 2010a; Mokkink et al, 2010b; Mokkink et al, 2006) aim to support evidence based selection of high quality outcome measurement instruments for specific purposes through the use of consensus based checklists.

1.3.2 What are the outcomes?

When evaluating care the definition of the 'outcomes' to be measured should be considered. To help explore the difficulties clinicians and researchers face a theoretical example relevant to people with hip fractures is described below (Box 1).

Box 1: Example of potential outcomes for clinical scenario

The use of an alternative surgical implant to fix a break in the femur at the hip could be evaluated by its effect on a number of different outcomes. If it is a quicker surgical procedure there are a multitude of potential benefits, for example it may save the valuable resources of the operating theatre, thus reducing waiting time for other patients who need surgery. A quicker operation may carry lower risks for the patient therefore potentially reducing the risk of mortality or other morbidities such as anaesthetic-induced delirium or chest infections. Or the alternative implant may give a more rigid fixation, reducing pain experienced by the patient when they first stand up. A reduction in pain could in turn mean the patient could get out of bed more quickly and therefore be less at risk of post-operative chest infections; they may be able to have a catheter removed more quickly and therefore reduce the risk of urinary tract infections. The reduced pain may mean they gain confidence more rapidly and therefore accelerate through the rehabilitation process. They may require less support from walking aids which could facilitate independent living and therefore be able to return home. Many of these aspects could reduce patients' length of stay in hospital, thereby reducing the cost to the NHS. Could an outcome such as the length of stay in hospital represent a valid measurement of whether the alternative implant has improved 'outcomes' for that patient?

In the example given above, what if the local community rehabilitation team has staff shortages and therefore patients remain in the hospital for an extra four days each before the team can support their return home? A scientific research design such as an RCT may be used with the assumption that if the participants in the study have been randomised between having the new implant or the traditional implant, the circumstances of the rehabilitation team will affect both groups equally. Therefore the 'truth' that one implant provides superior fixation to the other should still become evident if enough participants are involved in the study.

An alternative option might be to consider a more specific outcome, although this may depend on the theory of how the intervention is believed to be superior. For example if the new implant is anticipated to reduce pain, the patients' requirements for analgesia could be assessed. In recent years there has been a move towards using PROMs such as a pain score or a QoL questionnaire (Fernandez, Aquilina and Costa, 2016). Measuring an intervention with PROMs can provide insight into important effects of treatment that cannot be gained any other way such as symptom duration, frequency, severity, psychological impact and impact on the patient's daily life (Deshpande et al, 2011). PROMs have been shown to improve adherence to treatment and to empower patients (Deshpande et al, 2011; Carr and Higginson, 2001) however they need to be patient-centred and measure domains important to patients to be responsive to change (Carr and Higginson, 2001).

Clinical research seeking to evaluate a change to a patient's pathway is predominantly quantitative in nature and seeks to demonstrate a measurable impact. It aims to produce evidence that the change to the pathway under investigation has had a beneficial effect. This evidence can then be used to implement changes in the care provided to justify investment. However the definition of 'beneficial' may be different for different people, depending on their view point. For acute hospital managers, policymakers or commissioners a reduced length of stay or total cost of treatment may be the most important outcome. For the staff involved in rehabilitation the patient's ability to participate in rehabilitation, through good pain control, good muscle function or reducing acute confusion enabling a smooth discharge process, may be a good outcome. There is a resultant variety in primary outcomes and outcome measures used in clinical research reflecting these different viewpoints (Bryant et al 2009). Schuneman, Oxman and Fretheim (2006) in their review for the World Health Organisation "Improving the

use of research evidence in guideline development: 6. Determining which outcomes are important” discussed that patients and clinical experts sometimes assign different values to different outcomes. When considering evaluation of interventions Schuneman, Oxman and Fretheim (2006) proposed that patients should be asked which outcomes are really important to them, either by including patients and carers where possible or considering original research on patients’ perspectives and experiences where it is available.

Evaluating the effects of an intervention or care pathway may need to reflect a spectrum of these viewpoints, combining patient, clinical and managerial perspectives depending on the rationale of a specific study, and a range of outcome measures may need to be included for a comprehensive evaluation (Bryant et al, 2009).

1.3.3 Measuring outcomes in orthopaedic care

Conventionally in orthopaedic care, outcomes have been measured using objective measures such as mortality rates, rates of surgical complications (for example metalwork failure or dislocation rates) and success of operative treatment judged by radiological reduction of the fracture (Jaglal, Lakhani and Schatzker, 2000). However these outcomes often cannot explain the variation in ‘success’ of a treatment in different patients. In 1999 Swiontkowski suggested functional outcomes should be measured alongside the traditional clinical outcomes in orthopaedics. He stated item selection in the development of questionnaires could come from experts in the clinical area but ideally from patients who have or have had the problem to be addressed. He criticised the tendency for scales and measures to be developed by surgeons without patient input, mixing clinical and functional outcomes into one score. Among older adults who have had a hip fracture measuring outcomes is particularly difficult due to multiple comorbidities, the complex physiology of ageing, the requirement for multi-professional interventions across multiple models of care provision, and the variety of social circumstances. All of these factors can affect the apparent recovery from the hip fracture, potentially masking the effect of the intervention under investigation.

In orthopaedic care measurement of fracture healing could be a useful and appropriate point of assessment to be compared between two surgical or pharmaceutical treatment options. However measurement of fracture healing and time to fracture healing from radiological images or clinical assessment is notoriously difficult with subjectivity between assessors and differing opinions of criteria for fracture union (Corrales et al. 2008). Patients’ priorities in

relation to fracture healing have not been identified, but Corrales and colleagues (2008) proposed that composite measurements including patient-important outcomes such as function, in addition to radiographic and clinical assessments, may be more appropriate to evaluate the effect of an intervention. Although regaining function is generally accepted to be a key aspect of recovery from a hip fracture, patients' views on which aspects of function are important during recovering from an injury such as a hip fracture have only recently been investigated, since the majority of PROMs have been developed. PROMs should routinely include health domains that are important to the patient and therefore can be a good method to assess how patients believe they are functioning and judge their recovery (Parsons et al, 2014).

The Cochrane reviews (Handoll, Sherrington and Mak, 2011; Crotty et al, 2010; Handoll et al, 2009), previously discussed in Section 1.2, highlight the difficulties in comparing rehabilitation interventions. In a review of rehabilitation interventions for improving physical and psychosocial functioning after hip fracture (Crotty et al, 2010), recovery was considered to be the return or regain of mobility, independence and QoL. However they found that studies which focussed on QoL or any self-report measures were scarce and that evaluation of an intervention was more frequently a physical function such as walking independently. There were difficulties in pooling data from any of the rehabilitation studies due to the differences in outcomes measured. The poor quality of reporting meant they were unable to identify any recommendations to change practice to improve the recovery from hip fracture beyond the multidisciplinary approach to rehabilitation previously reviewed by Handoll et al (2009). The main recommendation from Crotty et al (2010) was that it was important to develop a core set of outcomes for hip fracture trials, including patient reported measures such as QoL and measures of impact on carers such as burden.

1.3.4 Consensus on outcome measurement

The varying opinions and lack of consensus on how to select the most appropriate outcome measures has led to a wide variety of measures in use in trials that evaluate interventions for the management of hip fractures (Hoang-Kim et al, 2013; Hutchings, Fox and Chesser, 2011). The need to find consensus on outcome measurement in hip fractures has been highlighted by Fernandez, Griffin and Costa (2015), Liem et al (2013), Hoang-Kim et al (2013) and Bryant et al (2009). This is in line with the ideals of the Core Outcome Measures in Effectiveness Trials Initiative (COMET, 2016). The heterogeneity of outcomes measured across trials in hip fracture

limits the opportunity to compare outcomes from different studies, limits the option to conduct meta-analysis when appropriate, and opens up the opportunity for reporting bias (Williamson et al, 2012). The purpose of a 'core outcome set' is to have an agreed minimum standardised group of outcomes to be measured in all trials for a specific condition, with additional outcomes added as appropriate for any individual trial, related to the question under investigation. There should be agreement on what outcomes should be measured as well as how and when (COMET, 2016). Adoption of this agreed core outcome set would, going forward, provide a set of common baseline outcomes for further analysis and meta-analysis and the opportunity to compare effects of different treatments and importantly, minimise the potential for reporting bias. However there is no agreement on the best methodology with which to gain consensus on what the core outcomes for any given condition should be (Williamson et al, 2012).

As reported by Fernandez, Griffin and Costa (2015) there have been attempts to suggest how to measure outcomes for use in hip fracture evaluation. Hutchings, Fox and Chesser (2011) set out to establish whether sufficient evidence existed to make recommendations on the selection and timing of outcome measurement for hip fracture evaluation through a systematic review. The review sought to identify which measures or scores of function were frequently in use in the literature and to investigate the validity and applicability of these. Fourteen scales across five major categories were identified (health related QoL, activities of daily living, mobility and physical performance, disease-specific and hip-specific), however the evidence to support individual scales was limited and the recommendations for timing of measurement could only be based on what seemed appropriate from the clinical pathway. Bryant et al (2009) summarised measures to cover a range of domains from published literature and professional opinion in line with the structure suggested by the International Classification of Functioning, Disability and Health [ICF]; namely body structure and function, limitations in activities and restrictions in participation. They presented outcome measures they felt had demonstrated good measurement properties mapped against the ICF structure, however it was not clear whether there were further potential measures not included. An understanding of how the benefits of an intervention may affect a patient's day to day life, activities and expectations was discussed as important. Bryant et al (2009) stated that the measures they summarised were relevant to patients and discussed validity as one of the properties of a good measurement instrument, however there was no evidence of input or

consultation with patients or review of patient involvement in development of measures in their selection process.

Liem et al (2013) sought to identify a standard set of outcome parameters for the evaluation of orthogeriatric co-management of hip fractures starting from a broad spectrum of outcome parameters (mortality, length of stay, time to surgery, complications, re-admission rate, mobility, QoL, pain, satisfaction, activities of daily living, falls, medication use, place of residence and costs) established from a previous literature review (Liem et al, 2014). These parameters were posed to a panel of experts for discussion and consensus. They present the consensus reached by the panel for what should be measured for each parameter and at what time point. No patients or carers were included in the process of producing the set of outcomes proposed. The multidisciplinary panel of experts involved in the consensus discussions in Liem et al (2013) included orthopaedic surgeons, trauma surgeons and geriatricians, and therefore excluded multiple other key professional groups involved in the care pathway for recovery from hip fracture (for example general practitioners, therapists, nurses) as well as excluding patients themselves. Therefore the only potential component of patient perspective included in these suggested outcomes to be measured would be if the scores chosen had originally been designed in conjunction with patients who had experienced hip fracture. Although these three publications (Liem et al, 2013; Hutchings, Fox and Chesser, 2011; Bryant et al 2009) recommended different outcomes scores there was overlap, with each suggesting a generic QoL score (EQ-5D or Short form 36 [SF36]).

The only explicit recommendation for a core outcome set for hip fracture trials was presented by Haywood et al (2014). They undertook a modified nominal group technique involving three stages; preparation of the information (including a systematic review of PROMs), nominal group postal questionnaire and a nominal group consensus meeting. Participants in the group included health professionals, researchers, health policy professionals, representatives from funding bodies and three lay members. The postal questionnaire followed by consensus meeting, reduced the original 34 suggested outcome domains (what to measure) as critical in hip fracture trials to six. How to measure these domains (i.e. which scores or individual items) was reduced from three potential PROMs and four items from the NHFD audit at the questionnaire stage to one PROM (the EQ-5D for measuring health related QoL) and three items – mortality, indoor walking status and outdoor walking status by the end of the consensus meeting stage. The authors presented these findings as a core set using the

grouped health outcome domains of pain, activities of daily living and mobility with the addition of mortality and health related QoL to give five core domains. Further critique of this proposed core set is discussed in Chapter Two.

Once consensus is achieved regarding what should be measured (the core domains), there also needs to be consensus regarding how to measure (which scores will best measure those domains). In studies using a face to face panel meeting, such as those undertaken by Liem et al (2013) and Haywood et al (2014), this may be discussed concurrently. Other methodologies such as Delphi surveys may undertake this in a step-wise approach. Reports of the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) study (Mokkink et al, 2010a; Mokkink et al, 2010b; Mokkink et al, 2006) present the attempts to reach a consensus for standards to be applied to the selection of instruments when measuring health outcomes. Particularly with PROMs where the constructs are subjective it is important that the measurement properties are defined to enable assessment and comparison of different scores. The key properties agreed on by the COSMIN study to assess any measure or score are internal consistency, reliability, measurement error, content validity, construct validity, criterion validity, responsiveness and interpretability (Mokkink et al, 2010a). The concept of content validity requires an assessment of a measurement score to consider the relevance of the items to be measured to the population under investigation and whether the items in the score when viewed together comprehensively reflect the concept being measured (Mokkink et al, 2010a). Therefore in a patient reported questionnaire measuring recovery from a hip fracture it would be important to ensure that the items within the questionnaire reflect a patient's view of recovery. This can only be ensured if, as determined by Schuneman, Oxman and Fretheim (2006), patients and/or their carers have either been involved in the development of the score or there has been close consideration of original research on patients' perspectives, experiences and priorities in recovery from a hip fracture.

The lack of patient involvement in the development of most QoL measures has been highlighted (Carr and Higginson, 2001). The EQ-5D, although developed through a long term systematic iterative process was developed by a multidisciplinary group including medical professionals, psychologists, economists, sociologists and social administrators (Brooks, 2015). During development empirical testing with samples of respondents was performed but patients were not included in the development process. However the EQ-5D has been

perceived as easy to understand and complete and considered good at describing health in a comprehensive way by patients (Nilsson et al, 2007).

The EQ-5D has attributes particularly beneficial in the hip fracture population as it has been shown to be responsive (Parsons et al, 2014), to correlate strongly with a hip specific score, and to be reliable via alternative means of completion such as telephone (McPhail et al, 2009) or when completed by a proxy (Bryan et al, 2005). This assists in achieving high rates of completion in clinical trials to avoid bias and it also means that an outcome can be obtained for the large proportion of hip fracture patients with cognitive impairment. This in turn enables evaluative research in inclusive samples to ensure applicability of the findings to the whole hip fracture population. Although the EQ-5D may be less sensitive to change than a specific hip fracture PROM might be, its design as a global health-related QoL measure means it appears ideally suited for a heterogeneous and complex population such as those with a hip fracture (Parsons et al, 2014). It is notable however that the studies of measurement properties of the EQ-5D in hip fracture patients have focused on responsiveness and reliability (Parsons et al, 2014; Tidermark and Bergstrom, 2007). Whether the breadth of the constructs or domains covered by the EQ-5D is valid in hip fracture patients remains unclear. Parsons et al (2014) suggested the EQ-5D covered the domains patients believe are important in their recovery from hip fracture, citing a consensus statement from the BOA Congress in 2013, however it is not clear whether there was patient involvement in this consensus statement. Fernandez, Griffin and Costa (2015) suggested that the EQ-5D reflected the impact of hip fracture on patients' lives.

In other patient groups a qualitative exploration of the perception of completing the EQ-5D of patients with long term conditions was conducted by Paterson (2004). The original EQ-5D (the EQ-5D-3L) which had three potential responses to each question was criticised for a lack of sensitivity and was shown to have floor and ceiling effects. The patients also raised the potential for response shift and contextual concerns when answering the questions in the EQ-5D for example how to rate their symptoms when there is variation between best and worst, when they perceive others might rate their symptoms differently and whether to score for a single health issue or to take into account comorbidities. Some participants interviewed by Paterson (2004) described a conflict between physical function and psychological effort or distress which the EQ-5D scoring system was not able to highlight.

The more recent version of the EQ-5D (the EQ-5D-5L) has five levels of response which may rectify some of the issues highlighted by the participants in Paterson's study (Paterson, 2004). Matza et al (2015) set out to examine content validity for the EQ-5D-5L in patients with type two diabetes through qualitative semi-structured interviews. In common with hip fracture despite established psychometric properties such as reliability and responsiveness, content validity was unknown for either the EQ-5D-3L or 5L. Half the participants in Matza's study (Matza et al, 2015) found the EQ-5D to be relevant to their own experience of health, however all participants reported aspects of condition specific quality of life missing from the questionnaire. Matza and colleagues (2015) acknowledged a generic measure was not designed to cover all domains of health for all patients and they suggested discussion was needed regarding what degree of content validity is sufficient and whether the addition or "bolt-on" of a condition specific question may be required. Deeper investigation into patient perspectives on the impact of hip fracture on their lives and the mapping of this against the EQ-5D, would enable identification of any missing domains of health and therefore strengthen or refute the recommendation of the EQ-5D as the central score in a core outcome set for hip fracture evaluation.

1.4 Summary

Despite the recent developments in this area, the underlying motivation behind this study – to explore what recovery means to patients to guide understanding of what domains should be included when evaluating recovery – remains under discussion. Understanding patient experiences and priorities, and how they might change and progress throughout the recovery process, should be used in addition to expert opinion to guide selection of outcome measures and development of a core set.

This study seeks to establish how patients experience and perceive recovery after a hip fracture with the intention that findings could inform future choice or design of outcome measures for research in the hip fracture population, for example when evaluating the effectiveness of an intervention. The following chapter (Chapter Two) reviews the literature, discussing how patients can be included in the development of outcome measurement and what is currently known about the patient experience of recovering from a hip fracture.

1.5 Context of study

This MPhil research was nested in an NHS pilot study (referred to as the ‘parent study’ throughout the thesis) which tested the design for a RCT comparing six weeks of daily injected parathyroid hormone to standard care in the recovery from operatively managed extracapsular hip fractures (Chesser et al, 2014. Appendix A published protocol). Intermittent parathyroid hormone had been proposed to accelerate fracture healing through an anabolic effect on bone. While designing the parent study it was difficult to identify reliable methods for measuring the effect of an intervention on fracture healing, and the potential benefits of accelerated healing for the patient. Those difficulties led to the development and inclusion of this MPhil study. The NHS pilot study (parent study) had four main objectives: to pilot the randomised design with this intervention and population; to define standard care for the comparison group; to determine the acceptability and feasibility of the daily injection therapy; and to pilot the intended outcome measures. This MPhil study formed part of this fourth objective.

The sample for this MPhil study was drawn from the parent study participants and was therefore subject to the same inclusion and exclusion criteria. The sample is further discussed in Chapter Three (Methodology and Methods) and the impact and potential meaning of the exclusion criteria is discussed in Chapter Five (Discussion). Broadly, the nesting of this study within the parent means the population under exploration were people aged 60 and over who had surgically managed, extracapsular hip fracture. As a trial of a medicinal product there were further extensive exclusion criteria applied in the parent study relating to kidney function and previous cancer diagnoses which therefore also applied to this MPhil sample.

I had full responsibility for the design, conduct, analysis and dissemination associated with this aspect of the research. It was agreed with the wider research team from the outset that this would form the basis of a research degree.

Chapter 2: Literature

The following chapter is presented in two sections. The first section reviews the role of patients' perception and involvement in outcome measurement and the current progress towards a core outcome set for hip fractures. The second section reviews the literature to establish what is currently known about the patient experience and priorities of recovery after a hip fracture. The chapter is summarised with a statement of the research aim and questions for this MPhil.

2.1 Patient perception and consultation in outcome measurement – relevance for hip fracture evaluation

2.1.1 Complexity of the patient perception of recovery

When seeking to measure outcomes in healthcare the purpose is often to assess whether an individual is 'better' following treatment. Randomised trials usually aim to compare treatments to evaluate which delivers better outcome for patients. An understanding of what is 'better' or what it means to recover is therefore important. The individual nature of the perception of recovery or 'getting better' in work-related upper limb musculoskeletal disorders (repetitive strain injury) was explored by Beaton and colleagues (2001). In their grounded theory interview study the authors argued that patients who saw themselves as 'better' experienced three different states: resolution of the disorder, readjustment to an ongoing disorder, or redefinition of being better. These three states demonstrate the complexity underlying the individual's construction behind an apparently simple response "yes I'm better". The reported experience of the disorder included themes such as symptoms, functional limitations, emotional and social limitations and role limitations. Which state of recovery was achieved was influenced by the participants' individual experience and was 'mediated' by three factors – perceived legitimacy, comparison (with others or self) and personal coping style.

The authors reflected on how their findings reinforced the need to understand the impact of a condition on an individual's life and how selection of outcome measures in clinical practice may need to encompass this. Scores where patients generate their own goals or item content were suggested (Beaton et al, 2001). Outcome measurement in evaluative research needs to consider the application of these findings as the change in an outcome score may have

different meaning to different individuals, adding complexity to the concept of responsiveness (the ability of an outcome measure to detect change accurately when it has occurred). Patient perception and involvement in the identification of outcome domains and development, assessment of and selection of outcome scores is of increasing importance when considering the complexity of interpreting what recovery means, as highlighted by Beaton et al (2001).

2.1.2 Patients in the development of core outcome sets

While RCTs can help minimise confounding variables and reduce bias, a study still needs to ask the right question and use suitable measurement tools to assess the impact of an intervention. The OMERACT group (Outcome Measures in Rheumatoid Arthritis Clinical Trials) was early to recognise the importance of the patient perspective in the evaluation of treatments in rheumatoid arthritis [RA] in 1993 (Boers et al, 2014 citing Wells et al, 1993) and in the inclusion of patients in development of measurement methodology in 2003 (Boers et al 2014; Kirwan et al 2003). The process of developing the methodologies and practices established by OMERACT can be applied by other clinical specialties such as trauma and orthopaedics. The OMERACT filter 2.0 was presented (Boers et al, 2014) as a methodology to develop core outcome sets. The methodology is underpinned by the inclusion of all stakeholders at all stages, particularly patients. The OMERACT filter 2.0 defines a framework of three core areas (death, impact on life and pathophysiologic manifestations) and one recommended area (resource use). Domains and sub domains should be chosen to represent each of these core areas through a literature review of measurement domains previously used and stakeholder consultation. Patient perspective is particularly important to the face and content validity of domains chosen to evaluate the 'impact on life' area and is essential to identify applicable subdomains and expose gaps in what has been measured before. Previous work by the OMERACT group has highlighted the potential for patients and professionals to evaluate interventions against different priorities in rheumatoid arthritis (Hewlett, 2003; Carr et al, 2003). Once consensus is achieved on what should be measured (i.e. the core domains with appropriate input from all parties), efforts can move on to how to measure those domains. OMERACT again stress the importance of including all stakeholders in the process of measurement selection including development of instruments where none is available for domains. The work of groups such as COSMIN were recognised in the procedure for measurement instrument selection to ensure quality is assessed.

A systematic review of functional outcomes used in RCTs in hip fractures (Hoang-Kim et al; 2013) between 1980 and 2008 concluded that wide variability in the measures used and their quality demonstrated the need for consensus. The inclusion of the patient's perspective in outcome measurement was recommended with the belief that this would support the medical community to improve their communication with patients about the expected outcomes and recovery after treatment and rehabilitation for a hip fracture. The need to include patients' perspectives and experiences of the condition under evaluation has been previously recommended in Orthopaedics as discussed in Chapter One (Schuneman, Oxman and Fretheim, 2006; Swiontkowski, 1999) and is now recognised beyond the OMERACT group in the drive to develop core outcome sets for use in clinical trials (Williamson et al, 2012).

Representing the COMET group prior to the publication of the OMERACT filter 2.0, Williamson et al (2012) discussed that there was no agreed methodology for the best approach to achieving consensus on a core outcome set. The use of questionnaires, focus groups or in-depth interviews to determine outcomes important to patients (in addition to a literature review of relevant studies showing which outcomes clinician's value) was recommended in the process of deciding which outcomes to put forward to the process of reaching consensus. An example of the contribution qualitative studies can bring to the process for consensus on core outcome sets was demonstrated by the OMERACT group. A focus group study of the patient's perspective of rheumatology outcomes (Carr et al, 2003) found that outcomes such as pain and mobility were found to vary in importance at different stages, for example early and later after diagnosis and during flares. Some outcomes shown to be important to patients were not currently measured at all (fatigue and a sense of well-being) and the understanding of the meaning of other outcomes, for example 'return to normal', was poor (Carr et al, 2003). These findings were taken further by Sanderson et al (2010a, 2010b) who produced a core set from the patient perspective to complement the core set developed by the professional community. An interview study with 23 rheumatoid patients produced a list of 63 different outcomes that were important to the patients, grouped into four major categories – 'RA under control', 'doing things', 'emotional health' and 'coping strategies' (Sanderson et al, 2010a). This list of 63 outcomes was reduced to the 32 most important through nominal group discussions which was followed by a postal survey of 254 participants. The postal survey produced a set of eight outcomes representing the three domains of 'direct disease impact', 'psychosocial wellbeing' and 'function/participation' (Sanderson et al, 2010b). Sanderson et al (2010b) suggested that the patient core set created (the Rheumatoid Arthritis Patient Priorities for Pharmacologic

Interventions Outcomes or RAPP-PI outcomes) could be used to complement the existing health professional core set (the American College of Rheumatology [ACR] core set) to give a broader evaluation. Producing a second core set to complement rather than replace the original could be seen to negate the purpose of a core set – to ensure all trials measure the same outcomes. In a medical condition such as hip fracture, where no previous professional core set existed it would be preferable to approach the development of the core set with this level of inclusion of the patients as key stakeholders from the outset, producing one core set that encompassed the priority outcomes of both patients and professionals.

Outcome measurement for the evaluation of treatment can be developed with greater content validity to more accurately reflect the impact of interventions important to the patient when patients are included in the process. Work by OMERACT and others (Sanderson et al 2010a; Sanderson et al 2010b, Carr et al, 2003; Hewlett, 2003; Kirwan et al, 2003; Carr and Higginson, 2001; Beaton et al, 2001) encourages use of an inductive qualitative method to initiate the process of understanding the patient priorities and important outcomes in hip fracture.

2.1.3 A Core Outcome Set for hip fracture

As identified in Chapter One, since this MPhil study began there has been a publication suggesting a core outcome set for evaluative research in the hip fracture population. Haywood et al (2014) undertook a modified nominal group technique involving three stages; preparation of the information (including a systematic review of PROMs), nominal group postal questionnaire and a nominal group consensus meeting (which included various professional groups and three lay members). The preparation of information stage was presented as an overview of the content of systematic reviews which focused on the patient-reported outcome measures currently in use with hip fractures and with older people, self-administered measures of physical activity and the process-based measures in the NHFD. Previous discussions on the methodological options for developing a core set have emphasised that information on the outcomes deemed important by health service users (i.e. patients) should be included in this first stage of deciding what information should be put forward to the consensus exercise (Williamson et al 2012). No patient experience or qualitative exploration of what outcomes are important to patients is reported to have been included in Haywood et al (2014) although the protocol published on the Warwick Medical School website does report

patient/carer dyad interviews and focus groups included in the evidence synthesis (Griffin et al.)

Haywood et al (2014) made efforts to include patients and carers in the second and third stages, the consensus survey and meeting, through invitations via a range of patient groups. Only one patient and three carers responded and on the day of the meeting the patient was unable to attend. Therefore the consensus meeting had no actual input from a patient who had experienced hip fracture. This is partially negated by the input from carers, however the experience reported after hip fracture by carers and patients has been shown to vary, particularly less than six months after the fracture (Jones and Feeny, 2006). The patient being unable to attend meant that one of the four break-out groups contained no non-professional representative.

Eight domains were identified as of critical importance at the post questionnaire stage; changing basic bodily position, walking, dressing, washing oneself, sensation of pain, emotional functions, moving around using equipment and moving around in different locations. The range of scores awarded by individual participants in the postal questionnaire for 32/34 domains ranged from a minimum of 1 or 2 (not important) to a maximum score of 8 or 9 (critically important) suggesting consensus was not self-evident at this stage. At the consensus meeting these were reduced to six domains with emotional function and moving around using equipment not gaining the required consensus vote of 70%. 18 people participated in the consensus meeting therefore presumably a minimum 13 votes was required to give the 70% agreement level for inclusion of a domain. In comparison to the patient core set developed by Sanderson et al (2010b) for rheumatoid arthritis where the consensus stage included 254 people, the small number of participants in the consensus meeting means just one vote made the decision between these two domains being excluded. That one vote could easily have been different with greater patient participation. Sanderson et al (2010b) conducted their methodology with 5 nominal groups rating the full list of outcomes then proceeding to a postal survey for the final consensus stage. It is possible using the techniques in the opposite order enabled inclusion of a greater number of people, which in turn gave greater consequence to the consensus gained.

How to measure outcome domains in hip fracture (i.e. which scores or individual items) was also discussed by Haywood et al (2014). Three potential patient reported outcome measures

(the EQ-5D, 3L and 5L versions and the Oxford Hip Score) and four items from the NHFD (mortality, indoor and outdoor walking and residential status) were ranked as the most relevant, feasible and suitable measures in the postal questionnaire and were reduced further at the consensus meeting stage. The Oxford hip score and residential status were dropped and the 3L version of the EQ-5D was selected over the 5L. These findings were summarised as a core set using the grouped health outcome domains of pain, activities of daily living and mobility with the addition of mortality and health related quality of life to give five core domains. The EQ-5D was discussed as a useful and practical measure in this population, as outlined in Chapter One. The consensus process undertaken by Haywood et al (2014) supported the continued use of the EQ-5D as a core outcome measure in the hip fracture population. Haywood et al (2014) did not seek consensus for when outcome assessments should be undertaken other than to suggest that retrospective pre-fracture assessment is reasonable due to recent comparisons with population norms.

The preliminary core outcome set for hip fracture proposed by Haywood et al (2014) provides a useful starting point for trials currently in development. However it would be beneficial to consider patient priorities in outcomes further through work to understand and explore the patient experience, particularly through the duration of the recovery process. Inclusion of such data in the initial information gathered and presented to consensus panels and inclusion of patients in those panels would strengthen the claims for validity of any core set. Haywood et al (2014) discussed limitations and difficulties of including the breadth of the heterogeneous hip fracture population in the consensus process. Additional information from qualitative patient experience could support the experience and opinions of those not able to take part to still be included.

2.1.4 Summary

In the area of rheumatoid arthritis OMERACT have highlighted the potential differences between professionals and patients in their opinion of good outcomes. Learning from the experience of OMERACT, this study set out to gain understanding of the experience of recovering from a hip fracture. Insight into the patients' perception of recovery will enable discussion and review of whether in hip fracture there are differences between the professional and patient's view of recovery. Exploration of the patients' perceptions and

priorities of recovery from hip fracture could strengthen the validity of the currently suggested core outcome set for hip fractures by Haywood et al (2014).

2.2 What is known about how patients experience recovery from a hip fracture?

As discussed by Creswell (1998) a study that asks questions such as 'how' or 'why' are best approached with a qualitative methodology. Qualitative studies are ideal for exploring a topic and gathering a detailed view of the phenomena under investigation. Therefore the literature review to establish current knowledge focused on qualitative literature detailing patients' experiences of recovering from a hip fracture.

2.2.1 Search strategy

The literature search was initially undertaken in 2009 to identify research that could give insight into patients' experiences of recovering from a hip fracture. It was updated in 2016. Due to the breadth of professional groups interested in this population a number of databases were included to ensure all key literature was identified. The databases searched are listed in Table 1.

The same search was carried out for all databases through three search engines and the articles found were compiled for review (Table 2). The search was limited to studies between 1980 and June 2016 in the English language. Due to the potential range of terms used to describe hip fracture and the process of recovery the search was performed in stages with multiple terms combined using the Boolean operator 'OR' to ensure a wide inclusive search for each concept and then the stages were combined with 'AND' to obtain a more specific overall list of literature for review.

Table 1 Search strategy: Databases and subject areas

Database	Search Engine	Subject Area (UWE, 2016)
CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature)	Via EBSCO	Nursing, biomedicine, consumer health and 17 other allied health disciplines.
AMED (Allied and Complementary medicine)		Complementary medicine, palliative care and professional allied to medicine (physiotherapy, occupational therapy, podiatry, rehabilitation, speech and language therapy).
MEDLINE		Biomedicine and health including life sciences, behavioural sciences, chemical sciences and bioengineering for health professionals.
PsychoINFO		Psychology, medicine, sociology, pharmacology, physiology and linguistics.
SocINDEX		Sociology
EMBASE	Via OVID	Biomedicine including psychiatry and pharmacology
BNI (British Nursing Index)	Via Proquest	Nursing, midwifery, medical, allied health and management.

The search terms for 'recovery' included additional synonyms that may have been used to describe the recovery process. The initial literature search in 2009 demonstrated that the term 'recovery' in qualitative research was largely used in mental health research. Therefore after considering a dictionary definition of recovery (Collins, 2006), reviewing studies of the experience of recovery in other conditions (Godfrey and Townsend, 2008; Tod, 2008; Wiles et al, 2002), reviewing one of the earliest qualitative studies in hip fracture (Fustenberg, 1986) and on discussion with the supervisory team additional search terms were added. The terms 'improving' or 'improvement', 'restoration' or 'restoring' and 'recuperation' or 'recuperating' were added (using truncation with a * to include all potential endings to the words). The addition of the term 'rehabilitat*' was considered after identification of one potential study through reviewing reference lists of the identified studies (Wykes, Pryor and Jeeawody, 2009). However further exploration of a sample search in one database produced significantly more citations not relevant to this search (such as RCTs) and no further qualitative studies therefore it was decided not to amend the search terms.

The abstracts of all the articles from the fourth search (Table 2, S4 - the accumulative combination of the three previous searches) were reviewed. Further exclusion of “randomised controlled trial” was made in Proquest to improve the accuracy of the search in BNI and to achieve a more manageable search list. Despite search engines such as EBSCO indicating duplicates were automatically removed a substantial number of duplicates were found and removed manually. There was a high level of duplication between the three search engines. The main difference between databases was the number of theses found through Proquest.

Table 2 Search strategy and outcome, performed between 27th May and 1st June 2016

Search Number	Search Terms	Search Engines & Databases, number of articles		
		EBSCO Cinahl Plus, AMED, MEDLINE, PschoINFO, SocINDEX	OVID EMBASE	Proquest BNI
S1	“hip fracture*” OR “proximal femoral fracture*” OR “fractured neck of femur” OR “femoral neck fracture*”	27,918	24,817	4,564
S2	qualitativ* OR interview* OR “focus group*” OR “patient experience*” OR ethnograph*	1,098,602	502,612	150,533
S3	recover* OR improv* OR recuperat* OR restor* OR convalesc*	3,269,309	2,737,818	317,718
S4	S1 AND S2 AND S3	315	227	NOT “randomised controlled trial” 958

Publications focusing on measuring outcome rather than the patient experience of outcome (for example RCTs, longitudinal observational studies or interventional cohort studies), qualitative studies of professionals’ or carers’ experiences and studies of pre-hospital or pre-surgical care were excluded. The inclusion of “interview*” as a search term located a number of quantitative studies because authors referred to interviews as a means of collecting quantitative data. Despite this, to ensure that any qualitative studies were not missed, the

decision was made to keep this search term and to screen and exclude quantitative studies manually after the initial search. All qualitative studies where the focus was patients' experiences of recovery were kept for further detailed review. On this further review qualitative interview studies where the focus of the interview was participants' experiences of a specific intervention were excluded, for example studies on the experience of wearing hip protectors, transitions between hospital and home or completing an exercise programme. Other qualitative studies which focused on the patients' experiences of a specific time or feature of the recovery process rather than the full recovery experience were also excluded. Reference lists of all articles were searched for any further relevant studies that had not been highlighted by this search. This repeated cycle of reviewing the list of citations from the databases and reference lists in further detail produced a final list of eight full articles and three abstracts from conferences for inclusion in the literature review. Two potentially relevant theses (Hair, 2003; Hazel, 2000) from the United States of America were identified but they were not available through interlibrary loan to confirm relevance and no further publications by these authors have been located.

2.2.2 Literature review

Eleven publications from nine studies were identified which had considered the patient experience of recovery without directing the patients to concentrate on specific aspects of the recovery process. These studies therefore allowed patients to discuss their priorities and the areas of the recovery experience most important to them. The aims of these studies broadly cover four areas. Three studies aimed to understand the experience of hip fracture patients to enhance development of health care provision (Jennison, Porter and Rankin, 2014; Brett, Tutton and Staniszewska, 2013; Archibald, 2003). Three studies sought to identify patients' concerns and difficulties through exploring their experience (Kondo et al 2014; McMillan et al 2014; McMillan et al 2012; Wykes, Pryor and Jeeawody, 2009). One study examined the consequences experienced early and late after a hip fracture (Ziden, Scherman and Wenestam, 2010; Ziden, Wenestam and Scherman, 2008). Two studies concentrated on patients' experiences of recovery from hip fracture and their relationship to the measurement of outcome (Griffiths et al, 2015; Haywood et al 2013). The findings of these studies are discussed in greater detail in the following sections.

2.2.2.1 Recovery as a sequential journey, regaining control

Three studies report the experience of hip fracture as a journey with recovery described through stages, in one study the stages were temporal (Archibald, 2003), the others (McMillan et al 2014, McMillan et al, 2012, Wykes Pryor and Jeeawody, 2009) were around the individuals sense of control. The methods and findings for these studies are summarised in Table 3.

Table 3 Summary of the studies presenting recovery as a journey.

Publication	Research method	Findings
Archibald 2003 (England, UK)	Phenomenographic interviews. 5 weeks to 3 month after the injurious fall. Unstructured, open ended questions. Phenomenological analysis using Colaizzi's framework. 5 participants	Four main themes: <ul style="list-style-type: none"> • The injury experience • Pain experience • Recovery experience • Disability experience
McMillan et al 2014, 2012 (Scotland, UK)	Semi-structured interviews between 2 and 12 weeks following discharge. Glasier's approach to grounded theory. 19 participants	Core category of 'taking control'. 3 stages: <ul style="list-style-type: none"> • 'Going under' • 'Keeping afloat' • 'Gaining ground'
Wykes, Pryor and Jeeawody 2009 (Australia)	Descriptive qualitative interviews. Thematic analysis (citing Burnard, 1991) 5 participants during in-patient rehabilitation.	Two main findings: <ul style="list-style-type: none"> • Loss of control • Concerns of participants <ul style="list-style-type: none"> ▪ Behaviour of others (what others said and thought, what others did and did not do) ▪ What was happening to them ▪ Impact on others ▪ Other health issues

Archibald's study of the patient experience of acute hip fracture aimed to inform the approach to daily nursing care and the care environment (Archibald, 2003). His phenomenographic approach aimed to facilitate the patient to describe their story and express their lived experience. The 'recovery experience' was summarised as a single theme and encompassed the operation, the initial difficulties and the gradual return to independence such as starting to walk to the toilet while on the ward. This 'recovery experience' was separated from the 'disability experience' with motivation being a key factor in 'recovery' and stoical acceptance (of dependency or being house bound) as an example of 'disability'. The themes were

sequential and temporal in nature and 'recovery' appeared to have been interpreted as a finite experience followed by the 'disability experience' at the point of discharge.

The narrow timing of the interviews by Archibald may have affected the analysis. The aim of the timing was to facilitate recall of the fall and injury but also to provide a full experience of the in-patient recovery period. However this means that experience of the extended recovery time beyond discharge from hospital would have been limited. Archibald himself questioned the assumption that rehabilitation and therefore recovery was completed once the patient had returned home, as was suggested by the sequential nature and timing of his themes.

McMillan et al (2012) aimed to explore the concerns of older people following the experience of a hip fracture with a view to understanding the impact on recovery. The stages of recovery described by McMillan et al (2012) had commonalities with the process described by Archibald (2003) where the feeling of 'going under' can be aligned with the experience of the injury and pain and the process of 'keeping afloat' and moving towards 'gaining ground' are akin to Archibald's experience of recovery. The experience of 'gaining ground' appears a softer end point to recovery than the experience of disability as described by Archibald, presenting a picture of gradual steps towards independence with periods of no change or feelings of going backwards. This is perhaps because of the concept of balancing risk whilst trying to take control through 'protective guarding' and following instructions from health professionals which McMillan and colleagues went on to describe in their second article giving more detail on the same study (McMillan et al, 2014).

McMillan et al (2012) described a well-constructed study moving from initial purposive sampling to theoretical sampling through constant comparison analysis, which led the authors to seek out participants who had experienced different routes to discharge home and those who had experienced being at home for slightly longer before being interviewed to see how this affected the description of 'taking control'. A changing process of gradually reducing dependence on others is described particularly in the 'keeping afloat' stage. The timing of the interviews is provided in relation to discharge, not fracture or surgery therefore it is difficult to gauge how long after fracture these interviews were conducted as the duration of admission could vary due to the individual circumstances around discharge. The potential for some participants to remain in the 'keeping afloat stage', being unable to progress and take back control was discussed. The experience of a cycle between 'keeping afloat' and 'making ground'

was also identified and reflects the potential for a cyclical process between stages or to be stuck in the recovery stage. For the participants in McMillan et al (2012) the lack of feeling of progress could be due to the timing of the interviews as there may have been an initial feeling of deterioration or going backwards on first leaving the supportive in-patient environment as described by other authors (Taylor, Barelli and Harding, 2010). The first four to six months following discharge are the period of greatest change in abilities following a hip fracture (Magaziner et al, 2000) therefore the expectation would be that participants experience the greatest feeling of progress in this timeframe once settled at home. Interviewing through a longer time frame would have been interesting to see if the feeling of gaining ground stabilised and a status quo was found with an acceptance of an equilibrium between risk and dependency.

The overarching finding by Wykes, Pryor and Jeeawody (2009) that the hip fracture had caused the participants to experience a feeling of loss of control may have been affected by the timing of the interviews. All participants were undergoing inpatient rehabilitation following their fracture which is likely to have influenced their priorities and would not necessarily reflect their experience of their longer term recovery. However concerns about what was happening to them did reflect concerns about the future such as possible changes in accommodation, loss of independence, reliance on others and financial implications. Further exploration of the experience of the recovery process could determine whether this persists once participants have returned home.

2.2.2.2 *Aids and hindrances to recovery*

Three studies (summarised in Table 4) aimed to identify difficulties after hip fracture and ways patients feel recovery and independence can be promoted. Cultural differences may affect perceptions of recovery after hip fracture. Huang and Acton (2009) described how multiple generations living together plus Chinese beliefs may affect the relevance of applying the inferences drawn from studies conducted with particular cultural or ethnic groups to other cultures. They give the example of their finding of 'accepting the natural process' as a Chinese view of ageing, illness and death as 'truths of nature' following the Confucianism, Taoism and Buddhist beliefs.

Robinson (1999) sought to clarify what factors promoted or inhibited function to allow a successful transition after a hip fracture. Kondo et al (2014) aimed to identify the difficulties

experienced in daily life by patients with hip fracture to provide information on their needs. There were some similarities between the findings by Kondo et al (2014) and some of the inhibiting and promoting factors presented by Robinson (1999) (mainly physical discomfort and making adaptations for ADLs), however the findings from Kondo et al (2014) lacked the detail of experiences reported by Robinson (1999). This would be anticipated with the methodological differences with Kondo et al (2014) relying on hand written responses to open questions in a survey therefore giving no opportunity to probe and seek clarification or expansion on topics brought up by the participants.

Table 4 Summary of studies aiming to identify aids and hindrances to recovery

Publication	Research method	Findings
Huang and Acton 2009 (Taiwan)	Face to face interviews within 12 months of fracture. Content analysis (citing Morse & Field, 1995) 15 participants	Three main themes: <ul style="list-style-type: none"> • Social support • Resilience • Accepting the natural processes of ageing
Robinson 1999 (USA)	3 focus groups with 15 community-dwelling women. Within 9 months of fracture. Grounded theory (citing Strauss & Corbin, 1990).	Function-inhibiting factors <ul style="list-style-type: none"> • Physical discomfort, feeling limited, bending precautions, need for assistive devices, loss of enabling skills. Adaptive approaches <ul style="list-style-type: none"> • Viewing age as strength, looking ahead, confronting head-on, minimising problems, seeing humour in frustration, faith. Function-promoting factors <ul style="list-style-type: none"> • Recognising progress, making adaptations for ADLs, accepting help to compensate for shortcomings. Expressions of well-being <ul style="list-style-type: none"> • Thankfulness, pride in conquering.
Kondo et al 2014 (Japan)	Written questionnaires. 126-1247 days since surgery. Qualitative content analysis (citing Graneheim & Lundman, 2004). 124 questionnaires (patients and families).	Four categories of difficulties formulated: <ul style="list-style-type: none"> • Difficulties in ADLs • Physical symptoms • Reduced social activities • Anxiety

2.2.2.3 *Changes to body, identity, relationships and situation after hip fracture*

Two abstracts, summarised in Table 5, were identified which aimed to understand the experience and impact of hip fracture. No further publication of either of these studies (Jennison, Porter and Rankin, 2014; Brett, Tutton and Staniszewska, 2013) has been identified.

Table 5 Summary of abstracts exploring the impact of hip fracture

Publication	Research method	Findings
Jennison, Porter and Rankin 2014 (England, UK) Abstract only	Semi-structured interviews. 15 participants.	<ul style="list-style-type: none"> • Returning to pre-fracture levels of mobility and living circumstances most important. • Participants were unaware of the effect the injury may have on their lives
Brett, Tutton and Staniszewska 2013 (England, UK) Abstract only	Semi-structured interviews 12-16 weeks after surgery. 25 interviews. Interpretative Phenomenology Analysis (IPA).	<ul style="list-style-type: none"> • Biographical disruption and impact on identity in younger participants. • Lack of information and communication after discharge from hospital, especially on how to optimise recovery.

Published as an abstract from a conference, no detail is available regarding the methodological or analysis techniques employed, how the participants were sampled, or duration of time since the injury in the study by Jennison, Porter and Rankin (2014). Therefore it is difficult to judge the integrity of the findings they present. More detail is available in the abstract by Brett, Tutton and Staniszewska (2013). The younger participants, more physically active before the fracture, reported feelings of frustration and incompetency. Participants felt other people's perceptions of them had changed, they felt labelled as 'old' or 'disabled'. The authors concluded that insight into patients' experiences of hip fracture at different stages of recovery was provided however even allowing that the pace of recovery varies between individuals, the stages explored in this study were limited to the first four months following surgery.

Two further studies by Ziden and colleagues (2010, 2008) with the same cohort of participants sampled from a larger interventional study sought to explore the early and late consequences of hip fracture (Table 6).

Table 6 Summary of studies exploring early and late impact of hip fracture

Publication	Research method	Findings
Ziden, Scherman and Wenestam 2008 (Sweden)	Phenomenographic semi-structured interviews at 1 month after discharge. 18 interviews.	<p>Changes related to their bodies and themselves.</p> <ul style="list-style-type: none"> • Limitation in moving. • Confidence with body. <p>Changes in relations to others.</p> <ul style="list-style-type: none"> • More dependent on others. <p>Changes in relation to their life situation.</p>
Ziden, Wenestam and Scherman 2010 (Sweden)	Phenomenographic semi-structured interviews at 12 months after discharge. 15 interviews.	<p>Isolation, restricted activity and fewer social contacts.</p> <ul style="list-style-type: none"> • More insecure and afraid. • More limited ability to move. <p>Disappointment and sadness with changes to life and identity.</p> <p>Satisfaction or improvements in situation.</p>

The participants were purposively sampled on the basis of living conditions, marital status, age and pre-fracture functional status. Asking the participants to relate what happened to them with further probing questions such as ‘tell me more about that’ was used to encourage them to relate their experiences in detail in the interviews. One similarity to the findings of Brett, Tutton and Staniszewska (2013) was a reported struggle to regain their former self-image following the loss of physical activity and confidence. In contrast to the negative feelings expressed by participants in Brett, Tutton and Staniszewska (2013), participants in Ziden, Wenestam and Scherman (2008) related feeling humbled and grateful for what they had and gaining positive human contact, experiencing kindness and consideration. In these early interviews participants in Ziden’s study described changes to their situation, feeling socially and physically less active and being more aware of their age with an uncertain future because of their ageing process. The reflection in both of these studies (Brett, Tutton and Staniszewska, 2013; Ziden, Wenestam and Scherman, 2008) of the negative effect of the fracture as part of the ageing process on self-identity contrasts with the experience of the participants in Huang and Acton (2009) who felt their personal integrity was preserved through their acceptance of the natural ageing process, presenting this as a positive theme and an enabler for maintenance of independence.

Participants in Ziden, Wenestam and Scherman (2010) continued to describe both mobility and social limitations as late consequences of a hip fracture. Although in the earlier interviews

participants were focused on physical consequences such as functional limitations causing dependency (Ziden, Wenestam and Scherman, 2008), in the later interviews the psychological impact of the fracture such social isolation and loss of hope was more dominant (Ziden, Scherman and Wenestam, 2010). It is not clear when or why this shift occurred. Similar to the early interviews, at one year after discharge some participants reported positive experiences, feeling satisfied or even better in their situation. Others reported sadness and frustration at the changes to their life. There was a change to their self-identity which was because of the negative impact of the fracture on their mood and joy in life or was related to their previous view of themselves as healthy, strong and active, which had now been challenged. After a year following discharge from hospital participants expressed contrasting views - some were deflated and their belief in a full recovery had abated, whilst others were content with expectations of recovery fulfilled.

2.2.2.4 Patient priorities in the recovery from hip fracture

Two studies directly explored the outcomes that mattered most to patients recovering from hip fracture (Griffiths et al, 2015; Haywood et al, 2013) (Table 7). An abstract was the only publication found for the study by Haywood et al (2013) therefore less detail was available regarding methodology and their discussion of their findings.

Griffiths et al (2015) was the only study identified which interviewed patients with cognitive impairment (12 participants). The interviewer had no clinical knowledge of hip fracture and used open questions to enquire about the participant's normal day, how bothersome their hip was and how different or same life was compared to before their fracture. Two approaches to analysis were used – a realist approach in recognition that hip fracture was an event identifiable outside the person's view of it and a phenomenological approach as they sought to understand the lived experience of a hip fracture. Participants were asked what was most important to them in terms of their recovery. Thematic analysis was used initially to explore what was important to patients, and following this a cross case analysis was used to compare the variation of experience between participants. Both studies, Griffiths et al (2015) and Haywood et al (2013) found that similar themes were important to patients, although the structure of the themes and sub-themes differed slightly. Despite the limited detail available in an abstract, there appears to be greater detail in the description of experience provided by the subthemes in Haywood et al (2013) than those presented by Griffiths et al (2015).

Table 7 Summary of studies exploring patient priorities in the recovery from hip fracture

Publication	Research method	Findings
Haywood et al 2013	Semi-structured interviews. 30 participants. 3-4 months after surgery. Interpretative Phenomenological approach (IPA).	Physical function <ul style="list-style-type: none"> • Mobility • ADLs Symptoms <ul style="list-style-type: none"> • Pain • Fatigue / Difficulties with concentration • Sleep quality Emotional well-being <ul style="list-style-type: none"> • Depression and low mood • Embarrassment • Sense of control Fear of falling <ul style="list-style-type: none"> • Confidence Social well-being and participation <ul style="list-style-type: none"> • Relationships • Social opportunities • Integration
Griffiths et al 2015	Semi-structured interviews. 41 interviews with 31 participants (10 interviewed twice). 19 interviews with hip fracture patients, 14 with carers and 8 interviews of patient/carers dyads. Interviews at 4 weeks or 4 months after surgery. Thematic analysis and cross case analysis.	Mobility Day to day activities Personal care Pain Mental well-being Fear of falling Leg shortening

The secondary cross case analysis by Griffiths et al (2015), demonstrated how the impact of the fracture varied depending on the individuals' circumstances, in particular their pre-existing health conditions. Participants who were already functionally limited had very specific difficulties caused by the fracture or possibly observed improvements after fracture. The effect of recent changes to health became inseparable from the fracture therefore presenting the fracture as part of a decline or ageing process. The diverse impact of cognitive impairment on recovery was represented by two participants – one was unaware of the fracture and continued as she had previously mobilising and taking herself to the toilet in a nursing home; whilst another participant required adaptations to his bathroom, professional carers four times a day and assistance with personal care following his fracture. Employing a private carer or moving to a nursing home were given as examples of adaptations to reduce the impact of

the fracture by Griffiths et al (2015). However one participant, who had been moved to a nursing home where she knew no one, “repeatedly expressed distress about being in the nursing home”. This may indicate that for her the move was a significant impact of the fracture which she was dissatisfied with, rather than an adaptation to “mitigate the effect of the fracture”. Adaptations for those participants who were active pre-fracture were considered temporary however they remained evident at four months. Without further interviews at a later time point it is not possible to judge whether the need for adaptations persisted.

Griffiths et al (2015) found the same emphasis on overarching themes about recovery was discussed at the two interview time points but the detail changed as recovery progressed. Experience such as limited mobility was discussed at both times but it had improved at four months, frustration at the activities that were difficult at four weeks had either been abandoned or adapted to by four months. This was in contrast to the shift observed by Ziden and colleagues (2010, 2008) who found the participants moved their focus between themes from early to late interviews (from changes to their bodies and relations with others and their life situations to the more psychological consequences of social isolation, loss of sense of self and emotions such as fear, sadness or contentment). This subtle difference in findings of how the experience of recovering from a hip fracture changed between two interview time points in these studies may be due to methodological differences with Ziden, Scherman and Wenestam (2010) interviewing the same participants at four weeks and 12 months after discharge, whilst Griffiths et al (2015) interviewed largely separate cohorts at four weeks and four months following hip fracture.

The shift towards a psychological impact of the fracture asserted by Ziden and colleagues may manifest later in the recovery process than investigated by Griffiths et al (2015). Griffiths et al (2015) reported an original intention to interview at 12 months which was not carried out because of the apparent lack of new data arising at the four month interviews which pertained directly to the hip fracture. The non-clinical background and lack of previous knowledge of hip fracture of the interviewer was discussed by Griffiths et al (2015) as reducing the potential for the interviewer to influence the data constructed by the interview process. However it was suggested that an interviewer with clinical knowledge may have been more able to prompt and assist the unpicking of experience related to the fracture which could have influenced the apparent need to continue to 12 month interviews.

2.2.2.5 Pre-fracture circumstance and pre-existing health conditions

The studies discussed in this literature review (Section 2.2.2) have generally concentrated on the experiences of patients who were living in the community before their fractures and returned there (McMillan et al, 2012; Huang and Acton, 2009; Ziden, Wenestam and Scherman, 2008) and who had no cognitive impairment or as a minimum were cognitively able to participate in the interviews (McMillan et al 2012; Ziden, Wenestam and Scherman, 2008; Archibald, 2003). Only Griffiths et al (2015) and Kondo et al (2014) included participants with cognitive impairment by including carers in the data collection process. This was in part due to the aims of the studies. Where the experiences discussed were to be used to improve care provision, it was important to include the experiences of patients who had 'successfully recovered'. As discussed in Chapter One Sections 1.2 and 1.3 return to one's own home to live in the community is interpreted as a successful outcome. Inclusion of family and carers is an opportunity to include the experience of recovery for the significant proportion of the hip fracture population (42% cognitive impaired (Seitz et al, 2011)) who do not have the cognitive function to participate fully in the interviews themselves. However it could be argued that then it is actually the carer's experience and interpretation of the recovery from hip fracture being reported and so answers a slightly different question. An alternative methodology would be to undertake ethnographic observations of hip fracture patients with cognitive impairment, although logistically achieving this outside of the hospital setting would be difficult. No examples of observational studies of the recovery of cognitively impaired hip fracture patients have been identified in the literature.

The complicated and individual nature of the patient experience of a hip fracture due to general health circumstances and pre-existing conditions was discussed by the authors of some studies (Griffiths et al, 2015; Wykes, Pryor and Jeeawody, 2009) but not others (Kondo et al, 2014; McMillan et al, 2012; Ziden, Scherman and Wenestam, 2010; Huang and Acton, 2009; Archibald, 2003; Robinson, 1999). The need to recover from the hip fracture affected options for treatment for other conditions (Wykes, Pryor and Jeeawody, 2009). The impact of the fracture was experienced less significantly by some participants who were already more dependent on support to live at home or whose other problems overshadowed difficulties that hip fracture created (Griffiths et al, 2015; Wykes, Pryor and Jeeawody, 2009). Where the impact of other health conditions may not have been discussed (perhaps due to a cohort of participants who were previously in good health), the resultant impact of the fracture was seen as representative of the ageing process which assisted acceptance of limitations in some

cases (Huang and Acton, 2009) but challenged self-identity in other cases (Brett, Tutton and Staniszewska, 2013; Ziden, Scherman and Wenestam, 2010).

2.2.2.6 Summary

The patient experience of the recovery after a hip fracture provided by the 11 publications reviewed presents a picture of changes to function (including mobility, basic activities and social activities), physical symptoms, concerns over living situation, independence and being a burden and emotional factors such as fear of falling and motivation. The impact of the fracture can also be experienced psychologically with loss of confidence and self-identity. The description of the impact of a hip fracture is individualised by the association with the process of ageing and the effects of other health conditions. The process of recovering from the fracture has been described as following a sequence of stages from experiencing the injury (Archibald, 2003) or 'going under' (McMillan et al, 2012), through pain and recovery or 'keeping afloat' though to 'making ground' (McMillan et al, 2012) or disability (Archibald, 2003).

The studies discussed in this review have explored the patients' experience of hip fracture initiated by different lines of enquiry. A range of study designs have been used including surveys with open questions (Kondo et al, 2014), focus groups (Robinson, 1999) and interviews. Open ended face to face interviews (Wykes, Pryor and Jeeawody, 2009; Huang and Acton, 2009; Archibald, 2003) and semi-structured interviews (Griffiths et al, 2015; Jennison, Porter and Rankin, 2014; Brett, Tutton and Staniszewska, 2013; Haywood et al, 2013; McMillan et al 2012; Ziden, Schermann and Wenestam, 2010; Ziden, Wenestam and Schermann, 2008) are the most frequent data collection method used with this population. The interview studies are based on a range of epistemologies and use associated analysis techniques (including content analysis, grounded theory, IPA, phenomenology, a realist approach using thematic analysis and cross case analysis). Only Ziden and colleagues (2010, 2008) and Griffiths et al (2015) considered the experience of hip fracture recovery at more than one time point with only Ziden and colleagues (2010, 2008) following the same participants at two time points up to 12 months following discharge. Some studies that did not conduct follow-up interviews with the same participants recognised that a longitudinal study design would provide valuable additional understanding of the experience of a hip fracture (Kondo et al, 2014; Wykes, Pryor and Jeeawody, 2009).

2.3 Chapter summary

A suggested core set (Haywood et al, 2014) and two studies (Griffiths et al 2015, Haywood et al 2014) with aims and questions closely aligned with this MPhil study have been published since the majority of the data collection was undertaken. These publications highlight the topical and important nature of the enquiry which was undertaken. However, the evidence leading to the current consensus on outcome measurement in hip fracture would be strengthened by a study considering what is important to hip fracture patients as recovery progresses over a longer time frame and by including this evidence in the preparatory information provided to a consensus panel.

2.4 Research aim, questions and objectives

The aim of this research was to establish an understanding of patients' experiences of recovery to identify what aspects of recovery following hip fracture are most important to them across a year after the injury. The ambition was that this understanding of the patient priorities could build on the existing qualitative evidence base to inform the decision-making process for selecting appropriate domains when evaluating hip fracture recovery. The study was therefore designed to address the following questions:

- 1) How do patients experience recovery from a hip fracture and what is important to them?
- 2) Does their experience of recovery and what is most important to them change over time following the injury?

The objectives of the study were therefore to:

- 1) Explore the patient experience of recovery following a hip fracture over the course of a year following the injury.
- 2) Explore what aspects of recovery are patients' priorities and whether these vary at different times following injury.

Chapter 3: Methodology and Methods

This chapter describes the philosophy underpinning the study and gives a detailed explanation of the methods used.

3.1 Overview of study design

To address the aims and objectives stated in Chapter Two Section 2.4 a qualitative longitudinal interview study was designed. Semi structured interviews were conducted at three time points after the participants had surgical fixation of an extracapsular hip fracture. These time points formed three phases over the course of twelve months; following discharge from hospital, at six months and twelve months post fracture and surgery.

A thematic analysis (Braun and Clarke, 2006) of the interviews was undertaken within each phase. Following this the data was reviewed again taking a longitudinal view of the themes.

3.2 Methodology

Denzin and Lincoln (1998) laid out a five stage process for research. This format provided a useful structure through which to consider the development and execution of a research project. This structure has been used below to lay out the methodological considerations in the design of this study.

3.2.1 Stage 1: The researcher as a “multicultural subject”

A researcher brings their beliefs, experiences and own interpretations of the social world to the research project; termed the “*biographically-situated*” researcher by Denzin and Lincoln (1998). The act of research is therefore interpreted through a researcher’s understanding of the world and so it is important for a researcher to reflect upon and acknowledge their view of the world and how that may influence all aspects of the study. Their interpretation will have affected not only how the research is designed and conducted but preceding this will also have influenced their approach to the topic and formulation of the research question. The present study was conceived while I was working in an NHS based clinical research environment. Clinical research has increasingly focused on how to measure outcome when assessing the efficacy of treatments (Williamson et al, 2012). My background training as a physiotherapist, providing personalised care while also aiming to contribute to the drive for evidence based

practice influenced the development of this study. This blend of the scientific approach to evidence based practice, whilst maintaining the importance of the individual patient, is an undercurrent throughout the following discussion of the methodology.

3.2.2 Stage 2: Theoretical paradigms and perspectives

The current study sought to contribute towards a position that enables empirical research to take place which can influence and guide decisions in caring for hip fracture patients. On the face of it this is an aim from a traditional positivist standpoint where research is seeking to identify cause and effect relationships through objective observation to generate 'true knowledge' of an independent reality (Hammersley, 2013; Snape and Spencer, 2003). The positivist approach however does not consider the potential for the individual's experiences to influence the relationship under examination and that the experience of the individual and the researcher may give a contextual interpretation of the phenomenon or relationship being studied (Snape and Spencer 2003). This study specifically sought to explore the experience of the person with the hip fracture and what was important to them within their life, inclusive of their health, social and cultural situation. The study sought to gain an understanding of the priorities of the people who have had the injury to inform how quality and success of care for this injury is evaluated and was conceived due to difficulties experienced while developing a quantitative research study with this population. This is at odds with traditional clinical positivist beliefs.

Placing importance on experience and seeking to understand the 'lived experience' of recovering from an injury such as a hip fracture could be viewed as a phenomenological approach (Creswell, 1998). Certainly this would fit with the broad aims of the study and has been the approach taken in previous research into the experience of hip fracture (Ziden, Schermann and Wenestam, 2010; Ziden, Wenestam and Schermann, 2008; Fustenberg, 1986). A phenomenological approach comes from an interpretivist stance where knowing about the world is more than a directly observable phenomenon; the emphasis is on understanding and exploring a lived experience in the context of an individual's social, cultural and historical world (Snape and Spencer, 2003). However, when considering that the aim of the study was to present the experience of individuals following a hip fracture to enable that experience to be cogent in the design or choice of outcome measures for use within a health sciences empirical research setting, an interpretivist phenomenological approach no longer felt applicable. It did not feel appropriate for the findings from a phenomenological study, where

the idealist views of no external reality form the basis of the study conception, to be taken forward and implemented in assisting the design of a quantitative clinical research study.

The approach taken in this study comes from more of a realist philosophy, where the personal aspects of the individual's circumstances and psychology are seen as important alongside the physiological healing from injury when considering recovery (Hammersley, 2013). A realist tradition recognises that there is an external reality (therefore there are cause and effect mechanisms to be identified) whilst acknowledging that there is an influence from human factors acting within the current social structure (Danermark et al, 2001). A realist therefore shares the positivist interest in the objective world – in generalising and finding causalities - but it disagrees with positivism in accepting this knowledge without seeking to understand the unobservable mechanisms acting within it. This realist view of knowledge is open to the idea that all knowledge is imperfect but that not all interpretations are equally valid. In contrast to phenomenology (where the researcher intends to 'bracket' or suspend one's own opinion in pursuit of the lived experience (Creswell, 1998)), or positivism (where the possible influence of the researcher is denied); the realist researcher acknowledges their background and view point will have an effect on the study (Hammersley, 2013). Therefore efforts should be made to be aware of this and limit it where possible in an attempt to produce a rigorous and valid study. Where it is not possible to limit the influence of the researcher a realist researcher should make their assumptions explicit and therefore the potential impact on the evidence produced transparent (Snape and Spencer, 2003).

The dual aspect of the realist approach – the belief there is a 'truth' of distinct knowledge to be identified and the acceptance of the individual's interpretation of the knowledge allows the application of a range of research strategies to explore and investigate the aims of the study within its wider remit. Realism is not wedded to any specific research method as all methods are seen to produce incomplete understanding of phenomena and approximations of reality within the view that all knowledge is imperfect. The aim of the realist researcher is therefore to produce a valid interpretation and therefore their choice of method depends on the type of study and its focus (Bergin, Wells and Owen, 2008).

3.2.3 Stage 3: Research strategy

This study aspired to establish a detailed understanding of patients' experiences of recovering from a hip fracture to inform how the clinical research community can evaluate the success of

interventions in the management of the injury. It comes from a belief that success of an intervention should be judged against what is deemed important by those who have experienced the injury. It therefore seeks to gain an in-depth understanding of the experience of people who have had a hip fracture and what is most important to them in the months afterwards. Identifying broad concepts in patients' experiences when recovering from the injury would then enable that understanding to be taken forward to inform which outcome measures may be best placed to reflect these priorities when evaluating the effects of clinical interventions in line with the aims of groups such as COMET.

Qualitative methods are best placed to explore and develop an understanding of patients' experiences from their own perspective (Pope and Mays, 2006); only the individual who has broken their hip can 'know' the experience. Fustenberg (1986), in one of the earliest qualitative studies after hip fracture, described how participants' expectations changed and were revised in response to experience. The experiences of hip fracture are likely to change as physiological recovery progresses and circumstances change, suggesting it is unrealistic to understand the experience of recovering from a hip fracture at one moment in time. Therefore it was also important to establish how that experience of a hip fracture may change over time and therefore whether patients' experiences and related priorities may alter as time passes.

A prospective longitudinal qualitative research [LQR] design was chosen to address the research questions of this study. The qualitative design addressed how patients experience recovery. The longitudinal element explored whether this experience and their priorities changed by following the same people over time, referred to as a 'panel' study by Blaikie (2000). Change in experience over time is a key focus for LQR designs (Calman, Brunton and Molassiotis, 2013). A planned prospective longitudinal study where the unit of analysis is the individual is a recognized LQR methodology (Calman, Brunton and Molassiotis, 2013, citing Holland, Thomson and Henderson, 2006). An LQR methodology is appropriate within the realist paradigm as it not only provides an opportunity to observe the changes at each time point but also to explore and aim to understand some of the unobservable mechanisms behind the changes (Hermanowicz, 2013).

Multiple rounds of data collection were designed to provide the opportunity for analysis both at specific points in time (within phase or cross sectional) and through time (across phases or longitudinally). Thus the study was a qualitative longitudinal exploration of the experience of a

year following a hip fracture. The following sections discuss the specific methods used and ethical and practical issues of this research design.

3.2.4 Stage 4: Methods of data collection and analysis

3.2.4.1 *Semi-structured interviews*

Individual interviews were the preferred qualitative data collection method for this study rather than group interviews, such as focus groups, for practical and methodological reasons. The aim was to gain a detailed understanding of experience and priorities following a hip fracture rather than seeking a consensus view for which a group interview would have been more appropriate (Kitzinger, 2006). Individual interviews were also more practical by enabling follow-up of participants over the course of a year whilst being able to accommodate the availability, potential frailty and poor mobility levels of the participants by the interviewer being able to attend a time and location of each participant's own choice.

Semi-structured interviews were chosen as an appropriate technique to gain in-depth understanding of a participant's experience and to develop knowledge of the phenomenon (Blaikie, 2000) rather than a structured interview or questionnaire which may have limited the breadth of a participant's response (Fontana and Frey, 1998) or lead the researcher to dictate the direction of the interview (Barbour, 2008). An open or narrative interview would also achieve this, however the use of a topic guide to define areas to be covered helps the interviewer meet the objectives of the study (Britten, 2006).

Multiple rounds of interviews with each participant were planned for this LQR study. The first interview was timed to occur after discharge from hospital, between eight and 12 weeks following their hip fracture. Conducting interviews with older adults while in hospital has been reported to present many challenges including interruptions, ambient noise, delirium, confusion and effects of surgery (Peel and Wilson, 2008 citing Berkman et al, 2001). The timing of the first interview provided the participants with a frame of reference (having recently left hospital) to reflect what had changed and progressed in their recovery journey to date. The second interview was timed approximately six months after surgery. Studies have found that at six months following hip fracture the majority of recovery has occurred (Penrod et al, 2008; Peterson et al, 2002, Jette et al, 1987). An interview at six months after their hip fracture was therefore included in the design to explore their experience of this phase of recovery. Ziden and colleagues (2010) discussed in their findings that they were unable to anticipate how the

individual's situation might be experienced later in the recovery process from their early interviews (at four weeks). Other studies have found that the recovery trajectory continued between six and 12 months (Magaziner et al, 2000; Fox et al, 1999) therefore it was decided to continue the interviewing into a third phase at 12 months.

3.2.4.2 Thematic analysis

Braun and Clarke (2006) argued that thematic analysis was a method free from theoretical or epistemological underpinnings and so it could be applied across a range of approaches. It is therefore appropriate for use with a realist approach. With no method explicitly designed for longitudinal designs with repeated interviews the flexibility of thematic analysis lent itself to this study as it provided a structured stepwise approach for analysis across an entire data set which enabled its application both within and across interview phases. Thematic analysis did not require an in-depth theoretical and technological knowledge of a specific approach; therefore making it suitable for use by a novice qualitative researcher (Braun and Clarke, 2006). This flexibility to apply the thematic analysis across the data set of individuals within each phase and for an individual across the phases was felt to be an advantage compared to, for example Interpretative Phenomenological Analysis [IPA] (Smith and Osborn, 2003). Grounded Theory (Corbin and Strauss 1990) was not chosen because the study did not aim to generate new theory but more to expand and apply understanding to existing outcome measurement theories.

Either an inductive or deductive approach can be adopted in a thematic analysis. In this case an inductive approach was appropriate because it fitted with the study aims to explore the patients' experiences and their priorities from the ground up. A more deductive approach was considered using the International Classification of Functioning, Disability and Health (ICF) (World Health Organisation, 2001) as a framework; however with the recognised limitations of the ICF in areas such as lack of integration of biopsychosocial theory; lack of distinction between activities and participation as components of functioning and the complexities of its application (Ravenek et al, 2013); the ICF was not pursued as there was potential for important aspects of experience to have been missed.

Thematic analysis can be at a semantic level, focusing on identifying the meanings within the data and aiming to describe and progressively summarise and interpret the content and patterns of the themes for their significance and implications. A thematic analysis can also

move beyond this to a latent level, where the themes are further interpreted and theorised (Braun and Clarke, 2006). In the current study the significance of the themes and implications were sought to use alongside and to apply to the existing theories of outcome measurement rather than to develop theories. Therefore the analysis was aimed at a semantic level which is also more in keeping with a realist approach.

3.2.5 Stage 5: The art of interpretation and presentation

In the interpretation of qualitative data it is important to judge the adequacy and quality of the data and the analysis process. Within the realist approach a researcher should aim to establish some credibility of their analysis by presenting how rigour has been maintained through the conduct of the study. As described by Green and Thorogood (2004 page 191) there are general principles that may be employed to maintain the integrity of a rigorous qualitative analysis. In the presentation of this study effort has been made to include these principles. The strategies used to maintain rigour and integrity included presenting transparency of procedures, maximising validity through presentation of divergent cases and provision of context, maximising reliability through use of the whole data set and efforts to involve some second coding, comparison within and between cases, and through reflexivity accounting for the role of the researcher.

Following this overview of the methodology which has discussed the approach, process and design of the research, the next section will present the detailed method undertaken in this study.

3.3 Method

3.3.1 Sample

A sample of adults over the age of 60 who had experienced a hip fracture was drawn for convenience from the parent study (described in Chapter One Section 1.5). A convenience sample as described by Morse (2007) is a selection of participants because they are accessible. It was anticipated that an adequate representation of the hip fracture population (extracapsular fractures) would be available within the context of the exclusion criteria of the parent study.

Approvals were sought to recruit up to 30 participants. This was to provide scope within the ethics approval to recruit sufficient participants to reach data saturation, acknowledging the

potential for participants to withdraw from the study. The concept of data saturation, where interview data eventually ceases to produce new themes, stems from Grounded Theory with an aim to continue sampling to the point where the lack of new themes infers theoretical saturation (Charmaz, 2006). In this study an awareness of data saturation was desired as a judgement of quality and rigour; it was intended that there would be sufficient interviews to reach the point where data collection and analysis produced no further changes to the code list and descriptions, aiming therefore for data saturation rather than theoretical saturation. Guest, Bunce and Johnson (2006) found that 94% of their high frequency codes were identified in the first six interviews and 92% of all codes had been created within the first twelve interviews. As mortality at one year in the hip fracture population is known to be approximately one third (RCP, 2016) the intention was to initially recruit sufficient participants to have capacity for at least this percentage to drop out over the year. Attrition of participants is also recognised to be a challenge in longitudinal research therefore ethical permission for over-recruitment gave scope to recruit more participants if early rates of attrition appeared high (Calman, Brunton and Molassiotis, 2013). Consistency of researcher and clear plans for contacting the participants have been suggested as the best strategy to minimize attrition (Thomson and Holland, 2003) and were successfully employed in this study. The aim to recruit 30 participants was therefore anticipated to secure a minimum of 12 recruits completing the study at the twelve month interview phase, allowing for potential 33% mortality and further potential withdrawals from the study due to loss of contact or consent.

3.3.2 Development of study resources

A topic guide was developed to guide the content of the interviews [Appendix B]. Barbour (2008) suggested a series of headings or few carefully worded open ended questions with prompts to be helpful to the researcher. Using a topic guide should allow the participant to elaborate rather than the researcher dictating the direction of the discussion, as was desired with the inductive aims for the study (Barbour, 2008). The approach recommended by Calman, Brunton and Molassiotis (2013) for topic guides in LQR was used, using broad questions to allow the participants to talk about what was important to them at the time of the interview. This enabled one topic guide to be approved and used for all three interview phases which is common in LQR studies designed in advance (Hermanowicz, 2013). Following review of previous qualitative studies with hip fracture patients (Archibald, 2003), studies with similar aims in other clinical specialties (Sanderson et al, 2010a), and discussion with the supervisory team, the topic guide included an initial introductory question and four main open questions.

The introductory question aimed to warm up and facilitate the building of rapport and to provide information for prompts about lifestyle and interests. This was followed by the main section with four questions aiming to engage the participant in a discussion about their experiences since they broke their hip (or their previous interview), their activities and function, how those may have changed, and what was most important to them (either things that had already been achieved or that they wanted to return to). A selection of potential sub questions to use for further prompting were included. Two final questions were also included for another objective within the parent study regarding the feasibility and acceptability of the outcome measures and injection. This aspect of the interview has not been included in the analysis or reporting for the purposes of this thesis.

3.3.3 Approvals and ethical considerations

The approval processes were managed in conjunction with those of the parent study from South West 2 Research Ethics Committee based in Exeter (Reference 10/H0206/34). The outcome of the NHS ethical application was then included in the submission for ethical review by the University of the West of England [UWE]. Approval from the Research and Development Department at North Bristol NHS Trust as the NHS site for recruitment of the participants was also secured in tandem with the approvals for the parent study. [Appendices C and D Approval documents]

During the course of the parent study a number of minor amendments were made which required official approval from the ethics committee as was the standard procedure for a Clinical Trial of an Investigational Medicinal Product (CtIMP). Due to difficulties with recruitment the parent study was expanded to a multi-centre study (a substantial amendment). The current MPhil qualitative study was also expanded to an additional site to take advantage of the increased potential recruitment. Again, the approvals were managed together.

A LQR design has potential ethical challenges specific to its longitudinal nature, particularly with populations who may be vulnerable such as hip fracture patients. A number of participant and researcher-related ethical considerations were highlighted by Calman et al (2013). Issues such as intrusion into people's lives, recruiting and collecting data in what may be a difficult and sensitive time in their life may be heightened with multiple contacts. To minimise this risk I emphasised at each contact (telephone and face to face) that consent was an ongoing process

and participants could withdraw from the study at any time. They were also reminded that the audio recording could be stopped at any time. The known mortality rate following hip fracture also presented the risk that participants may die between interviews. As participants in the parent study the wider research team had access to their medical records and was able to inform me of any changes to the participant's health so this could be dealt with sensitively.

The increased relationship and potential for dependency developed through the nature of an LQR study can also affect the researcher (Calman et al, 2013). Researchers may see participants deteriorate during the course of the research. Supportive networks were available for me through the wider research team for the parent study and the academic supervisory team. Access to further counselling support was available through the university if required.

3.3.4 Recruitment

The North Bristol NHS Trust research team for the parent study screened all participants in the parent study for inclusion in this qualitative study. All English speaking participants well enough to discuss the study with the research team were approached about the study. Those who expressed interest were provided with the participant information sheet [PIS] and were asked for verbal permission to pass their contact details on to me. This normally occurred approximately six weeks after their hip fracture [Appendix E Participant information sheet]. Once the potential participants had provided their verbal agreement I telephoned them to answer any questions regarding the PIS and to discuss participation in the study. No further exclusion criteria were applied. Formal written consent was provided when I visited them for the first interview. The same recruitment process as described above was followed at the additional centre. Only one participant was recruited from this additional site.

3.3.5 Data collection

3.3.5.1 First interview

Once a potential participant agreed I arranged to visit a convenient location chosen by the participant. All participants chose to be interviewed in their own homes. On arrival at their home the content of the PIS was reviewed; the purpose of study was discussed, the plan to repeat two further interviews over the course of a year, the recording, transcription and anonymisation process and the potential to use anonymised quotes were reiterated. Informed written consent was provided by the participants prior to the interview being conducted

[Appendix E page 170]. All first phase interviews were completed between eight and 12 weeks after injury.

The interview was recorded using a digital audio recorder located between interviewer and respondent, as unobtrusively as possible. The recording was stopped during any interruptions, for example if the participant took a telephone call, and was restarted afterwards. The questions as laid out in the topic guide were followed, using prompts and sub-questions within each section as required [Appendix B].

Notes were taken as required and as possible without being intrusive. Effort was made to maintain eye contact for reassurance and rapport but the notes were also important to keep track of topics to return to for further prompts, a balance that was occasionally challenging. Notes were also used to describe non-verbal gestures where necessary, for example if the participant was indicating parts of their body or equipment without saying the words, and these notes were later used to clarify the interview transcripts. Recommendations for interviewing frail older people as participants in research by Peel and Wilson (2008) were attended to, for example punctuality, carrying identification, dressing appropriately to show respect and gain initial trust, attention to practicalities such as access to hearing aids, glasses, walking aids and being seated comfortably. There was also an awareness of personal interaction such as adjusting volume and speed of speech as appropriate.

Arrangements were made to contact the participants prior to the next interview to arrange a convenient time approximately three to four months later. The interviews varied in duration ranging between 25 and 105 minutes (mean 62 minutes). Further notes were made about any thoughts on the content of the interview, any circumstances in the house believed pertinent, or any discussion and comments of interest after the audio recorder was switched off. As discussed by Peel and Wilson (2008) the volume of data produced by a longitudinal study can be overwhelming. The notes helped provide a context and a reminder of the interview, along with listening to the interviews before returning to complete the next interview with the participant, to recap the participant's circumstances, initial thoughts on themes and topics to clarify and revisit.

Following the first three interviews the interview topic guide was revisited and edited to produce an improved layout to facilitate prompts and sub questions. The changes positioned

the main questions more centrally and provided the interviewer with more suggestions for open prompts in an eye catching position, therefore easier to manage whilst multi-tasking between active listening and taking notes [Appendix B Interview topic guide versions 1 and 2].

3.3.5.2 *Second and third interviews*

As previously agreed with the participant I telephoned them approaching the time for the six month interview to check that they were willing to take part in a second interview and to arrange the visit. Notes were taken during the telephone call if details were given that could then be used as prompts during the subsequent face-to-face interview, this was largely so that it was clear to the participant that I had heard what they had said to me during the telephone call. Prior to the interview the audio-recording of the previous interview was listened to and notes were made regarding any points of interest to be followed up on or used as prompts. The phase two interviews were conducted between six and seven months following surgery. The same system was used leading up to the twelve month interviews which were completed between 12 and 15 months following surgery.

The second and third phase interviews were conducted and audio-recorded following the same topic guide as the first interview. Notes were taken during and after as at the first interview. These second phase interviews ranged between 36 and 71 minutes (mean 55 minutes) in duration. The third phase interviews lasted between 28 and 70 minutes (mean 50 minutes). The tendency for subsequent interviews to be shorter than the first one was noted by Calman, Brunton and Molassiotis (2013) who proposed that this was due to the ability to focus more on the longitudinal elements of the study, in other words, what has changed since last time. The rapport developed and awareness of a participant's social circumstances, hobbies and interests helped me to open up areas of discussion quickly, without long preambles using simple open enquiries and may have assisted the participant to feel they had had an opportunity to discuss their current priorities. For example several participants kept dogs as pets, and the enquiry in the third phase of interviewing 'how do you manage with the dog?' for one participant led to a simple 'he's fine' and he continued to discuss his wife and garden [284]. For another participant [146] this led into a discussion of the improvement now that he could drive to take the dog for walks but his frustration with the limitation on the distance he could walk due to his limp. The rapport gained and both the interviewer's and interviewee's memories of previous conversations enabled a rapid return to the priority issues.

3.3.6 Impact of role of the researcher

In a realist enquiry it is recognised *“the analysis brings the researchers’ prejudices and prejudgements, theories, frames of reference and concepts into engagement with the evidence collected in the research”* (Emmel, 2013 page 81). Therefore explicit examination of the context in which the analysis is produced is important to allow an interpretation of any claims made from the research. Braun and Clark (2013) discuss the importance of reflexivity and the ability to reflect on our ‘insider’ and ‘outsider’ positions. As a physiotherapist and the granddaughter of someone who died within months of fracturing her hip I have personal experience of different potential routes through the recovery from hip fracture. My experiences as a young teenager of my grandmother left a memory of a brief, difficult, painful fight to regain some independence or mobility which ended tragically, unable to return home with my grandfather and dying only weeks later in residential care. My expectations and approach to this research study could have been very different if this experience had not been counter-balanced with professional experience of large numbers of men and women returning home with varying degrees of recovery from their injuries. This broad experience over fifteen years of professional practice has shown me that although certain complexities of health and social situations can make it more complicated, people can always surprise you. I therefore went into this study with an open mind and a range of expectations regarding the recovery the participants might experience over the twelve months that I knew them.

As described in Chapter One I was the trial coordinator of the parent study. Due to this, and as a physiotherapist, there was the potential to be seen by the participants as part of the team providing their care. Although this could have encouraged disclosure and participation in the interviews due to the potential to build rapport there was also the risk that it could influence the experiences reported. My role was therefore explained to the participants as a post graduate student from the University. In most cases this was successful, with the participants comfortably disclosing their opinions of the physiotherapists that had treated them and relating their communication with medical professionals in general. In one case my background as a physiotherapist was disclosed by a doctor during a follow up consultation and the patient’s subsequent interview was complicated by his asking questions and for my opinion on his experience. On these occasions I continued to emphasise to him that as I had never broken my hip myself I was interested in his (and the other participants’) experience and that the experience over time was not well understood which was why I wanted to speak to him multiple times over twelve months.

When working to rehabilitate this patient group my role as a physiotherapist is to optimise function and well-being. Using the patient's individual goals the aim is to assist them to return to their chosen lifestyle therefore limiting their restrictions following their fracture (Chartered Society of Physiotherapy [CSP] 2014). My training is to facilitate each patient to achieve their individual potential following an injury such as hip fracture – for example to regain and maintain range of movement of the joints, the strength of the muscle groups and coordinate functional processes such as being able to stand from sitting and walk; thus enabling them to function within their surroundings and society. It is important to recognise that this training and background knowledge had the potential to affect all aspects of my approach to the study – from design, through to how the questioning and prompting was performed during the interviews, to which data excerpts were identified for coding, and how the data was interpreted.

Acknowledging this and being aware of it is the primary way to mitigate any effect on the outcome of the study. However, sharing the study process with the supervisory team and introducing processes such as a review of a sample transcript by a second coder were included in the study design to enhance the credibility of the findings. A journal was maintained throughout the duration of the study. The process of writing the journal formalised my reflection, increasing the consciousness of my thinking processes, and recording changes in my awareness throughout the duration of the study. The notes have supported the analysis and development of this thesis over the continuation of the seven years the study has been ongoing.

3.3.7 Thematic analysis of interview phases

Braun and Clark (2006) offered a six stage model for thematic analysis. These stages were used to guide the analysis process and are described below. The thematic analysis for the phase one interviews (conducted between eight and twelve weeks after hip fracture) is described in detail first, followed by details for phase two and three.

3.3.7.1 Phase one

Stage 1 – Familiarisation with the data

Transcribing, reading and re-reading the data was the essential first step described by Braun and Clark (2006) in common with other qualitative analysis methods (Silverman, 2011 citing Rapley, 2011). Acknowledging the importance of the transcription as a mechanism for

becoming immersed in the data, I transcribed the initial three interviews. However, for practicalities of time, the rest of the interviews were transcribed by an independent typist. In line with the minimum standards for thematic analysis a verbatim account of all verbal and some non-verbal communication were transcribed. A basic template using labels of 'Interviewer' and 'Respondent' was used. Punctuation was used in line with normal speech patterns to convey as far as possible the original phrasing and meaning.

The transcripts were then reviewed while listening again to the audio files. Further anonymisation, clarification, correction for accuracy and addition of the non-verbal communication was completed, using notes from the interview as appropriate. The transcripts were titled with a pseudonym (taken from characters from a novel), interview phase and date. Notes from the interview were typed up and added to the transcript. A pseudonym table was maintained. A participant log was maintained to record progress and electronic copies of the anonymised transcripts were archived with the NHS Sponsor.

Stage 2 – Generating initial codes

The transcripts were uploaded to a software package, QSR International's NVivo 10 for Windows (NVivo, 2012). The software was used to facilitate the management of the data. Coding was undertaken line by line within the NVivo package. Any excerpt of text (or data) that was of interest was coded creating a code name that described its meaning, using the participant's own words where appropriate. Multiple codes were applied to the same section of data as necessary (termed simultaneous coding by Saldana, 2013). Simultaneous coding meant it was possible to consider multiple levels of recovery being discussed in combination, for example frustration at the pain when walking that meant it was difficult to walk the dog and see friends could be coded at multiple levels. Saldana (2013) refers to this style of coding as 'splitting', an initial elemental coding for description which is a first step and is a framework for the next stage. Throughout coding a list of the codes was created and a description of each was maintained to aid the consistent application of codes to the data [Appendix F Code list and descriptions]. These initial codes were created as 'free codes' within the NVivo package, thus initially giving all codes the same importance and attention with no initial structure or hierarchy, fitting the inductive approach to the analysis. During the manual process of coding sufficient surrounding text was included to ensure the context of the excerpt was maintained (Bryman 2001). In conjunction with the code list and descriptions, a reflexive journal of thoughts and emergent patterns was maintained throughout this process which was then

referred to during stage three of analysis. The code list and descriptions with some examples of coded text were reviewed with supervisors after the first three interviews were coded.

A log of the dates of code creation in the initial coding process was kept to allow assessment of progression towards data saturation. At the outset of the study the intention had been to transcribe and code interviews as they were created therefore enabling an ongoing assessment of whether new codes were continuing to be produced i.e. whether the breadth of potential experience had been explored and data saturation had been achieved. As previously discussed, and taking into account the potential for participants to drop out of the study in this population, this approach would have enabled ongoing judgement of the size of the sample required. In practice, the difficulties experienced with running the parent study and the sporadic timing of recruitment made maintaining this aim impossible. The majority of analysis was therefore performed following completion of the interviewing. The recruitment of participants stopped when the pool of potential participants was exhausted.

After eight transcripts were coded, an anonymised transcript was shared with a post graduate research peer from the UWE for second insight into the coding process. This was in acknowledgement of the potential influence of my background as a physiotherapist and role in the parent study. Although hip fracture is recognised as an injury with a very physical impact on the individual's life it was important that my approach to the analysis gave equal weight to the other aspects of their experience such as the potential emotional and social impact; which unknowingly could have been overshadowed by my previous knowledge and interests.

Barbour (2008) referred to this as the presentation of main categories being likely to reflect the disciplinary body of knowledge with corresponding habitual application of a theoretical framework. Additional coders was suggested to have the potential to strengthen the rigour in a study (Barbour, 2008). A non-healthcare professional with qualitative experience was sought to give a different perspective. A summary of the study was provided and this methodological premise of the second coding was discussed. The existing code list and descriptions were not shared with the second coder. Discussions throughout the coding process with the supervisory team who also had a range of backgrounds also supported the rigour of the analysis.

The second coder inductively coded the transcript coding text using the comments function in Microsoft Word. The codes applied by the second coder were pulled together in a table as a code list. We reviewed the transcript together, discussing the codes applied, focusing

particularly where there were differences. Where appropriate, changes were made to the code name or descriptions, additional existing codes were applied to the data or new codes were created. For example in the transcript the participant discussed their recovery from a previous hip fracture. This had not originally been coded as it was not the injury currently being considered for this study. Following discussion with the second coder it was coded, acknowledging that his previous experience will have shaped his expectations and experience of the current recovery process. The second coder tended to code with broader concepts, including both the affect and the functional or practical topic under discussion in one phrase in comparison to my more detailed 'splitting' style where the physical or functional and the emotion were coded separately. A log of the changes made through this discussion was kept. Coding of the remaining transcripts continued whilst awaiting completion of the second coding. Initial coding was then completed across the whole data set of first phase interviews with a continuously updated code list and descriptions.

Stage 3 – Searching for themes

Once the whole first phase data set had been coded the process of collating relevant codes into initial groups began. Mind maps were used to assist visualising this process [Appendix G]. In some cases a new code was created and the initial codes were grouped within this code. In other cases an existing code was used as the parent node and other codes were clustered within it. If during this process codes were felt not to address the research questions and objectives of the study they were not brought forward to this stage.

Stage 4 – Reviewing themes

The groups of codes became the process for developing the initial themes. The gradual building of a hierarchy within the codes in the groups formed the basis of the themes. These emerging themes were then reviewed on two levels. At a detailed level the coded data extracts were reviewed and the code descriptions checked for a coherent pattern, gradually reworking the hierarchy of codes within the themes. Diagrammatic methods were used again as a pictorial aid creating a thematic map to display the distinctions between themes or the suitability for aggregation into broader themes. A descriptive account was developed where quotes were selected to represent the themes and codes within the themes.

The second level of review described by Braun and Clarke (2006) is a review of the thematic map's accurate reflection of the meanings of the entire data set [Appendix H]. The entire

phase one data set was re-read for two purposes – to reflect on whether the themes work in the bigger picture and to code any additional data that may have been missed.

Stage 5 – Defining and naming themes

Following the return to the full data set the themes were further defined and refined, identifying the essence of each theme. The data extracts were further collated into a coherent and consistent account of each theme with accompanying narrative – building on the previous descriptive account. Larger, more complex themes were structured with sub themes where necessary.

Stage 6 – Producing the report

The following chapter, Chapter Four Findings, describes the experience of recovery through the themes developed during the analysis. Data extracts or quotes are provided to demonstrate the essence of each theme. As described by Braun and Clarke (2006), analysis is a recursive process where these stages are not completed in a strict order but where the researcher can move between the stages as required, taking time to review and rework the coding and the themes until a reasonable representation of the data is achieved. In this longitudinal study this recursive process was not only within an interview phase but also between the interview phases when necessary.

3.3.7.2 Phases two and three

The code list and descriptions from the first phase were carried forward into the process of coding the later phase interviews. The code log was maintained to demonstrate addition of new codes longitudinally as well as within an interview phase. The same six stage process was followed with each stage in turn. Although the analysis of each interview phase was approached separately it should be recognized that my long-term involvement with the participants and the subject means that the interpretation of the data will have continued to develop throughout. The first participant completed her third interview before the seventh participant completed their first interview therefore a longitudinal view of the recovery process gradually developed even though it is presented as a distinct cross sectional analysis here. The use of thematic analysis and the freedom to iteratively develop the understanding of the themes, not only between participants but also with further description through time, was particularly useful in this way.

3.3.8 Thematic longitudinal analysis

The previous sections describe the process for the cross-sectional analysis of the data within each interview phase. The study also aimed to explore and understand more about how the experience of recovery might change over time. The data produced from the three interview phases were therefore considered across the phases – longitudinally. Calman, Brunton and Molassiotis (2008) discussed the potential to use multiple theoretical frameworks, different paradigms and analysis techniques within a LQR study. In their study of cancer patients, Calman, Brunton and Molassiotis (2013) used different analysis approaches such as IPA, interpretative description, thematic analysis and narrative analysis for different sub-groups of tumor type within their sample. They reflected that this was due to both the experience of the researchers and the type of information gathered in the interviews. Calman, Brunton and Molassiotis et al (2013) reported thematic analysis to be one of the most commonly used analysis techniques in LQR studies but warned there was a risk of it being restricted to cross-sectional descriptive accounts and missing the focus on change through time. However their critique of their own work which used multiple analysis techniques is that it reported predominantly cross-sectional data. Therefore whatever the analysis technique chosen there needs to be focus on the research question to ensure the appropriate focus on change is maintained. As previously discussed the longitudinal interpretation of the data had been entwined throughout the recursive process of the thematic analysis therefore the thematic approach was continued for the longitudinal analysis.

Saldana (2013) recommended the use of matrices to organise data in temporal categories as a technique to reflect on the similarities and differences from one time point to the next. An overview for the experience for each participant relating to each of the three main themes was tabulated, with a column for each theme and a row for each participant that completed more than one interview. The use of these overviews of change through time are similar to the ‘case profiles’ described by Thomson and Holland (2003), who describe a narrative analysis after each interview phase followed by a ‘case profile’ after the three rounds of interviews were completed to trace change and continuities in the participants’ narratives. The difficulties summarising the volume of data for each box representing a participant’s experience of a theme was managed by maintaining focus on the purpose of the additional longitudinal analysis – what was the participant’s experience over time and did their priorities change over time? The process of drawing out the themes for an individual across the study phases gave an opportunity to view and interpret the experiences being described in a different way, not

comparing their experience to another's, but their experience and how it changed (or not) from one interview to the next. This change of view produced additional detail and interpretations aligned to and enhancing the original three main themes (Chapter Four, Section 4.7).

3.4 Summary

A longitudinal qualitative research study from a realist perspective was undertaken to explore and gain understanding of patients' experiences of recovering from hip fracture and how this might change over the course of a year. Semi-structured interviews were completed with participants in three phases, 2-3, 6-7 and 12-15 months following surgery for their hip fracture in a convenience sample drawn from a parent study. Thematic analysis was used both within phase (cross-sectional) and across phases (longitudinally).

Chapter 4: Findings

4.1 Introduction

The following chapter presents the findings from the analysis of the qualitative interviews conducted at three different time intervals over the 12 month period of the study. The participants are introduced with some context about their personal circumstances, where this is relevant to their experience of recovering from their hip fracture. The main themes and sub-themes are presented, both within each phase of interviews (cross-sectional) and also longitudinally – how the experiences and priorities of the participants changed over time. As described in Chapter Three pseudonyms for participants have been used throughout and care taken to anonymise identifying features such as locations to protect the participants' confidentiality.

4.2 Participants

Eleven participants provided their informed consent to take part in the study. Ten were recruited from the main site running the parent study, and one from an alternative participating site. All 11 participants completed the first interview, eight completed the second interview at six months and seven completed all three interviews across the 12 months (26 interviews completed in total). One participant died four months after her hip fracture. Of the three further participants who did not complete the interviews, one withdrew consent after the first interview as she was too busy moving house, but she continued to complete the parent study. The second withdrew from both qualitative and parent studies prior to completing the six month time point as she was 'too stressed'. The third participant was admitted to hospital acutely unwell at the time of his 12 month follow up and it was not possible to arrange alternative times to meet with him.

Two further potential participants, one from each recruiting site, did agree to be approached but went on to decline to participate. In one case, when contacted by telephone to discuss further the PIS and what the study would entail the participant had other medical issues ongoing and felt they did not have the time to be involved. In the other case they initially agreed but once I reached their house for the first interview they had changed their mind, reporting they 'had a lot going on at the moment'.

Table 8 provides an overview of the basic demographics, social circumstances and comorbidities of the participants. Six of the eleven participants were men and participants ranged from 69 to 92 years of age. All participants were retired and living in their own homes prior to the study. All of the men and none of the women drove a car prior to their hip fractures. Two participants went to an inpatient rehabilitation facility on discharge from acute hospital before returning to their own homes. All others returned to their own homes directly; seven with support from a community rehab team, and the remaining two participants were referred for domiciliary physiotherapy.

Table 8 Participant summary

Study ID	Pseudonym	Age range (years)	Gender	Recruiting site	Phase 1 (months since surgery)	Phase 2 (months since surgery)	Phase 3 (months since surgery)	Comorbidities	Social Circumstances prior to hip fracture
101	Clare	70-79	Female	1	2	6	12	Depression; Diabetes; Hypertension; Hypercholestraemia.	Divorced; Lived alone in house with stairs; Fully mobile with no aids.
107	Jenny	80-89	Female	1	2	~	~	Hypertension; Glaucoma; Oesophagitis; Gastritis; Myocardial Infarct; Pneumonia.	Married; Lived with husband in bungalow; Used a 4 wheeled walker outdoors; No walking aids indoors.
110	Jamie	≥90	Male	1	2.5	6.5	12	Hypertension; Benign prostatic hypertrophy; Wears calliper left leg to brace knee – unclear why.	Widower; Lived alone in split level bungalow; Extended family lived next door; Wore calliper when walking and used 2 sticks outdoors.
146	Ian	<70	Male	1	2.5	6	13	Fractured hip contralateral side; Right wrist fracture; Spinal spondylosis C4,5,6; Stomach Ulcer.	Married; Lived with wife and adult son with learning disability in house with stairs; Fully mobile with no aids.
195	Brianna	80-89	Female	1	2.5	~	~	Hypertension; Arthritis; Inguinal hernia; Depression.	Widower; Lived alone without support; Used 1 stick walking outdoors.
239	Gillian	80-89	Female	1	2.5	7	15	Asthma with previous hospital admissions; Hypertension.	Widower; Lived alone in a bungalow; Used 1 stick walking outdoors; Family took her shopping.

Study ID	Pseudonym	Age (years)	Gender	Recruiting site	Phase 1 (months since surgery)	Phase 2 (months since surgery)	Phase 3 (months since surgery)	Comorbidities	Social Circumstances prior to hip fracture
240	Fiona	80-89	Female	1	2	~	~	Osteoporosis; Osteoarthritis; Osteomyelitis both feet; Right wrist fracture; Right elbow fracture	Carer for husband with dementia who had recently moved into a care home; Now lived alone in house; Mobilised with 1 stick outdoors.
270	Dougal	70-79	Male	1	2.5	7	14	Celiac disease; Chronic pancreatitis; Ischaemic heart disease with bypass graft; Peripheral Vascular disease; Pacemaker; Atrial Fibrillation; Insulin dependent diabetes; Hypothyroidism; Dermatitis.	Married; Lived with wife (who still worked) in house with stairs; Walking with no aids prior to fracture but distance and pace limited by leg pain from peripheral vascular disease.
284	Collum	80-89	Male	1	2.5	6.5	13	Cardiac bypass graft; Asbestosis; Non-insulin dependent diabetes; Urinary frequency.	Married; Carer for wife with dementia; Lived with wife and grown up son in house with stairs; Fully mobile with no aids.
349	Jack	70-79	Male	2	3	6	13	Rheumatoid arthritis; Urinary frequency; Heart failure; Hypertension; Hypercholestraemia	Married; Lived with wife in house with stairs; Fully mobile with no aids.
060	Frank	80-89	Male	1	2	6.5	~	Hypertension.	Married; Lived with wife in house with stairs; Fully mobile with no aids.

4.3 Participants' wider circumstances

Each participant's life experiences and social background are naturally framed by their individual context. Their social circumstances and general state of health will have affected their need for and experience of healthcare prior to their hip fracture and expectations of their future health outcomes. Their experience of recovering from their hip fracture is bound up within this wider picture. Pre-existing physical and mental health conditions could affect the recovery process following a hip fracture. It may be difficult to isolate the effects of the hip fracture from deterioration in their original condition which may have occurred anyway.

The participants frequently discussed their comorbidities, general health and perception of ageing when reflecting on whether they were "*back to normal*" [Clare 101]. Their experience of recovery from the hip fracture was interwoven with their other health experiences. These discussions have not therefore been identified as a theme from the interviews in the following sections but will be discussed further in the following chapter, reflecting on the influence of these factors on the concept of outcome from the recovery process.

4.4 Phase one

Eleven participants were interviewed in phase one, between two to three months (eight and 12 weeks) following their surgery. Three overarching themes were identified relating to the experience of recovery or returning to normal in the first three months after hip fracture. The three themes identified through detailed analysis were '*physical and functional recovery*', '*effect on lifestyle*' and '*emotional response to circumstances*'. Each theme is in turn represented by sub-themes which are summarised below. Throughout all three phases of interviews there was also a conversation around what the participants viewed as progress and how they judged or recognised what recovery they were making. This underlying topic of progress is discussed and referred to throughout the discussion of the themes.

4.4.1 Theme One: Physical and functional recovery

The theme of physical and functional recovery incorporates discussion of a diverse range of physical and functional activities; the participant's symptoms and limitations while carrying out activities, their need for assistance and coping strategies, and the effect of the environment they were functioning in.

The tree diagram (Figure 2) demonstrates the subthemes within this theme and gives examples of the categorisation of the codes within the subthemes.

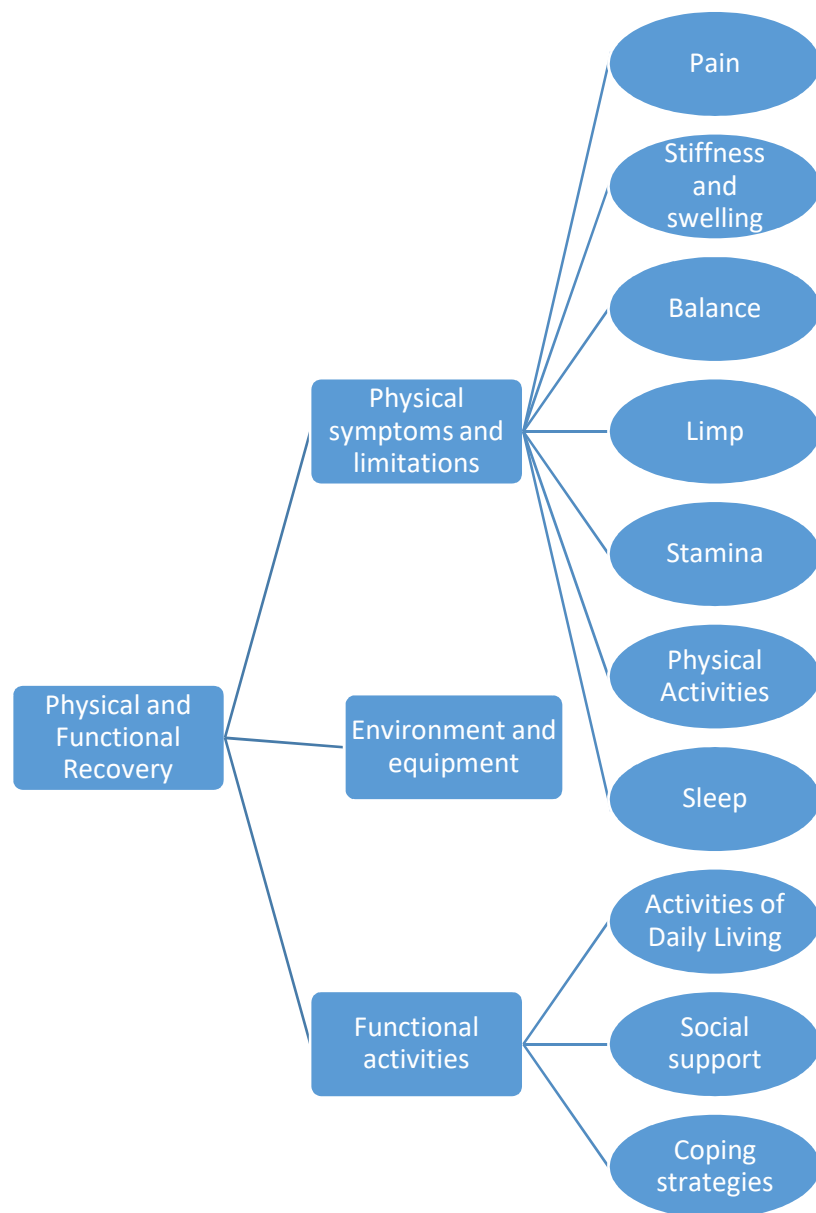


Figure 2 Phase 1, Theme 1: Experience of physical and functional recovery

4.4.1.1 Physical symptoms and limitations

The physical recovery experienced after a hip fracture described by the participants varied in both the nature of the symptom and the extent to which it was experienced. The most frequent symptoms identified included pain, swelling and stiffness. For example the experience of pain was along a continuum, where some were living with severe pain, whilst others expressed surprise at how little pain they felt. In no particular order the following excerpts give examples of their experience of the physical symptoms:

Pain

Pain was often discussed as the reason for not being able to do functions such as standing or stairs. Participants often felt unsure whether the amount of pain they were feeling was appropriate and questioned why their experience was different to other people or previous personal experiences. For some there was a sense of relief that their experience of pain was improving quickly or that their pain was not as bad as they had expected.

And I'm sitting down and what it is here where the sc ohh if I just touch it it's very painful still, the scar is very painful. It's bearable you know it's not I can't bear it but I'm fed up with pain all the time. [Clare 101]

But fortunately I've not suffered any real pain or anything like that with my – with my hip. It hasn't been painful at all, um thank goodness... Yeah it's – as I say, it's not causing me any – any problems at all. But um, yeah, I've been surprised at the lack of – the lack of pain, yeah, yeah, ... I – I was aware of my leg, but not painfully, but I was aware of my leg when I got back from this big shopping expedition at [supermarket]'s ... But um, as I say, not really painfully. In fact, that's the thing: I've not really suffered any, phew, pain at all. I anticipated that I would. [Frank 060]

Stiffness and swelling

Participants discussed the effects of stiffness and swelling – their discomfort, how it limited them and their frustration at the difficulties presented when trying to dress, both in getting clothes to fit over swollen legs but also being able to reach their feet.

Cos when I sit down when I come in, and then I go to get up again, my legs were very stiff. And er so well I put my legs up sometimes 'cos I mean that relieves – they swell, swell up quite a lot, this one ... And um I thought, "Well I'll sit down for a bit and then I'll go and do some exercises." But it's hard, it's hard to do exercises when your leg is very stiff. [Fiona 240]

Um dressing, I've never had a problem, except the fact that I do it slow, and I curse, by getting a sock on and always using the bad foot, as I call it, first, rather than the good one. And er I've done that slowly but surely... Um they tended to – first of all my – my – my leg was so swollen, um I asked my wife to go out and buy um some bigger size pants for a start, because I couldn't get them on. [Dougal 270]

Balance

Participants described feeling off-balance – some related this to not being able to weight bear through the leg. Some felt at risk of further injury because their balance was affected, whilst others reported no balance problems.

At the moment the balance I think more than anything else would stop me walking without some kind of support system, probably, I mean I can sort of walk um and hop you know, sort of not put too much weight on this leg and hop onto the other one but

then um if I lose my balance in that then I would do further damage. It's not the I mean I don't mind the hop so much the fact that it feels very unsafe. [Jamie 110]

But – but I mustn't – I mustn't walk quickly, I – I mustn't walk um – I mustn't turn quickly or, you know, I must be very careful how I walk. I easily go over, real easy. It's my balance really that's wrong. [Fiona 240]

Others reflected on the changes they had made because they perceived a lack of balance.

I lose my balance as well that's what I'm worried about. I lose my balance, I couldn't go out on my own like that, could I? [Brianna 195]

Well things like I've been sat down for quite a time now, and I stand up, and I'm tending to wait because I feel wobbly ... I've been sat there for, what, half an hour or so, and um I then stand up, then I'm – I'm sort of a bit wobbly ... And I don't like that, I don't like that feeling at all. Um because I just don't like it, it don't feel natural. [Dougal 270]

Limp

Participants described having a limp – often using an alternative word such as “waddle” [Brianna 195], “clump” [Collum 284] or “shuffle” [Ian 146]. Limping was thought by some to be because of the pain of standing on the injured leg or a lack of strength. Others described feeling like they were unable to put pressure through their leg, concerned it was not able to take their weight. The limp or this lack of trust in the leg represented not walking very well yet which they interpreted as a sign that they had not yet recovered. The use of walking aids was often entwined with having a limp.

I'm just waiting so that I can go out to walk, go out and clean my windows, do all things like that without having to have crutches or zimmer frames this that and the other, be ordinary again, walk you know without a limp. [Clare 101]

I mean you can you can jump almost from one you or put hardly any leg weight on it for a fraction of a second to get to the other one. [Jamie 110]

Some people reported problems with their uninjured leg which seemed to be related to symptoms experienced in the injured side.

My hip is absolutely no trouble whatsoever. Well when I say I have no trouble whatsoever, it aches now and again, you know. But um nothing really. This is the one that gives me all the trouble, this side. Well that's er – Dr [GP] said it's probably, “That one,” he said, “is probably because you've been using all the weight on there.” keeping the weight off of this one you see. [Collum 284]

Stamina

The specific task or function being discussed differs but respondents often related being exhausted because they had “*done a bit too much*” (Jenny 107) or not attempting something yet because the distances would be too far or the duration would be too long.

err what's stopping me going to the shops I cannot walk from here, the distance to [local town] on um crutches. Not yet anyway. [Clare 101]

But then I've got the other aspect of them sometimes, the stairs wear me out, you know, the exertion of them... and they – they make the legs er say, “Hey, hold back.” Um so I – I've gotta balance the two so that I'm – I'm not, not cutting down on trying to get my – my right side, the hip side um as normal, what I would look on as normal. Well I don't think I'll be doing any marathons. [Jenny 107]

Physical activities

The physical activities most frequently identified by participants included walking, standing, sitting, bending, kneeling, stairs and their ability to carry things. As highlighted in the previous excerpts (and those in the following subthemes) these physical activities are woven into the discussion of their other symptoms and their functional activities. They discussed how they were currently managing and frequently returned to these issues when asked what was most important to them in the coming months.

Er well it's bending down. I – I'm getting better at bending. I – I still have to sit on a stool when I dry myself after a shower, you know, I have shower and I sit on the stool, 'cos I can't get down to that foot yet very well. [Gillian 239]

Well obviously just sitting down, getting up, walking to pick up anything I want, move to a and b, just being freedom of what I want to do, you know, that would would be what I want to do [Jamie 110]

I wanna be back to being able to walk properly. [Jenny 107]

Well like I used to go to the – you know, when there was anything on I could always go and that. But I know now that I won't be able to. 'Cos no way could I get up the stairs. These stairs seem a silly thing, don't they, to worry about? [Brianna 195]

Sleep

Difficulties sleeping at night in the early weeks had frequently been an issue for participants. Most reported this as improving by the first interview eight to 12 weeks since injury. The difficulties sleeping were attributed by participants to pain and discomfort, having to adopt a different sleeping position to their normal preference and insomnia or frequent waking; possibly habitual after a period of disturbed sleep whilst in hospital or waking due to stress.

When I first came home I wasn't sleeping at all. I wasn't. And I was just laid up in bed and I get a portable DVD run by batteries and mains and I put a DVD on, headphones, like them one of those lights on your head you know with a band and I'm sat in bed, of course the wife's snoring her head off, and I'm like that. I've got a 'teas maid' there and I press the button and get a cup of tea, look at the clock, 20 past 2 in the morning I'm watching a DVD. Well that's not right, that's not normal. [Ian 146]

The biggest problem with it was sleeping. I don't sleep – I don't sleep well on my back. Well, as you can understand, um at first I had to sleep on – try to sleep on my back, which meant that I spent about four hours in bed and the rest of the night sitting here with my feet up. Um but now I've managed to turn on my side I get a full night's sleep, so that's no problem, yeah. [Frank 060]

4.4.1.2 Environment and equipment

The importance of the effect of their environment (such as the height of steps and the presence of handrails) and its ability to help or hinder activities was highlighted. There were different outlooks on requiring changes to their environment and routines – some were appreciative of the assistive equipment provided and the fact that it promoted their independence. Others were frustrated by the equipment and felt it represented their difficulties and indicated they were 'old' or 'disabled'.

Environment

Participants were very aware of the environment around them– wet kitchen floors or frosty uneven pavements were a concern when relying on walking aids. Having to manage stairs or steep steps meant that some participants found it hard to manage once back in their own homes.

INTERVIEWER: So what difference will that make then, why do you want the one bedroom bungalow?

RESPONDENT: Well I'd be all on the level. Wouldn't have to go upstairs and that, be much easier. [Brianna 195]

I can't go out I can't, if I go out I can only walk out if the sun's shining. If it's raining, cos I'm worrying about this this end when we get to frost, what's going to happen with these two on on when it's a frosty pavement [indicates crutches] [Ian 146]

The only thing is, round the corner all the tree stumps are coming up out of the ground and it's not very even ... That's when I find crutches a bit hard, you know. [Jack 349]

Equipment

Walking aids and other assistive equipment were discussed by most participants. Some valued the various aids, others did not like them. For some they symbolised unwelcome ageing and disability. Changing the walking aid to reduce the amount of support they required was for

some seen as progression and was an indicator that they were improving. Being able to return to the walking aid they used before the fractured hip or not needing any aid represented returning to normal. Not progressing from an aid was perceived as a lack of improvement.

RESPONDENT: And I've got me little trolley for bringing things in if I've got a plate and cups and things, you know, that's handy for pushing about, things about on.

INTERVIEWER: And carrying things is difficult?

RESPONDENT: Hmm it is difficult sometimes. But the perching stool is quite handy 'cos I can sit on that out in the kitchen for ten minutes if I feel a bit tired. [Gillian 239]

You know and um then I get a back ache and those stupid seats that they give you they're hopeless when I sit on it hurts me here anyways so ... I don't use it [Clare 101]

ooorr embarrassed, yeah, they gave me a commode I mean at my age! [Ian 146]

RESPONDENT See I shouldn't be using this, should I? (laughs)

INTERVIEWER: What makes you say you shouldn't be using your trolley?

RESPONDENT: Well it's been a long time hasn't it? (laughs) It has been a while hasn't it? [Brianna 195]

INTERVIEWER: Why does the stick bother you?

RESPONDENT: It makes me feel a bit old and not capable of er - you know, er using people's sympathy and – and – and I don't, I really don't want that, I really don't want that. [Dougal 270]

4.4.1.3 Functional activities

Participants often seemed to judge their recovery with respect to their typical functional activities. Participants referred to activities of daily living (washing, dressing, cooking), housework, gardening and food shopping. It was when trying to complete these activities that participants noticed the difficulties they were now experiencing since they fractured their hip. For example which tasks they still found difficult, took them longer to complete, or needed to improve for them to be able to regard themselves as back to normal.

It didn't worry me too much, you know, my daughter would come up and give it a clean through and er do what wanted doing. And then I began to sort of sit up and look around and I think, "Hmm." The best day of my – (laughs) you'll laugh at this – the best day of my life was about a fortnight ago, I expect it was a fortnight ago, and I'd made up my mind on a Wednesday to er – I was going to have a good clean through, right through like, you know... And it took me all day till 4 o'clock, but I did it, you know, I hoovered, polished, did everything. (laughs) And I was so pleased with myself (laughs) when I finished. [Gillian 239]

Social support

Everyone mentioned needing help from their family or friends at some point during their recovery. As with functional activities, needing assistance highlighted their limitations

compared to before the fracture. There were some concerns of the physical demands and stress they were placing on those supporting them.

But I mean I can't do work like – well I didn't do it every day; I'd do so much each day and whatever. Er now I mean I can't take – you know, upstairs, the floors of the bathroom and all that, things like that. My daughter's coming in the week, next week to do it for me, but it's not the same. (laughs) And when you've gotta depend on them like to get you some shopping. I know I'm having the meals, the [meal deliveries], but I mean that's not – you've got other things to get. (laughs) [Brianna 195]

I had a granddaughter, one of my granddaughters comes out once a fortnight and sees me on a Saturday, and she er – she does sort of jobs for me. Like this last Saturday she took down my net curtains, cleaned all my windows inside, and I washed them, you know, I was able to wash the curtains, which have been annoying me for some while. So that sort of thing that I used to be able to do, and I can't do now, not only because of my leg but because of my age as well, I can't climb up on chairs and things like that... she's very good that one, she'll do anything. [Gillian 239]

Coping strategies

Participants reported finding alternative ways of doing things – breaking down jobs, enlisting help when needed, or doing tasks in a different physical position.

I've managed to cook – well when I say cook, I don't go to the stove, I mean I don't – I can't lift because of using this all the time [gestures towards zimmer frame], I can't use both hands – walking, that's walking. But I've managed to cook a couple of dinners, or several actually, but only by preparing them, and then my husband sticks them in the oven, or whatever we're having. [Jenny 107]

Anything got to come down that's not breakable, I can throw it down the stairs. (laughs) It's silly little things really [Brianna 195]

I even take it upstairs [laundry], you know, I – I put it say on the third or the fourth stair, and then I go up behind it, you see, and that's how I do, I find ways and means of doing things. [Fiona 240]

Often they reported having to “take it steady” [Fiona 240] or pace themselves taking regular rests when doing a task, or reflected that although they were able to do it, it was a struggle or tiring.

So I sit on the stool to sort of dry myself off. And I get a bit tired any rate when I'm doing it. You know, you get a bit er a bit tired. So I sit down in case – rather than fall down again... I just think to myself, “Well I ought to sit down a minute,” you know, not because it's hurting or – or (laughs) anything like that, but I just sort of think well I ought to give it a rest, you know, five minutes. But it's not that long really, I suppose, when you think about it. [Gillian 239]

4.4.2 Theme Two: Effect on lifestyle

The variety of lifestyles lived by the participants, depending on their social circumstances, hobbies and interests meant they had differing experiences of the effect of their hip fracture. The ability to be able to get out and about was highlighted by all participants but the reason for its importance and the desired method varied. This ability to leave the house affected other aspects of their lifestyle.

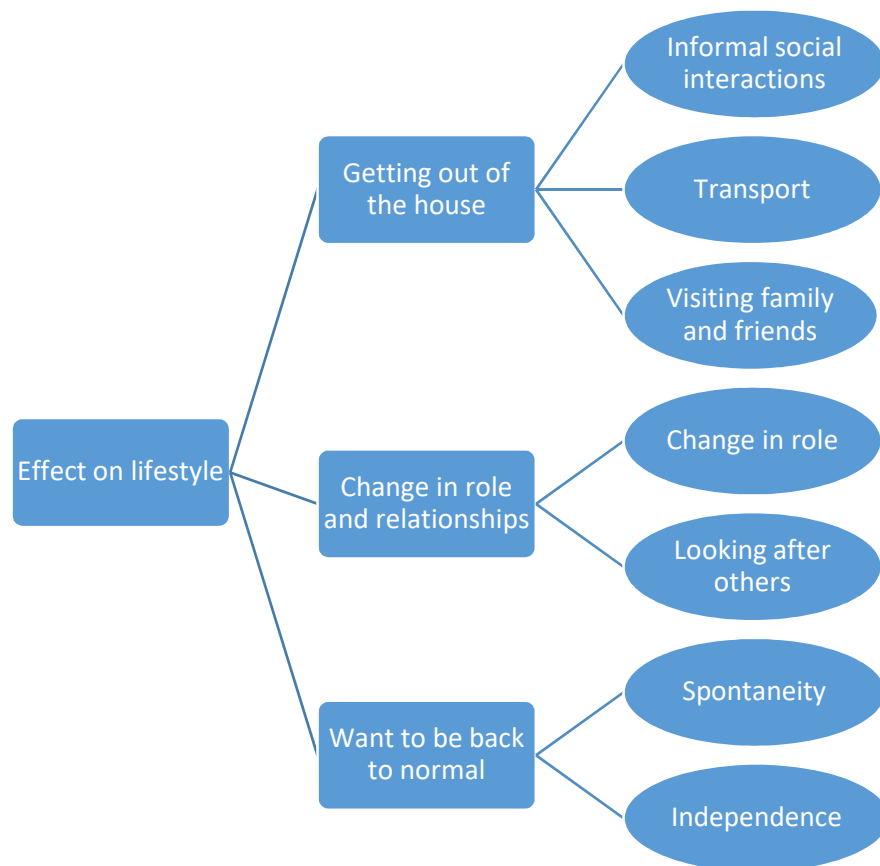


Figure 3 Phase 1, Theme 2: Effect on lifestyle

4.4.2.1 Getting out of the house

An underlying theme that came through all the interviews was the desire to be able to get out of the house independently. The sense of why this was important differed. For some it was about the informal social interactions with others in their communities. For others it was to be able to join in the lives of people important to them – for example meeting friends for lunch, attending their grandchild's birthday party or being able to go and stay with family and friends. Other people just wanted to know they had the freedom to get out if they wanted. The reasons for not being able to get out also varied; for some their physical symptoms (such as pain or stamina) was the limiting factor on their desired activity. The importance of transport was a common concern which depended on an individual's circumstances.

INTERVIEWER: You feel like it's getting better. Could you talk me through kind of what your day is like and maybe why it's better than it was?

RESPONDENT: Well yes, well I can get out, that's the main thing, you know, getting out. [Jack 349]

I'm getting there very slowly. I just want to get out. I just want to get the dog for a walk and get to drive my car and I wish I could put her in the back of the car, take the car to the shop and used to go for hours, walk miles with her. She loved it, she can tell she can tell I don't take her. [Ian 146]

Informal social interactions

Several participants missed the informal interactions with others in their community that is only possible through impromptu and spontaneous socialisation by being out and about, for example talking to other dog walkers, shop assistants or in the hairdressers.

I meet other people down there [hairdressers] that I've got to know, you know, other women. And er – and it's nice to talk to people, nice to meet people. I don't mind that sort of social, but I would hate to go to a social, or a thing where I was expected to do, you know, play bingo or cards or it's too – you know, I wouldn't want to do that. [Gillian 239]

Every time the wife takes the dog for a walk 'give my love to him mind', cos they, cos you, when you take a dog for a walk you see a lot of people you see loads and it's the same people. You have a chat on a morning 'good morning' even when it's dark in the winter you still talk to them. I've seen many a young girl or a woman with her dogs 7 o'clock in a morning in darkness. And we have a chat, 2 dogs sniffing, two chatting 'see you again bye'. They say to the wife - 'how's your husband now, give my love to him' you know 'hope he gets better' all that. I said blimey I must have more friends than I know you know (laughs) but you know what I'm trying to say is I miss all that look. I miss all that. [Ian 146]

Transport

Returning to their previous transport solution to continue with their usual activities was extremely important to the participants, for example returning to driving themselves, being able to access a bus or community transport system as they had done previously, or being able to tolerate a longer journey as a passenger. Alternative methods of transport were often considered but felt to be less favourable. For example, participants saw taxis as expensive, said that relying on others for lifts was inconvenient and burdened others. Participants also expressed concern about how they would manage public transport.

I mean they got their own lives to lead you can't drop everything just take me to [Hospital B]. It well, to drive it, you're your own boss. You haven't got to be restricted, you haven't got to rely on people. [Ian 146]

I met my brother and sister-in-law over [name of shopping centre] on a Saturday, most Saturdays. And I'd go, get the bus and go down into [neighbourhood] or go up to [neighbourhood] and things like that, not to carry shopping but, you know, just to um –

yeah everything's gone. (laughs) And I cannot see it coming, not now ... But I used to love going with Dial A Ride, booking up and going and they'd carry it for you and things like that. [Brianna 195]

I use the community transport, you know, to take me down, and then me sister picks me up. And I meet my second eldest sister as well, she comes to the same place, so we meet once a week ... I didn't go for some weeks (to the hairdressers), not until I was sure I could – I could manage the transport steps and that, you know. But er I had to go in the end 'cos I – I don't know what I'd have looked like. (laughs) ... Getting back into the routine has been good yeah, yeah, it's helped a lot, yeah. It's the only vice I've got left now, spend my money on my hair. (laughs) But er, yeah, I enjoy that, 'cos the three of us, as I say, we don't see a lot of each other. [Gillian 239]

Yeah but um, no, it's um – I – I don't know, it's a bit difficult. I mean we went over to [town name] to see my boy and his wife, but we went on the train, but um I got about over there pretty well. But er I used the crutches then though, I had the two crutches when I was there. Um but, no, I ... The only thing that did worry me a bit is I needed – if I needed to go to the toilet while I was on the train, because I didn't fancy that with the train going like this, (laughs) you know. But I got away with that. [Collum 284]

Visiting family and friends

Being able to visit family and friends, go out to join in family occasions, or being able to visit them in their homes was a high priority for many participants. Participants were concerned with transport for these visits and physically being able to manage in the environment once there.

I can't er – I'm alright with my sister's car 'cos the seats are high, I can just get in, slide in, you know. But low cars, I can't get into a low car, not yet. But er otherwise I don't think it's hampered me that much ... Well it would be (difficult), 'cos it's a three hour drive. He would come out and fetch me, you know, but it's a long time to sit. [Gillian 239]

And um, as I said, I can go over to [name of granddaughter]'s in [town name], but I used to stay there when they went away too – but I won't be able to do that, 'cos going upstairs to the bath, you know, the bedrooms and the – she's got a toilet down and like the bath, the bathroom up. Um [Name of Daughter] that lives up [name of neighbourhood], her toilet's upstairs. Er and my other daughter, hers is as well. So I mean I used to go out with them and go to their houses. [Brianna 195]

4.4.2.2 Change in role and relationships

Change in role

For some the hip fracture had a wider impact on the roles they were able to undertake in their families or wider communities for example being a verger in their local church, fulfilling their role as “head of the family” [Dougal 270], or being able to assist with care of great-grandchildren. This challenged the participant's relationships with their families and their personal sense of independence.

...because I feel my independence is gone, to a certain degree. Now it's still about independence, that's my problem. Er um, you know, I – I started – I brought up a subject to my eldest son right here.... But he got on lecturing me about what I should do and what I should think about, quite unintentionally I'm sure. In fact he sent me an email to say what he was thinking, and he hoped that I didn't um misconstrue what he was saying. But um I didn't like it, I didn't like it because – simply because I – I felt as though, no, I – I've always been in charge. I've always been in charge, and it's taken away my independence. I don't want that. [Dougal 270]

Looking after others

Some participants had caring responsibilities that became difficult to continue with due to the change in their circumstances resulting from the hip fracture. These participants expressed frustration and guilt that their ability to fulfil these roles was compromised.

Well I can't – I couldn't do anything for him. 'Cos, you know, I used to take him to the toilet, you see, but what could I do? You know, I couldn't do anything to help him really. I – I tried to, but I couldn't, not really. Like er sometimes the nurse came in and I said, "I can't do anything here," I said, "you'll have to carry on." ... I didn't have my hands free. And sometimes only had one hand free. And um – and it was difficult. [Fiona 240]

er like my sister in a home, I've always done the looking after her. And I – I'm still concerned that I – I'm not taking back the reins in the home like I have done. I – I don't go and see her um and I don't do her washing and things like that, because they've taken over all that. [Dougal 270]

4.4.2.3 Want to be back to normal

"I didn't want to get like this" [Brianna 195]

The participants expressed their irritation with their lifestyle in these early months after the injury. Many felt the fracture had left them in a situation that they had hoped to avoid and it made them feel old. In particular they felt the need to use a walking aid or assistive equipment in their homes, walking with a limp, being stuck downstairs in the house or not being able to wear their 'normal' high heeled shoes stigmatised them as old, which they did not feel ready for.

Makes me feel awful. (laughs) I'm missing out on such a lot. I mean it was my granddaughter's – well I said, her birthday today. And they're gone out, you know. Lots of things. (laughs) I didn't want to get like this. I wanted to be, when I finished work, I wanted to carry on and do things. [Brianna 195]

Spontaneity

Even where the participants were physically able to do activities they wanted or there was the support to assist them they found they had to think about things more in advance. They had to plan access to walking aids or foot positions prior to an activity, or they had to keep the

telephone near them because it took too long to get across the room. They missed the freedom of just being able to get on with something, not having to pre-plan all their activities.

it's just a feeling that you you can't, you know, I I mean I wasn't going out every minute of the day but any anything I wanted I could do I and felt free to do it and the only difference mainly was not in the fact that of the doing but the fact that I wouldn't be able to do it if I wanted to do it... free to do anything I wanted to do if I wanted to do it [Jamie 110]

being able to do things without having to think about whether me leg's going to be right, or have I got it, have I just twisted it the wrong way or – you know. [Gillian 239]

Independence

Closely linked with their frustration with changes to their lifestyle the participants were keen to regain the levels of independence they were used to prior to their fractures. Many did not even consider that not regaining their independence was an option, others were concerned about it and remaining dependent on family and friends' support, walking aids and other assistive equipment was seen to be depressing. Not having to ask for help – to be able to carry a drink through to another room, take out a bin, being able to pop out for shopping they had forgotten, being able to clean something or sort something in the garden that was annoying them were seen as simple aims but at present they were not able to achieve them independently.

I'm looking ahead to re- getting life complete. If I was on the downward path it would be very depressing but I'm going to drive a car again and all this kind of thing. And um if I thought I wasn't going to be able to drive a car again or I'd never be able to walk again or anything like that that would be that would be a misery [Jamie 110]

INTERVIEWER: If you think about getting kind of back to normal, what would be most important?

RESPONDENT: Well to be able to do things and be independent, like putting a bag of rubbish out. I mean at the moment I couldn't carry it. [Brianna 195]

4.4.3 Theme Three: Emotional responses to circumstances

A range of emotions were portrayed by the participants. Frustration, depression, fear and a sense of needing to be cautious were experienced by some individuals. They were frustrated and bored being unable to do their normal activities and being stuck in the house, and they were worried about being a burden and causing stress to their families.

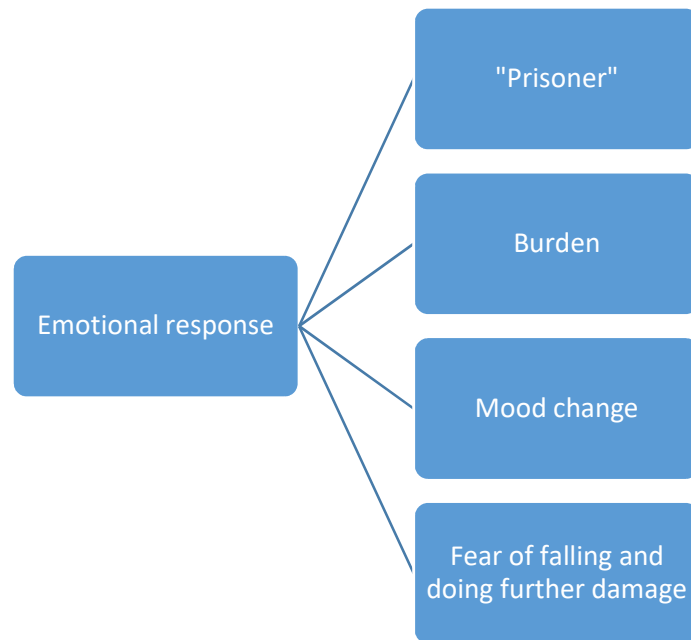


Figure 4 Phase 1, Theme 3: Emotional responses to circumstances

4.4.3.1 "Prisoner" [Ian 146]

Being unable to get out the house and being much less active was boring and frustrating for the participants. Overlapping with the previous subtheme 'getting out of the house' the participants expressed their irritation and frustration with feeling trapped in their homes and unable to participate in their normal activities.

You know so I'm I'm knackered, I'm knackered. I am me own prisoner. Even though these surgeons say 'oh go on get on with life' and all that but you can't... That's the honest truth, that's what it like, so when they tell you you know, get on with things you, if you can't walk you can't get on. Take your arm away yeah you could, take a leg away you can't do nothing you're just just stuck. Yeah. Yeah. [Ian 146]

I'm missing that dreadfully you know and I'm not one for sitting around I am very active and this sitting like this or just going around the house, it's driving me crazy... It's boredom. Really bored, and when it's only me you clean the house how many times can you clean the house in a day? [Clare 101]

4.4.3.2 Burden

Overlapping with practical aspects of social support, some participants were worried about being a burden on their family and friends and were dismayed about the time and stress their situation was imposing. Sometimes this was as simple as knowing they were causing family to worry and therefore they avoided activities that may have been viewed as having increased risk. For others it was concern they were placing a physical demand on those assisting them.

but I couldn't even do that [lift legs] so if I went to the toilet I had to wake her up, break her sleep for her to get me back into bed you know, its things like that you know, its its like being back in your second childhood again like you know. [Ian 146]

I tend to keep a frame upstairs, so if I'm upstairs I tend to use the frame, yeah. Um only because, as much as anything I think, my daughter has threatened me with what she'll do if I fall down again. (laughs) Well, you know, it puts a lot of – she's under a fair amount of pressure... yes, I think, you know, I think much of it is a question of not making her stressed out, yeah, 'cos she really can't afford to get stressed out, yeah.
[Frank 060]

4.4.3.3 Mood change

The majority of participants could clearly relate that they found their restricted lifestyle and change in circumstances depressing. They identified different causes or triggers for these feelings including the experience of pain, the boredom of being restricted to staying in the house or the loss of independence and having to rely on others.

I sat here one day and I know I don't tell many people, but I sat here one day, the wife was gone up the bank up [high street], son's gone out, I'm all on my own here I broke down and cried. I absolutely cried, I never cried so much since my mum and dad died I just broke my, it just, I had to get it out my system. Once I got it out I felt great after. The dog was laid out on the settee asleep and I was crying me eyes out. The wife said "what's the matter?" I said I don't know, I said I'm just depressed. I'm just bloody fed up with you know, not with life, but you what I mean I said I just can't do nothing I can't go anyway I gotta rely on you to do this cos I was relying on her because I couldn't go anywhere look.
[Ian 146]

But they also expressed a sense of achievement when they could see things were improving. Physically achieving things for the first time since their fracture in particular were identified as high points and indicators they were making progress.

That was a big lift, that really was, to think I'd done it, you know. I was tired, mind you, but er to think I'd done it. [Gillian 239]

So I'm ever so pleased about that, you know, because, you know, even a week ago I thought, "My leg's never going to get better." (laughs) I thought, "Now whatever am I going to do?" [Fiona 240]

And I am getting to that stage whereby I'm doing just that, which is making me extremely pleased. [Dougal 270]

4.4.3.4 Fear of falling and doing further damage

The fear of falling and further injuring themselves was a common emotion. Sometimes this was focused around the activity or environment where the participants fell and sustained the hip fracture. Others felt the injury was purely bad luck and were less inclined to be concerned about further injury. This appeared to be more common where there was previous experience of non-injurious falls. Participants reported intentionally restricting their activities to minimise risk and reported a heightened awareness and nervousness using different walking aids or on different surfaces.

but I'm still frightened of that floor I'm still, there we aww, I washed it this morning I narr I'm still scared [Clare 101]

I'm not gonna attempt to carry things upstairs, like washing and that. 'Cos I hold onto both [rails] – whereas before I'd hold onto one and put the washing and then put it so far up, and things like that. But I'm not going to chance that. It's not worth it. (laughs) [Brianna 195]

This fear and self-limitation was associated with the 'Spontaneity' subtheme in theme two; some participants reflected that they were unable to forget about the injury and get on with things. They were always aware of their leg in the back of their minds.

I'm more aware [of leg], and of things around me, you know, I make sure there's not anything I can fall over, or try to any rate... it's not being able to do things, get up, you know, when you get up you've sort of got to think to yourself, "Well get up." I walk about the house without a stick but I take one when I go out... I do think more about what I'm doing. [Gillian 239]

4.4.4 Summary of phase one

The participants measured their progress by perceiving a change within all the themes discussed; what they had already achieved and as an aim for the future. Most were able to express the feeling that things were improving – they felt they were getting better. The timescale since their return home from hospital was useful in assisting them to reflect on what had changed. For example a change in a physical symptom or functional activity (theme one) such as being able to lift their leg off the floor and therefore being to get in and out of bed themselves or improving function with their mobility such as being able to walk further was seen as a sign that they were recovering. Regaining the freedom to be out of the house, interacting with their communities (theme two) was an important aim and a sign they were returning to normal. Many felt these changes were occurring but that progress was slow; others were surprised at how much they had improved so quickly. As discussed in theme three participants recognised that their emotions were entwined in how they felt they were progressing. Comments from friends, family and professionals were reflected on and assisted them to judge their progress. Some participants could clearly express exactly what would make them feel they had recovered from their hip fracture; what would define being back to normal for them.

Cause I don't want to be like this, I I really want to be normal, wear my high heels and (laughs) you know? ... but um what I'm waiting to do is be able to go and do my own shopping and be able to walk, where I want, when I want and go back to normal. That's what I'm waiting for and it seems to be taking a long time, taking a long time for me [Clare 101]

4.5 Phase Two

Eight participants completed interviews in phase two of the study between six and seven months following their surgery. The participants' discussions revealed the same three overarching themes during the second phase as during the first phase: namely '*physical and functional recovery*', '*effect on lifestyle*' and '*emotional response*'. However participants described actions, feelings and experiences relating to these themes in new ways. As in the previous phase the themes are presented and discussed with sub-themes.

4.5.1 Theme One: Physical and functional recovery

Ability to complete day to day functions was discussed by the participants as in the first phase. At approximately six months following the injury the participants were rapidly able to relate the tasks they had previously struggled with but were now able to perform independently. Most were able to reflect on the change in activities over the months since the previous interview. Participants could identify physical and functional activities which continued to be difficult for them. For some the pain they experienced during physical movements resulted in functional limitations.

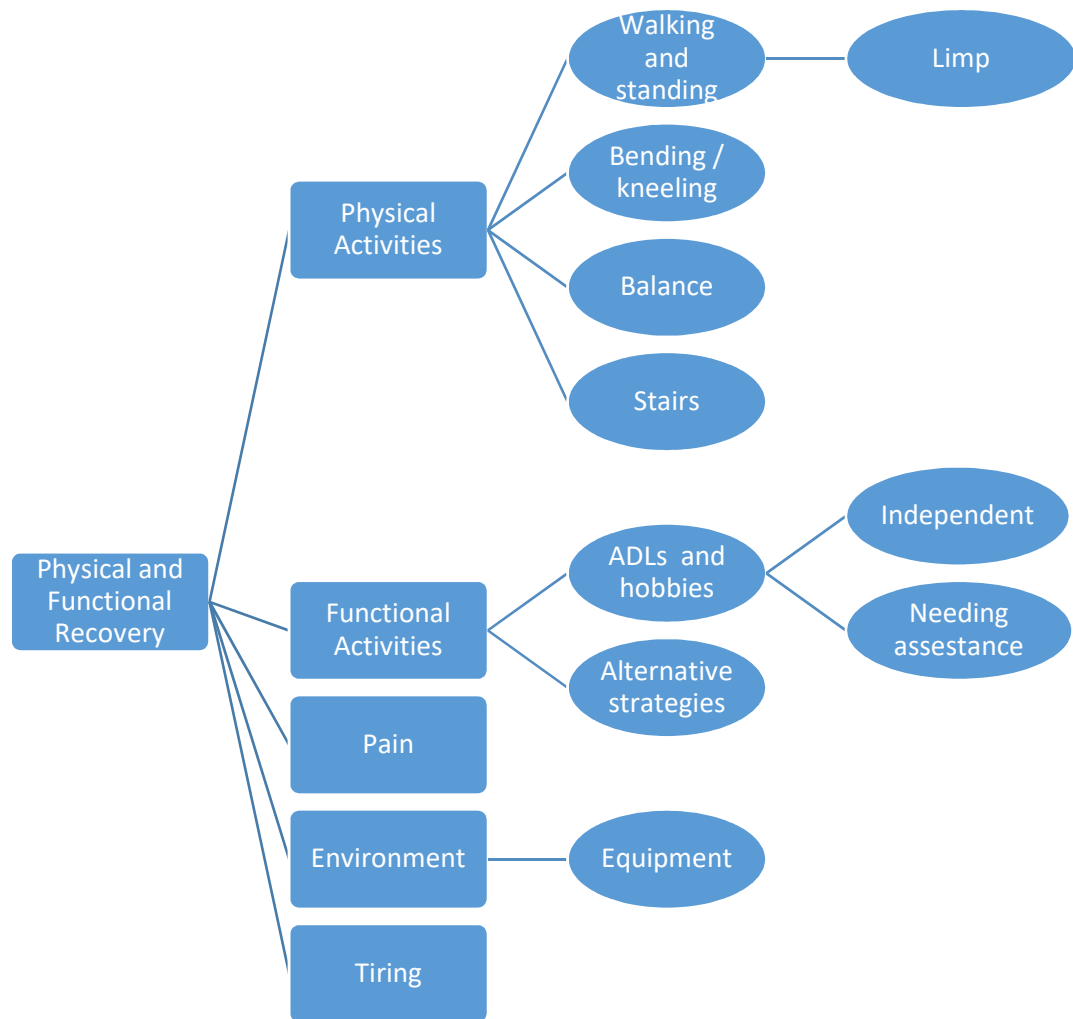


Figure 5 Phase 2, Theme 1: Physical and functional recovery

4.5.1.1 Physical activities

Walking and standing

Walking was important to all participants – they felt their walking was limited by pain, and that they needed walking aids to assist by taking the weight or pressure off their leg, or their distance was limited. In general, standing still had by this stage ceased to be an issue. Some participants identified walking to be the most important aspect of recovery because it was the solution to so many of their other concerns, ranging from walking the dog, shopping, reaching the bus stop or joining family on trips out. Some were concerned about walking on different surfaces, for example shiny shopping centre floors or pavements with wet leaves. Most participants however were generally relieved and pleased by progress with their walking although they still felt it was difficult, tiring and they had to rest regularly.

Well most of it's difficult, more difficult than it was before I broke me hip. Um then I was able to sort of walk, and I mean walk. Now I can walk, but it's more er well like a trundle,

if you know what I mean, as opposed to striding out. I can walk, but striding out like I used to, no, that's a thing of the past. [Collum284]

Some participants were no longer using a walking aid or reflected it was for reassurance. The need for a walking aid was generally seen as a hassle – participants had to pick them up from the floor, forgot them or worried about getting their feet caught up in them. Most however did recognise an aid helped support the injured leg to take their weight while walking.

I feel much safer with the stick. I take quite a percentage of weight on the stick, or two sticks, I mean two sticks is ideal, one stick on the other side is enough to sort of jump, jump around, you know what I mean, sort of – not exactly – I mean in other words it's putting the minimum of weight on the er operated leg. [Jamie 110]

Being able to walk without a limp was a frequent ambition. For some the limp was a personal indicator for measuring their progress and symbolised they had not yet fully recovered. The limp signified persistent pain, discomfort, weakness or their balance was still not right. Some participants saw the limp as a signal to others that they had something wrong with them.

walking, the limping is a bit tiring. You know, after I have walked I have to sit down to rest this here... The most important thing for me is to be able to get up from a chair without pain and to walk, walk straight, and walk as far as I want to walk like I did before, without a limp, without my body being sideways. I wanna be straight, my leg straight like it was... You know, and um 'cos at my age I don't feel I have to be an old woman. You know, and that's what I wanna do, I want to walk properly without a limp, and my body straight like it was before, that's what I want. [Clare 101]

Bending and kneeling

Most participants reported some improvements with tasks that required bending at the hip, for example cutting toe nails or putting socks on, but still reflected that it was more difficult to complete these activities compared to the uninjured leg. Activities such as gardening and getting up and down from the floor remained a challenge.

the thing to help me put me tights on, that was a very handy gadget too. But er I can bend now and I – this one's alright, but the this one I can – I've still got to get down, right down to get it on over me foot, but I can do it. [Gillian 239]

Balance

Balance appeared to be less of an issue for participants at this stage and was not discussed by a number of participants. They seemed to have learnt how to manage risk, for example knowing which footwear they were most steady in, using their walking aids to help or being cautious when the environment was a risk, for example slippery floors. There remained some fear of falling, even for those who felt their hip fracture was an unfortunate misadventure.

Well I came through the passage way there didn't I, when I came back that way this morning, I looked at me stick and it went 'whoosh'. Only I was waiting for it so I thought well a good job I didn't put any weight on the stick. [Jack 349]

Stairs

Regaining the ability to climb stairs was seen as progress back towards normal. For some participants this was just being able to climb a flight of stairs, for others it was returning to their normal pre-injury reciprocal stepping pattern. At this point all the participants who needed to had returned to having their beds upstairs. Stairs were seen as important because it opened up more destinations outside the home – for example participants remaining unable were limited in terms of visiting relatives' homes where bathroom facilities were upstairs. Most commented that, although able to do the stairs, they were more reliant on handrails, were slower, found them painful or tiring and hard work.

Well I can go upstairs but quite a lot of the time I've gotta do it one step at a time, you know, like that... But before I was able to 'bump, bump, bump' up, you know. Oh it's not slow going up there, but I need a banister or something nowadays because this leg just won't take the pressure. I can put this one up, that'll take the pressure, but this one won't take the pressure. All the muscles is sort of wasted there. [Collum 284]

4.5.1.2 Functional activities

In general, participants were pleased to be returning to their previous levels of independence in their day to day activities. They mentioned changes and adaptations to their routines and environments that supported this return to independence.

Activities of Daily Living and hobbies

Some activities continued to need support such as the heavier jobs in the home (for example moving furniture, standing on chairs to take down curtains) and gardening. Those with more active hobbies such as walking the dog or golf were more frustrated by the difficulties returning to their previous pastimes. By now most had returned to their previous activities or often had found alternative approaches to continuing their activities but some participants remained frustrated and bored with their enforced lifestyle changes.

I miss it, and she's [neighbour's dog] missing me. But I did try her on the lead, but I can't do it... she pulls me it makes me go forward and then it just pulls my hip, and I can't do it. [Clare 101]

I've had to abandon (laughs) the idea of playing a reasonable game of golf. I just get round now, you know, with my friends, and it's great, er it's good to be out there... I don't know if you know anything about golf, but you transfer all the weight onto the left side as you come through to hit the ball, well transferring the weight to the left hand, left side is

not all that easy to do... So you find yourself hitting, well, what a golfer would say, hitting off your right foot, which is wrong. [Frank 060]

I shower and dress myself, and I've always done that. I – I do everything myself really. And, as I say, it's only the very sort of heavier things that I need a bit of help with. And I don't always ask for help with it, I struggle to do it myself, but it's not always the wisest thing. But it depends whether I've got to wait any length of time for somebody to come. [Gillian 239]

Alternative strategies

Some participants had adapted their routines to enable them to continue with the activities they enjoyed. Some of these adaptations resulted from a reduced walking distance. One participant and his wife had exchanged their car for an automatic and starting going to a different cinema which they could drive to and park outside, rather than walking to the bus stop and taking a bus into a town centre cinema. Another avid reader had arranged a lift to the local mobile library once a week as she was no longer confident to walk and carry the books the distance required.

There were also smaller strategies for day to day tasks such as resting during house work, carrying shopping in more, smaller loads; reading to help with boredom and using the computer to keep in touch with family. Some mentioned how pleased they were not to need the alternative method they had initially adopted and to return to doing things “*what I call ordinary*” [Clare 101].

I have done a bit of shopping this week, er yeah, no, quite normal. Yeah, I wouldn't say that it was any different to what it was... except that um maybe I do it in two journeys instead of one. Mainly because – you probably, not playing golf you don't know – I have a battery powered er golf buggy and the batteries are so incredibly heavy, whereas previously I would have carried that and my bag and all in with it, I'd probably do it in two goes. [Frank 060]

4.5.1.3 Pain

Most participants continued to report some pain when doing certain activities but overall described the pain as improving, though still varying day to day. Some continued to experience pain when taking weight through the leg. Typical activities affected included standing on the injured side during walking and pushing through the leg to step. Some participants continued to report pain when lying on their back or side at night. Others reported pain in their groin. Those who approached their medical professionals were told the pain was probably caused by the muscles continuing to heal and re-strengthen following the incision for the operation. The intensity of pain experienced varied from sufficiently severe to make participants stop the

activity and rest until it passed, to an ache that they were aware of but was not incapacitating. Some of the participants reported an increase in pain in other areas (knees, back, shoulders) which they attributed to more strain on their other joints while compensating for their hip.

it's not an ache that makes me want to sit down or – or stops me from doing anything. It's just now and again you think, "Oh, you know, just a little ache," but nothing incapacitating, let's say that. [Gillian 239]

4.5.1.4 Environment

Participants remained aware of the environment outdoors, expressing increased caution in strong winds, snow or when there were wet leaves on the pavements, compared to before their injury. They generally managed this by adapting their plans, for example delaying an activity or driving instead of walking to a bus stop. Most participants were now managing well in their home environments and had returned the assistive equipment they had been provided with. Some reported continuing to find it helpful, for example perching stools enabling them to cook in the kitchen when their endurance for standing remained reduced. This appeared to be when there was other comorbidities that were also limiting such as respiratory conditions or arthritis in the back and upper limbs. Other participants had returned the equipment even if they had found it helpful – for example toilet frames because they did not like having the equipment in their homes.

Well I suppose it did help. The toilet thing helped very much, the toilet seat helped very much, but I didn't like it on the toilet, I didn't. Come up the stairs and it was like a great spider with these legs, and I took it off. And I still have difficulty with the toilet, 'cos I have to press on the cistern and the seat to get myself up. But I would rather do that than have that toilet thing, I didn't like it. [Clare 101]

4.5.1.5 Tiring

In many cases, although participants were now able to do activities, they reflected that these were more tiring than previously. Some reported that although back to driving and going out they tended to go only for a few hours rather than going out for full days, or that they now had to nap to recover after cleaning the house. It appeared that, although physically able to function, they had not regained the stamina they had previously had. This often overlapped with the alternative strategies previously discussed.

I mean this morning... I washed up, made my bed, put the hoover round, dusted, put the washing out. Came back in, and I sat down there where you are, and I did drop off to sleep for a few minutes, you know. (laughs) I find that I do that sometimes, and then I wake up and I'm alright and I go on again. But I do get tired yeah, yeah. [Gillian 239]

4.5.2 Theme Two: Effect on lifestyle

The most important aspect of recovery identified by the participants at six months after injury (phase two) was that they could see and relate that their lives were “*gradually getting back to normal, whatever normal is*” [Ian 146]. They described how their daily routines had been changed following the fracture and how they were getting back towards what they had been previously. This was discussed with positivity because the participants felt they were regaining their independence, even though there remained difficulties (within their physical and functional recovery and emotional responses to their circumstances, as well as aspects of their lifestyle).

Just the fact of being able to go and do something yourself is – is the thing really. [Gillian 239]

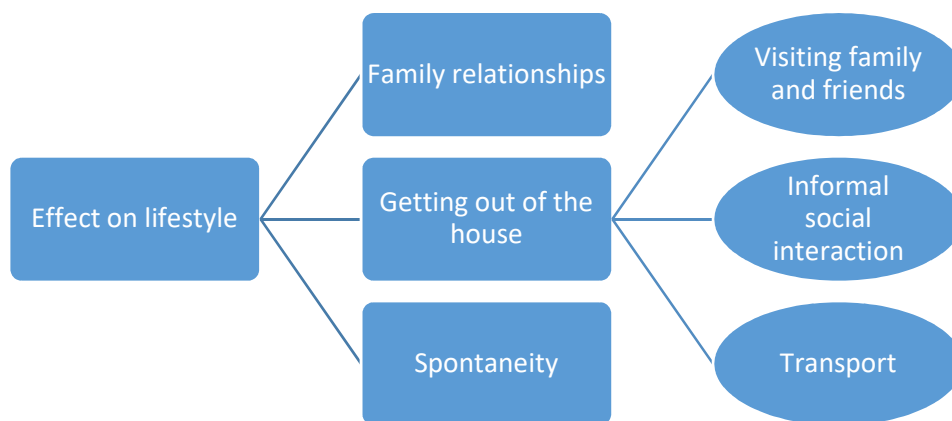


Figure 6 Phase 2, Theme 2: Effect on lifestyle

4.5.2.1 Family relationships

The importance of their relationships with their families was reflected by participants. They took comfort in knowing they were there “*to fall back on if I need to*” [Gillian 239]. They also reflected that their relationships with their grandchildren and younger family helped keep them going; they were a motivation to stay positive.

Family could also be a restraining factor – participants reported family instructing them not to take on tasks without assistance and in general the participants accepted this intervention in their actions.

it's the lifting, you know, moving it. And the fact that my kids say, the girls say to me, you know, "Don't you dare do that without asking one of us to come and help." [Gillian 239]

Those that were carers for others had at this point been able to take back and confidently continue those roles. Returning to being able to drive was the catalyst for two participants, enabling them to return to caring for their family members. For participants living with a spouse the relationship had generally returned closer to their previous balance of roles within the home, although in some cases there was some anxiety over the participant's ability to take back some physical tasks which could cause some disagreements. One participant had been bereaved since the previous interview and understandably any difficulties with his hip seemed insignificant in comparison to the other changes to his lifestyle.

I think the biggest change in my life, to be fair, has not been my hip, but the fact that my wife is no longer here... You know, that's the biggest single change. Um and if I could reverse anything it would be that. But the hip, oh it's incidental but, you know, it's not that significant to me. [Frank 060]

4.5.2.2 Getting out of the house

Being able to get out of the house on their own terms remained very important to the participants. Many had returned to activities that had previously required them to go out although, overlapping with the functional activities sub theme, they sometimes accepted alternative ways to accomplish them.

Despite being able to do more some participants still reflected on what aspects of their previous lives they had not been able to return to.

It does get me down sometimes, like I can't go out walking like other people do. Yeah you see people walking round here with the dog and everything and I do, I get upset about that. And being in so much gets me down. [Clare 101]

Visiting family and friends

Being able to visit family and friends who did not live locally was an important aim for the participants. There were annual routines and family traditions such as shopping at Christmas markets that they had not been able to do. Some participants had returned to visiting those further away, usually where they had found it easy to return to driving. The reasons for participants not being able to make these visits varied, for example difficult transport when distances were deemed too far. For others it remained the practicality of coping in the environment once they were there – for example town houses with multiple sets of stairs. It was hoped these visits would be able to happen in the future when family moved house or when the days were longer allowing greater distances to be driven in daylight.

Informal social interaction

For some participants un-staged opportunities to interact with others remained an important part of returning to normal. Others for whom this had been an issue earlier did not refer to it directly. This appeared to be because they had returned to the routines that met that need.

I can walk a bit farther, 'cos I've got my stick, so it takes a while, I'm slow, but um I can do it. With the playing field, at the very end, the very far end where the houses are, I walk all around there. Takes me quite a while, but then there's people I know and we chat and, yeah, it's quite a nice break from in the home, you know. [Clare 101]

Transport

Transport remained an issue and could be a defining feature of participants' lifestyles. As a level of physical recovery is required the ability to use transport crosses over with many of the themes and sub-themes. Most of the men had returned to driving by 6 months which was an important enabler, facilitating them to return to many of their activities. None of the female participants drove but most reflected on the opportunities that being able to physically access a car provided. Some continued to struggle, finding getting into and out of a car difficult and remaining sat in a car for any length of time uncomfortable.

First of all, my legs, I found it difficult getting in. And I tend to be um – I get in and out a little bit awkwardly, I think. I don't sort of jump in as what I used to, but maybe that's because of me age, I don't know... I find driving quite easy, quite easy, there's no problems at all... It's brought my world back into – into being. You know, I'm back into the human er um lifestyle [Dougal 270]

A number of participants had not returned to using the bus service. As described in the environment and physical activities sub-themes this was often due to their ability to walk sufficient distances and caution regarding the weather and pavement conditions. They had generally adapted their routines to allow for this. Other transport systems such as taxis or 'dial-a-ride' type community buses were being used but generally by those who were returning to previous routines; they had not been adopted as a new transport solution since the hip fracture.

4.5.2.3 Spontaneity

"it's not so spontaneous as it used to be, you know" [Collum 284]

Although participants were now able to do many of the activities they wanted to, they continued to report that they had to approach things slowly and with planning; their activities

continued to lack spontaneity. They described a continual internal assessment of whether they would be able to do something and how much they could do before setting out to do something.

I am more careful. It makes you think about what you can do and what you can't do. And whether you can do it, you know, whether if you start out - that was – that was the problem in the beginning about walking too far, I was afraid I wouldn't get back. [Gillian 239]

I think to myself, "Ooh now shall I get down there or not?" And before I'd have automatically done it. You know, "Can I get back up again?" (laughs) Or, "OK, I'll go down the shops," I'll say to myself like, "I'll go down the shops and get that. Ooh, don't know, better take the car or I'll never get back up again," that sort of thing. But before it was a case of just, whoosh, down the shops, sort of back up again. [Collum 284]

4.5.3 Theme Three: Emotional response to circumstances

The participants continued to recognise that their circumstances affected their frame of mind. Some described feeling frustrated but also that they were persevering, determined to keep progressing. Other participants were considering that perhaps age and other health issues were responsible for some of the changes they had experienced since their hip fracture and it could be part of a permanent decline. For some therefore there remained the desire to get back to normal, others had got used to the changes to their lives.

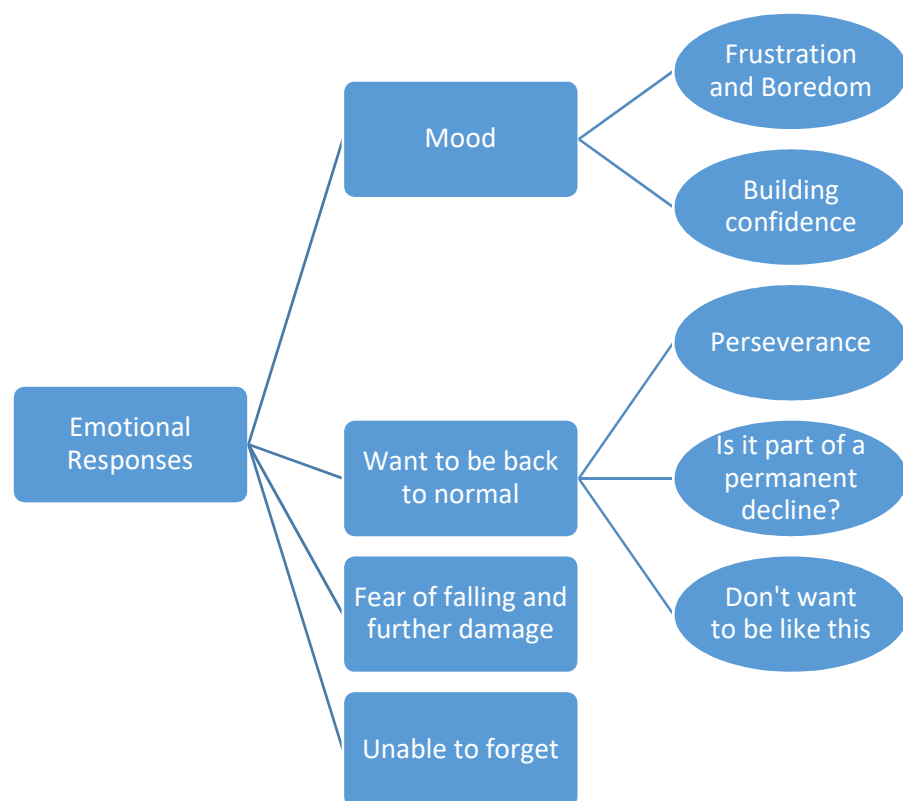


Figure 7 Phase 2, Theme 3: Emotional responses

4.5.3.1 Mood

The participants' moods were closely related to their perception of their improvements in the other main themes. They reflected on their physical and functional ability and the extent to which they had returned to their previous lifestyles and expressed how this made them feel.

Oh (laughs) it's another world... This is what I wanted to do when you came last, when you said to me. I mean all I want to do is just drive a car and take the dog for a walk. I was – I was peed right off just sat on that settee. I was (big sigh) you know. [Ian 146]

Frustration and boredom

In general boredom and frustration had reduced compared to the first phase interviews. The participants were able to reflect on this and reason that it was possible they were getting used to it but that it had improved as they had been able to do more physically.

It's not as boring now as it was... because I've got used to it, and I can move around a bit more, yeah it might be that...I can walk a bit farther, 'cos I've got my stick, so it takes a while, I'm slow, but um I can do it. [Clare 101]

The main frustration was still having to ask for help with some tasks.

that's the sort of frustrating things really [asking for help to change the cover on an armchair], silly things that you shouldn't let frustrate you really, but it's because you've always been used to doing it. [Gillian 239]

Building confidence

Just as their moods were affected by their physical improvements, their confidence was promoted by achievements; each activity they were able to perform for the first time was a step back towards their previous lives.

I've done it now, I've walked to the post box and I've walked to the shop and I've walked down to the library so I've – and back, so I – I've done that now... When you've done it, yeah, you – you – you feel, "Oh good, you know, that's another mile gone, another milestone gone," yeah. [Gillian 239]

4.5.3.2 Want to be back to normal

I don't want to look as though I've got something wrong with me, you know, I want to go back to normal. [Clare 101]

Many continued to battle for everything to return to the way it was before the hip fracture. The motivation for this varied – for some it was the activities they wanted to return to as discussed in themes one and two. For others it was the representation of not having anything wrong, and of not wanting to display signs of age. Other participants however recognised perhaps that some changes may remain; acceptance of this was mixed.

Perseverance

Participants described their daily efforts to push themselves, even when painful. They reflected that their willpower and attitude were important to their successful recovery. Some participants however felt they had not had to work hard and that they had had a smooth recovery.

Yeah many things I've taken ages to do and I've thought, "Oh why did I start?" But no, you just persevere, you push on and it gets better the next time, then it gets better again. You know, so that's how I look at it: if you can't do it once, try it twice and it'll get easier each time, and it does. [Clare 101]

I was surprised that I was able to get round doing things, you know, that I suppose really it's your own bit of willpower, bit of self that makes you do it. [Gillian 239]

Is it part of a permanent decline?

A background concern the participants expressed was that the hip fracture was a feature of a process of gradual permanent decline. This was more common where the participants were older or when there were additional background health conditions that were expected to deteriorate.

it's a worry, yes. Well it's um – is it part of a permanent decline? Um is it a thing that's going to get worse? I – I would like to see it getting better, wouldn't I? Not – I mean the fact that I've got it at all, on top of the leg, is it anything to do with the leg, would I have had it anyway? And all sorts of things, you know. Um I'm not suicidal (laughs) – and I'm optimistic, you know. But um it's depressing, it's depressing, yes. [Jamie 110]

Don't want to be like this

There was a reluctance to accept appearing and becoming old or the attributes that are associated with age for example bathroom equipment and walking aids. This was apparent across the full age range of participants (69 – 92 years). For many the period of recovery after the hip fracture had made them consider the restrictions that in our society are often associated with advancing age.

cos at my age I don't feel I have to be an old woman. You know, and that's what I wanna do, I want to walk properly without a limp, and my body straight like it was before, that's what I want. [Clare 101]

4.5.3.3 Fear of falling and doing further damage

Most participants expressed that they were afraid of falling again and injuring the other hip. For some it was a constant worry, for others it was around specific activities such as coming down stairs, stepping off kerbs or climbing onto steps. Participants described adapting their activities to avoid risks, such as walking to find lowered pavements or waiting for family to

change light bulbs for them. Participants did not want to have to go through the recovery process again with a second injury.

Because I don't like the thought of hitting that ground and putting the other hip out of – out of focus. And um I'm not going through all this again. [Dougal 270]

4.5.3.4 Unable to forget

Associated to the physical loss of spontaneity the participants described an emotional limitation closely related to their fear of falling – that they were unable to forget about the injury. There was a sense that participants felt they had to limit themselves because this had happened to their bodies and their lives even if physically it was not a problem.

well it's made me think about myself a bit more perhaps, that I'm not – you know, you've got to be careful, and that sort of thing. You just can't go blindly on when you're ... As you get older you don't – well I suppose you don't think that you're as old as you are, and you go on doing the same, and you think you can go on doing the same. Then something happens and it pulls you up short and you – you've got to start thinking, well yes I'd better, you know, start thinking about (laughs) what can happen. [Gillian 239]

4.5.4 Summary of phase two

In the second phase of interviewing at approximately six months after the injury, the emphasis from the participants in theme one had shifted from the detail of physical symptoms and activities to functional activities. Participants continued to judge the progress of their recovery in relation to their increasing independence and reduced need for assistance, even at times when it resulted in tasks taking a long time or being painful. Throughout theme two there was a mixed attitude amongst the participants between accepting changes to their lifestyles and continuing to persevere and strive for a full return to their previous situation. The participants reflected on perceptions of disability and age in our society and judged themselves in this context. Aligned with this the participants were more reflective about their other comorbidities and health. The participants appraised their emotional state around their circumstances differently – some were content, pleased with their progress and settling into new routines with just some ongoing frustrations. Others continued to question the pace of their recovery and had high expectations of what would constitute being back to normal.

4.6 Phase Three

Seven participants completed the final round of interviews approximately 12 months after their hip fractures. Review of the data and coding revealed the same themes were discussed, '*physical and functional recovery*', '*effect on lifestyle*' and '*emotional responses*'; but again their experiences within these themes were different to the previous time points and to each other. For the majority the focus between these themes had shifted with a briefer discussion of symptoms and basic functions and more focus on their lifestyle activities. In this phase it became apparent that the overall trajectory of recovery experienced by the participants had varied; some had continued to improve since the six month interviews, for some not much had changed and for others things had deteriorated. As in the previous phases the themes are presented and discussed with sub-themes.

4.6.1 Theme One: Physical and functional recovery

The different trajectories of recovery and diversity of experience was very apparent in the physical and functional recovery theme. The interaction between physical limitations, pain and functional limitations was highlighted by their diverging recovery patterns, with one participant becoming more debilitated and now waiting for further surgery on her hip (Clare 101).

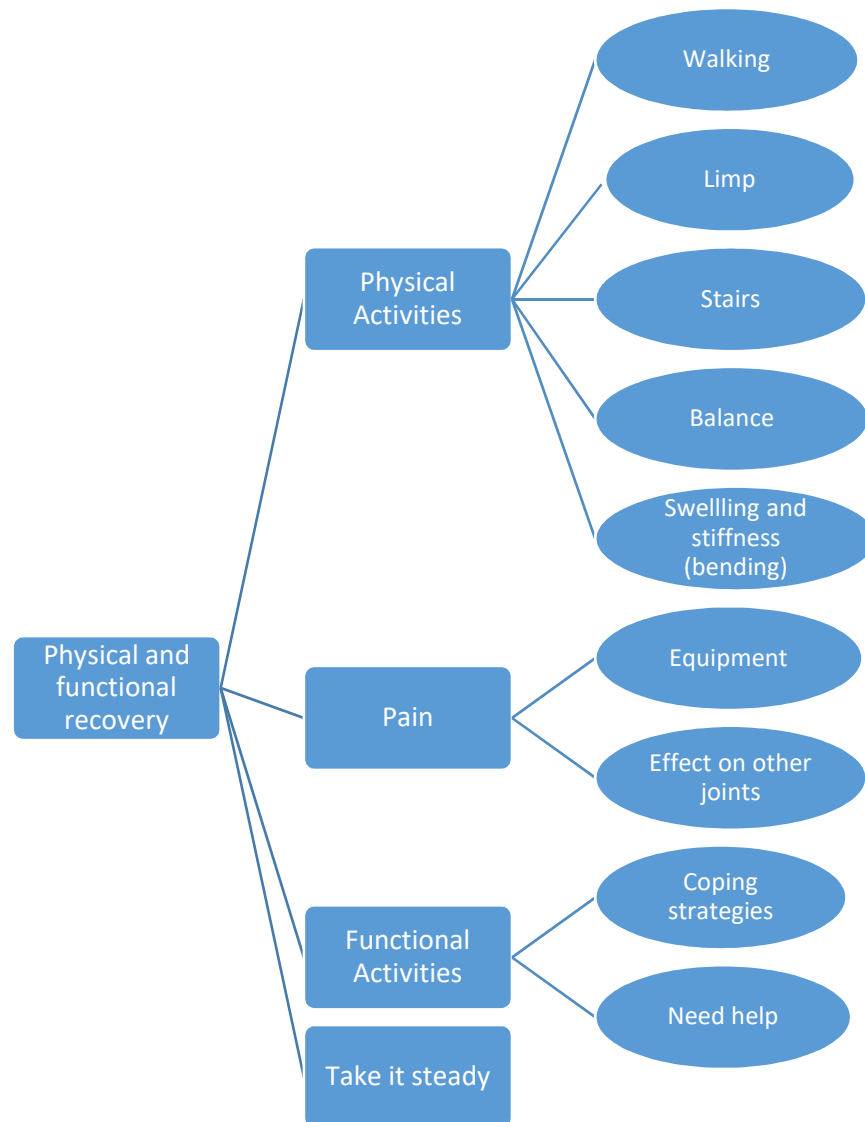


Figure 8 Phase 3, Theme 1: Physical and functional recovery

4.6.1.1 Physical activities

Walking

Some participants felt their walking had continued to improve although none reported it to be back to how it was prior to the hip fracture. Participants reported their walking to be slower, limited by distance, causing aches elsewhere, less confident or more dependent on a walking stick than prior to their injury. One participant felt their walking had deteriorated and was more painful than in the previous interview.

I can walk, but I mean an hour, that's my – that's my limit. And I mean I love walking the dog, I love walking, but after about an hour, on me way home it's beginning to get a chore, you know what I mean... Because I'm going out to get some fresh air, but after it's so painful limping, I'm like this all the time [Ian 146]

Limp

A number of participants reported a continued limp. The two participants most concerned about their limp discussed their leg being shorter and that they had been given a shoe with a 'built up' sole to enable them to walk despite the discrepancy in leg length. These participants had sought Orthopaedic review to consider further surgery.

And limping of course, you know, that is the worst part, is the leg being shorter...I it's horrible. I mean I used to – I've not been able to wear my high heeled shoes and all that I wore before. Oh I can have it built up, but um how I walk now, it's – it's quite a limp. [Clare 101]

Stairs

The participants reported a wide range of experience on stairs ranging from no problems to deterioration due to pain. They adopted a range of strategies for stairs including minimising the use of rooms that required stairs to access them or coming down steep stairs backwards.

I can, I do come down, when we go to the cinema, if I've got a stick I can put the stick down and, you know, one step at a time: I go down forward then. But er (at home) I find it much easier just to go backwards downstairs – well it's quicker (laughs). [Jack 349]

Balance

In common with the other physical activities participants' impressions of their balance varied from never believing it had been a problem to feeling it had deteriorated since the previous interview. Some participants attributed their need for a walking aid to assist with their balance (rather than to take weight) and felt they would have fallen without it. Some participants felt their balance continued to improve.

Well any time that I'm wanting to move from A to B, I've got to be vertical, then it becomes a problem. So every time I sit down, and get up to go to the sink, I have to say, "Where are my sticks?" because I've either got to do that or go very quickly before I fall over, grabbing things as I go. [Jamie 110]

Swelling and stiffness

A few participants continued to report some difficulties with ankles swelling on the injured side. Although none referred to stiffness in the hip, they did discuss ongoing frustration with bending for example to reach low cupboards or to put on their socks and shoes on the leg they fractured.

I do find bending and that sort of thing is a bit er – I can't bend with – with that leg so well as I used to be able to... It doesn't hurt, no, it doesn't, not really hurt: just seems to not go as easily as the other one, you know. [Gillian 239]

4.6.1.2 Pain

The pain experienced by the participants also varied. Most participants continued to report some pain or discomfort. For some it was mainly pain from arthritis in other joints or other conditions such as claudication that overshadowed any discomfort from their hip. Other participants felt their pain had continued to improve. Some continued to report discomfort in their groin or front of their thighs after recent activities which medical professionals had told them was muscle pain. Two participants continued to complain of pain affecting their function. One felt his pain limited his walking and had a sensitive scar, however he reported he could tolerate the scar sensitivity and was more bothered by his limp. The other participant reported severe increasing pain which was affecting her mood, appetite and sleep. She was concerned about 'addiction' to painkillers and therefore endured pain while waiting for another operation.

I can't eat; I have lost so much weight. I'm not going anywhere 'cos I can't walk very far. I've got so much pain that I'm feeling sick, you know, and it's just something's gotta be done otherwise I'm gonna put myself out of it. And I just can't stand it anymore. [Clare 101]

Equipment

Most participants reported no longer needing equipment such as supports for their feet in bed or aids to help them bend to put underwear on, and no longer required a wheelchair when out with family. However, Clare (101), the participant whose pain had increased, had requested the return of assistive equipment such as the toilet frame and chair raises to her home.

I've had to ask for the toilet thing to come back... See um, yeah, the things that I gave back I've had to – I've asked for them, or they're going to bring them back to me. And um pain has got gradually worse. [Clare 101]

4.6.1.3 Functional activities

Most participants were comfortably managing their daily activities in the home such as washing and dressing and managing the house. However many continued to require assistance with heavier activities such as gardening and shopping. They had been unable to return to tasks that required supporting themselves on one leg such as digging with a fork or spade or climbing a ladder. Many participants had accepted the alternative solutions to managing functions that they had adapted to at six months and these were now routine, such as using a mobility scooter to get to the post box or changing to an automatic car. Clare, who felt she had deteriorated was still able to manage independently in the home but found tasks exhausting and slow.

I can't do my shopping; my son does that. I write a list and he goes and gets everything... I was going around choosing what I wanted and, oh, I felt so sick that he had to take me out to sit on a seat, and he finished it for me. So I don't – I haven't attempted that again. [Clare 101]

I seem to, you know, when I'm alright I seem to be able to do most of my own jobs. Get a bit of help from my daughters, anything heavy... bed changing and things like that. [Gillian 239]

4.6.1.4 Take it steady

Some participants reflected that, although they generally managed functions well, they had to pace themselves during some tasks. For example taking rests or if they started a task and found it tiring, too difficult or had concerns; they had to stop and wait for assistance to complete it. Participants could relate stories where they had done too much for example in the garden and ached for days afterwards.

Cos I take the Hoover out, and I will do a little, then I have to stop because I can't do it with the pain... So then I relax a little, maybe have a cup of coffee or something, and then I will do a little more. [Clare 101]

certainly, now, I've gotta consider the fact that I have got a certain amount of restrictions, and if anything happens I'm back to zero again, and I don't want that. [Dougal 270]

4.6.2 Theme Two: Effect on lifestyle

The participants discussed their lifestyle after hip fracture; similarities and differences to before the injury, progression since the previous interview phase and what changes they had accepted for the long term.

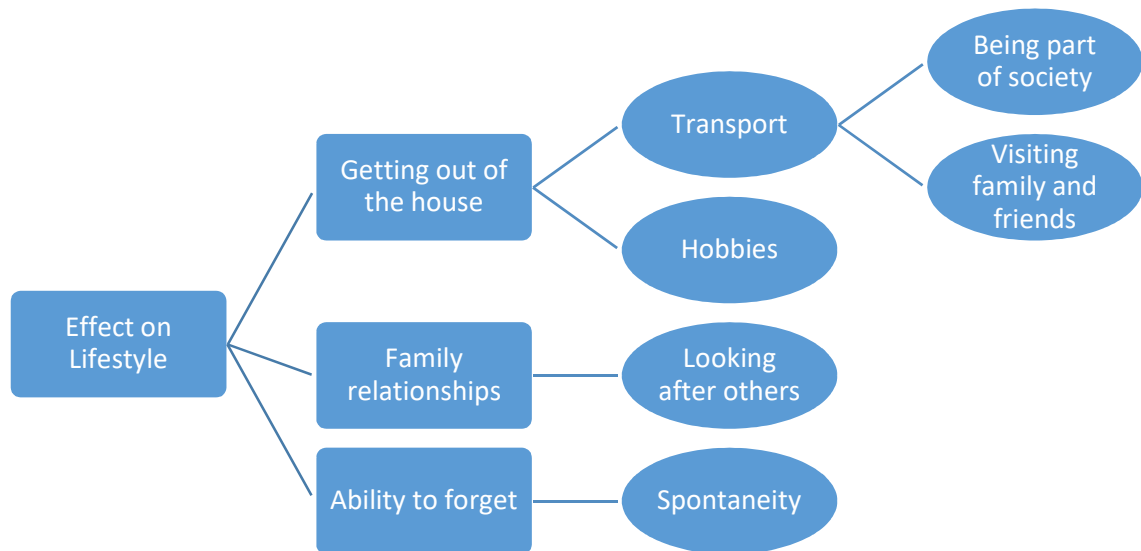


Figure 9 Phase 3, Theme 2: Effect on lifestyle

4.6.2.1 Getting out of the house

Being restricted in their ability to get out of the house remained an important focus for the participants. Their limitations varied but accessing transport was a common sub-theme throughout. For some participants the freedom to get out of the house was influenced by the health of their spouse, for example making them more reliant on driving a private car in order to facilitate their spouse being able to join them.

Transport

Transport as a facilitator to enable participants to get out of the house was a frequent topic of discussion in this phase. Participants relied on either driving themselves or having lifts from people to access many of the activities key to their lifestyles. For example getting to the library, the hairdressers, being able to visit family or going on holiday. One participant reflected that before being able to drive he had not been able to go to vote and being able to take part in those activities helped him feel part of society again. Some participants felt unlimited in the distances they were able to drive, others were meeting family half way due to not wanting to drive long distances or were limited by discomfort being sat as a passenger.

My sister's son got married, and I was supposed to go to that – I couldn't even go to it... I went out and sat in the car and I couldn't, I couldn't get comfort anywhere. And I said, "There's no way I can go down there in that pain."... I just couldn't do it. I sat in the front,

I sat in the back with my leg on the seat, but I just couldn't do it... It's not just the hip and the leg; it's my back as well. So I'm losing out on everything. [Clare 101]

One participant was now accepting lifts for distances she would have previously walked; once her elderly friend was no longer able to drive they both relied on her friend's son. Other modes of transport such as public buses were more difficult for participants (and their spouses) to access due to the walking distances required at either end and they had therefore changed their routines. Community buses appeared more user friendly because they picked you up from home; however these were only used by those who had used them prior to the fracture. A mobility scooter had assisted one participant regain some freedom for local short distances but he continued to depend on family for most activities out of the house.

it's much better for us [than going by public bus] because you go up there and just walk straight – park the car and walk straight in. [Jack 349]

Hobbies

Many participants had returned to their hobbies although they had had to make changes. For example going to the cinema at a different venue or walking the dog but for shorter distances. Returning to hobbies such as reading and singing in a choir were dependant on transport as discussed previously. Wider constraints on time with tasks such as gardening taking longer and caring for a spouse had limited one participant's opportunities to pursue his hobbies such as skittles and golf.

I'm out in the garden and um I've got a bit of painting out there to do now. I've got this house to do but, to be honest, it's finding the time. [Collum 284]

4.6.2.2 Family relationships

Some participants reported finding their continued reliance on family frustrating which could be a strain on the relationship at times – for example when there were different opinions on the urgency of a task they needed assistance with. Others had found the protectiveness of family stifling and were much happier now they were being treated normally again. Sometimes the relationships between participant and family had not changed with family either being very helpful and involved or not, as before the fracture. The health of a spouse had a great impact on a participant's lifestyle – with some participants either caring for the spouse or having to adapt their lifestyle to accommodate for changes to their spouses' limitations.

He didn't say, "Oh can you make it? Will it be OK? Would it be too much for you?" and all that business, you know. And that's good. So he takes me – he just says, "Oh I'm at [a work location], you pick me up dad." You know, that's normal. I love it. [Dougal 270]

Actually, to be quite honest about it, her injury has helped me inasmuch as I've got to do these things... I've got to move. I've got to. I can't, I can't sit there going, "Oh my leg." Up, and I don't give it a thought see. [Collum 284]

4.6.2.3 Ability to forget

Some participants felt they still had a tendency to hold back on things, they were not as likely to get involved in new things as they had been prior to the fracture. However many felt they did forget it had happened at times and did not have to plan tasks or think about things in advance as much as they had to at the six month interviews.

I do tend to forget sometimes that I did break it... though sometimes you try to do things that you (laughs) perhaps shouldn't do. [Gillian 239]

4.6.3 Theme Three: Emotional responses

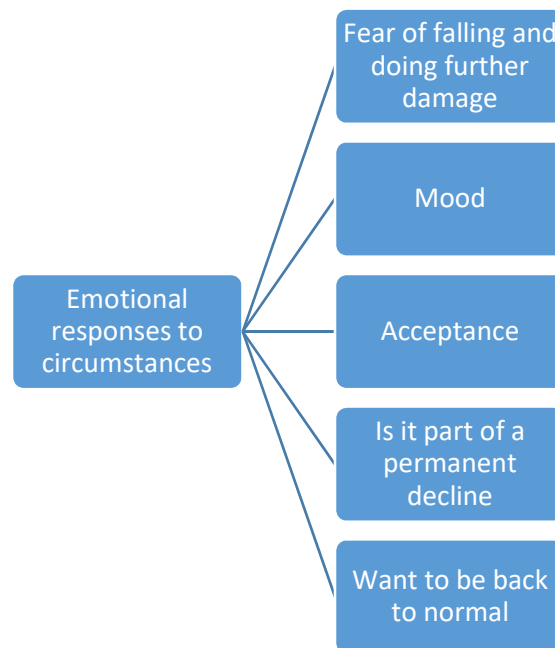


Figure 10 Phase 3, Theme 3: Emotional responses to circumstances

4.6.3.1 Fear of falling and doing further damage

Many of the participants were afraid of falling and injuring themselves again. These fears were often focused around the task or location where they had the fall that resulted in the hip fracture. This was less prominent where the fall could be attributed to something out of their control such as a loose paving stone or being knocked over by a dog – but even for those participants some activities such as climbing step ladders were viewed as too risky and were avoided.

it's only about these last six months I've been walking up the garden path up the steps. I was really frightened to go out in the garden up the steps... when I broke my hip it took the ambulance driver nearly half an hour to manoeuvre me out the garage door to come down. They couldn't get me down the steps. [Ian 146]

I always think that one day I'm going to fall down again and lie on the floor in a position or something in some way, and not being able to – so I'm stuck, you know, until the next person comes in. So from that point of view it um is comfortable to feel that somebody is going to come in some time and find me lying there on the floor. [Jamie 110]

4.6.3.2 Mood

In general participants seemed to be more stable in terms of their moods and it was discussed less than in the previous phase. There was still frustration expressed by some participants although this was a wider frustration that their physical limitations were hampering the retirement they had anticipated. Other participants reflected they had had to curb their frustrations for the sake of their family relationships. One participant in particular, Clare 101, continued to have problems with depression. Although she recognised she had already been struggling with depression prior to the fracture she attributed much of her current problem to the pain she was experiencing. Her experience at this stage in terms of her moods – feeling like a prisoner, frustration and feeling like she was struggling was more aligned with the early experiences after a fracture but she continued to remain determined and not to give up.

It's really got me down. I was depressed before, but I've got a depression now (sighs) that's really bad. But there you are. [Clare 101]

4.6.3.3 Acceptance

The degree to which the participants accepted their current circumstances varied. Some were very accepting of new routines, especially where there were additional comorbidities affecting their health or where they were accommodating the health of a spouse. Some had come to accept they were not going to achieve aims they had at the previous interview, reflecting that this awareness had come gradually. Others were reluctant to accept their status quo and had sought review from the surgeons.

I can't give you a definite date... it's sort of an automatic [car], so it's only – it's only my right leg, but that unfortunately is the one that you have to have for an automatic, isn't it? And um it – it was obvious that I wasn't fit to drive straight away. And so it um – it came gradually [Jamie 110]

Well I've just gotta deal with it, haven't I? I can't like blink and it's all gone away like, you know. [Ian 146]

4.6.3.4 Is it part of a permanent decline?

Some participants expressed the feeling that some of the changes they had experienced were to be expected as part of the aging process rather than their hip, or that the hip fracture had seemed to age them. The participants discussing this tended to be older or had other deteriorating chronic conditions.

I don't put it down to that [the hip fracture]. It's just that you can't move about as quickly as you used to when you're older. You've got to take your time. I don't er – I don't think it inhibits me that much, not really. [Gillian 239]

One participant, Jamie 110, was concerned that his mental alertness had declined in recent months and felt this was more of a priority to him now than his physical limitations following the hip fracture. He also reflected that it was difficult to know whether the various health issues that had cropped up over the 12 months since his fracture were to be expected as part of ageing but found it hard to believe the fracture had not been involved in some way.

I think more has happened in the last year than has happened in any sort of 5-10 years before. And so I can only attribute it to the hip breakage. [Jamie 110]

4.6.3.5 Want to be back to normal

Many participants reported feeling like they were back to normal but then qualified their statement with an explanation of what was slightly different to their normal prior to the hip fracture; as if they were describing a new normal that was a satisfactory outcome for them. For example they were completely back to normal but “*not at the same pace*” [Gillian 239], or just that they “*hold back on things that they never did before*” [Dougal 270]. If the current state was not satisfactory then it was not described as normal. Some participants with continued pain or what they felt was an unacceptable limp had by this time sought further review by the surgeons as they continued to strive to get back to normal. Others accepted their physical limitations or changes to their lifestyle despite it not being what they had hoped.

“Not normal but a manageable situation” [Jamie 110]

4.6.4 Summary of phase three

The interviews in this third phase often reflected on the changes the participants had experienced over the 12 months since the hip fracture. Some of the participants were surprised and content with the progress they had made. Some felt they were still limited in terms of the distances they could walk but felt this was still improving. A few participants felt they had gone downhill and, although they were functioning in their home, their progress over

the year was a disappointment to them. The change they experienced over the 12 months was further explored in the longitudinal analysis.

I shan't be disappointed if I don't get any better because I'm as good as I feel now like, you know, it's um, yeah, as far as I know it's as good as it will be. [Gillian 239]

4.7 Change over time – longitudinal analysis of main themes

Longitudinal summaries for the three main themes are presented in Table 9 for the seven participants who completed all three interview phases across the 12 months and the one participant who completed two interviews up to six months. Each of the three main themes from the previous sections were reviewed (including all sub-themes) in turn for each individual participant.

Table 9 Longitudinal thematic analysis

Participant Pseudonym	Theme 1: Physical and Functional Recovery	Theme 2: Effect on Lifestyle	Theme 3: Emotional Responses to Circumstances
101 Clare	Pain at her hip gradually improved across the first 6 months but had deteriorated again by 12 months. In line with changes in pain she had gradually built up walking distances, independence with ADLs and managed stairs more easily but these were worse again at 12 months. At 12 months she was waiting for revision surgery.	Struggled to return to previous activities such as clothes shopping and walking the dog. She missed informal social interaction with the community. At 12 months she continued to miss out on family occasions as unable to travel. She adapted her routines and approaches to tasks to keep independence as she physically deteriorated. Relationship with her son was a bit strained by 12 months.	Bored and frustrated with inactivity. Fear of falling around hallway where injurious fall occurred at first. Fear remained across the 12 months but the focus moved away from the hallway floor. Initially determined to return to normal as prior to fracture; by 12 months she had reduced her ambitions accepting some things would not return but was not accepting of her current situation. Her depression was exacerbated by situation.
107 Jenny	Participated in 1 st phase only. Died 4 months following hip fracture from an abdominal aortic aneurysm.		
110 James	Disliked reliance on walking aids but needed them for balance. Felt restricted because hands were not free. Balance remained difficult at 12 months.	More reliance on support from family continued across 12 months. Did not return to driving. Early feeling of restriction improved slightly by 12 months. Adapted to more indoor, less active pastimes. Used a scooter for short distances out of the house by 12 months.	Initially very positive about eventual outcome, but disappointed not improving quicker. By 12 months showed gradual acceptance of changes and alternatives and some loss of confidence. General feeling of dissatisfaction and loss of health / mental acuity. Fear of falling and doing further damage continued despite original confidence that fracture was just misfortune.
146 Ian	Gradual improvement of pain and walking distance across 12 months. Sleeping positions and ability to carry things remained limited at 6 months. At 12 months remained restricted with getting up from floor, carrying things and walking duration (due to limp which resulted in back pain). Sought surgical review regarding limp.	Found lack of independence and change in role difficult at first. Improved once able to drive. Missed occupation and social interaction whilst unable to walk dog. By 6 months reliance on wife improved but continued to avoid garden steps to garage where injurious fall occurred into 12 months. Returned to most aspects of previous lifestyle but not the same.	Feelings of depression, being like a prisoner improved as freedom of movement and independence improved through mobility and driving. Disappointed didn't have a hip replacement from the start and remained dissatisfied. Begrudgingly accepted situation but frustrated that everything had not returned to how it previously was. Challenged his sense of identity. Fear of falling and further injury continued throughout, being particularly anxious / hesitant of mechanism of injury.
195 Brianna	Participated in 1 st phase only. Withdrew from study.		
240 Fiona	Participated in 1 st phase only. Withdrew from study.		
239 Gillian	Not much pain from hip. Initial difficulty bending, limited tolerance standing and slow pace improved over first 6 months. Aimed to progress walking further but by 12 months accepted that was not going to happen. Needed help for heavier jobs and difficulty carrying things – felt this was due to age and comorbidities as much as hip.	By 6 months felt most routines were back to normal although needed more support with transport. Regained independence in day to day life mainly but things took longer. Throughout the year she continued to report feeling she had to be careful and think more before she did things. Her ambition to return to walking to her activities at 6 months had been forgotten about by 12 months and she had accepted assistance with lifts for example.	Early frustration settled as she regained her independence. She continued to have a heightened awareness of things that could go wrong and was nervous and cautious. She worried about doing things even after she had done them. By 12 months she had accepted the changes to her lifestyle and mobility but tended to see them as due to age or comorbidities rather than her hip.

Participant Pseudonym	Theme 1: Physical and Functional Recovery	Theme 2: Effect on Lifestyle	Theme 3: Emotional Responses to Circumstances
270 Dougal	Initial difficulties with standing tolerance, stamina and unsteadiness improved across the 12 months. Pain from hip not a concern, more limited by leg pain from peripheral vascular disease. Returned to walking without aid. Reliant on car prior to fracture due to comorbidities therefore return to driving prior to 6 months was important. Returned to all main functions as 'house husband' cooking, cleaning and gardening.	Lack of independence challenged his sense of himself in terms of his role within the family, as a carer for his sister and being part of society. Returning to driving was the main facilitator to this returning. By 12 months had returned to the roles he wanted but was choosing to take on less.	Found dependence at beginning difficult. Used exercise to help him cope with low mood so was difficult not to be able to do this. Mood and anxiety improved as independence returned. He felt the fracture made others consider his age more rather than just being him. At 12 months some fear of falling remained, preferred to accept some limitations than take risks.
284 Collum	Initial groin pain and pain in other leg taking the weight improved over the 12 months but continued to report pain in muscles. Initial reliance on walking aids improved and returned to walking without aid although still had some limp. Returned to driving in first few months. At 6 months functioning remained a conscious effort, this had improved by 12 months.	As the carer for his wife they required support from their family at first. His caring role became easier once he was able to drive. Over 6 months he found activities still felt more of a chore than previously and had lost spontaneity. By 12 months his wife had also fractured her hip, he felt the additional care she required had pushed him to continue to progress.	In the early stages he felt down with the circumstances but by 6 months felt better able to cope because was able to get out and chat to people. By 6 months was generally accepting of changes and attributed most to age or comorbidities rather than hip.
349 Jack	Initially living downstairs and dependent on walking aids and various equipment; by 6 months he was back to managing stairs with an altered pattern and was walking with one stick outdoors. Minimal hip pain reported, more problems from other arthritic joints. He returned to driving but changed to an automatic car. His arthritis in other joints was worse following the fracture but gradually improved across the 12 months. Continued to be restricted with carrying and jobs about house requiring steps.	Initially he was more reliant on his wife and family. As a couple they were unable to resume their previous activities until his mobility and stamina improved. By 6 months and his return to driving (an automatic car) many of their routines had been adapted, enabled by becoming more car dependent. By 12 months issues with wife's health meant the changes were accepted as permanent.	Limited discussion of emotional effects (wife was present throughout all interviews). He reported remaining cautious and not being confident to try things at 6 months. By 12 months he didn't think the fracture had made much difference. He attributed changes to comorbidities and circumstances around wife's health and had accepted them.
060 Frank Note: Participated in phase 1 and 2 only	Surprised that he had experienced no real pain. Initial difficulties on stairs had improved by 6 months but he continued to feel safer with two hand rails. By 6 months he no longer required a walking stick outdoors but remained cautious of slippery surfaces and only carried smaller loads. By 6 months he had returned to the golf course but game was limited by difficulties transferring weight onto left foot.	Initially unable to participate in key aspects of his lifestyle and was keen to regain independence to relieve stress on his daughter and return to his social activities. At 6 months he felt returning to driving had been the biggest aid to returning to his lifestyle as it gave his independence and social life back. His wife died since the first interview which was the biggest change to his lifestyle. He was seeking support for gardening and cleaning and using facilities such as supermarket car washing as a lifestyle choice rather than inability to do it himself.	Frank was confident of his progress throughout. He initially self-limited because he didn't want to cause his daughter worry. He was happy to accept some change as long as his priorities were OK. He felt lucky that he had so few restrictions. Even though the fall resulting in fracture was explicable he had some fear of falling – he did not avoid doing things but described risk assessing and taking more care. This was still present at 6 months where he described adapting his approach to some tasks to minimise risk to his balance, including having a walk-in shower fitted in the bathroom.

4.7.1 Physical and functional recovery

The divergence in experiences between participants was immediately evident in the physical and functional recovery theme. The experience of pain varied between participants – most participants who reported minimal pain in the first phase did not have problems with pain at the later phases. Those who struggled with pain initially tended to continue to report some pain later. For most, pain improved, except for Clare (101) whose pain experience had deteriorated.

Four participants continued to describe a limp beyond the first phase and in the later phases were concerned about differences in their leg length (loss of length had been measured and a shoe raise provided for two participants (Clare 101, Ian 146) but was unconfirmed for two others (Jamie 110, Collum 284)). The main physical functions discussed by the participants – walking, bending, kneeling, balance, stairs and ability to carry things - all followed similar patterns across the 12 months. For example in the first six months all participants reported a gradual improvement in walking, relating either to more comfort, less reliance on walking aids, increased pace or stamina. From six to 12 months there was greater variance with three trajectories reported - one participant reporting more difficulty, while others either stayed essentially the same and some continued to feel gradual improvements.

All the participants essentially returned to their previous daily activities within the home, despite variations in the trajectory of their physical recovery. Some assistance from family continued to be relied on for infrequent heavier jobs like moving furniture. By the end of the study the two men living on their own had support with cleaning; one by choice and the other had this support prior to his injury. Most participants reported adopting alternative strategies to complete functional activities, particularly in the early months following the fracture, for example using stools during washing and dressing or in the kitchen, or pacing activities, taking frequent rests. For some these strategies were adopted long term. The strategy most frequently still reported at 12 months was the requirement for pacing and taking their time over activities such as housework or gardening.

Functional activities outside the home such as food shopping required more support. Particularly the women who had previously walked or used public transport to do their shopping independently and the man who did not return to driving became more reliant on others, normally family, to assist with their shopping. Their walking stamina and tolerance for

distances was more of an issue than when functioning within the home. Some participants had initially been taken shopping by their family but by 12 months their family had taken over the task.

4.7.2 Effect on lifestyle

The importance of access to transport was evident for all the participants and was a catalyst for their ability to return to the lifestyle and activities they had previously enjoyed. The physical limitations that prevented driving resolved (or an alternative was found, such as an automatic car) within the first three months following the fracture for the men that returned to driving. The resumption of driving was an important milestone, enabling them to regain their roles within their families and communities and to access their social networks. In some ways driving provided protection against residual physical limitations and was seen as the most important factor in promoting independence outside the home.

In comparison, the women had not driven prior to their fractures and found it more difficult to return to their previous transport solutions. Walking to the shops, to bus stops and using community transport was more reliant on regaining sufficient walking stamina, being able to carry, confidence with balance for kerbs and managing steps. The difficulties they faced attempting to visit family members and to integrate with their communities informally resulted in more social isolation compared with the men who drove. After 12 months the women remained dependent on lifts being offered but even then discomfort as a passenger in a car made some longer journeys impractical.

One aspect of lifestyle a few participants found frustrating was the loss of freedom of movement. This was a manifestation of the inability to act spontaneously, described as having to consider every activity and action before you do it, having to think before you move, or consider whether you could finish something before you start it. It was most prominent in the second phase. By the third phase, freedom of movement was not discussed as much but it was not clear whether this was because it had improved or whether they had become accustomed to it.

The ability to return to their preferred or necessary hobbies and activities, be that reading and accessing the library, walking the dog, being the house husband, their wife's 'chauffeur', active within their church community or writing their memoirs was a key factor in the participants

regaining their sense of self. Initially featuring with the phase one sub-theme 'change in role and relationships', the resumption of lifestyle and participation in activities at a personal, family, social and community level restored the participants' sense of identity. Over the 12 months this became more of their focus and seemed to be the essence of their satisfaction with their recovery and acceptance of a new normal.

4.7.3 Emotional responses to circumstances

The attitude to change varied between the participants. Some accepted and embraced the need to adapt. Others had adapted and accepted the need for these adaptations by the third phase interviews, and for some this was an unconscious and gradual process. A few participants fought the need to accept and continued to strive to return to their previous functions and lifestyle. This seemed to be influenced by age and general health, with the older participants, or those already living with deteriorating comorbidities, more accepting of their new restrictions.

Fear of falling and further injury featured throughout the three phases although it became gradually less acute and restrictive over time. For most, especially in the early phases, it focused on the circumstances of their injurious fall and therefore participants tended to avoid or to be very cautious of that situation, even after 12 months. For example, always switching on living room lights before closing the curtains or avoiding steep garden steps, even when walking confidently in public spaces.

By 12 months participants were more inclined to attribute changes to their lifestyle and physical and functional limitations on age and therefore viewed them as permanent and inevitable; whereas in the earlier phases they had discussed their restrictions more as a residual part of returning to normal after the hip fracture. It seemed as if those participants who remained in the study for 12 months came to accept their hip fracture as part of their ageing process rather than a traumatic injury, however it is unclear whether there were external influences at play to make this happen.

I think more has happened in the last year than has happened in any sort of 5-10 years before. And so I can only attribute it to the hip breakage. I don't know whether that was possible, whether it has any effect on your overall sort of state. Yeah I mean part of it is – is brought about, isn't it, by the fact that there are certain physical signs that are connected with it presumably, which affect you mentally. And so you have to sort of mix in, you have to tie the two things together slightly. [Jamie 110]

4.8 Summary

This chapter has presented the findings from the three phases of qualitative interviews for the 11 participants and a longitudinal view of the data for the eight participants who completed more than one interview. Three overarching themes have been used to demonstrate the way these participants discuss their experience of recovering from a hip fracture over a 12 month period.

Physical and functional recovery was experienced differently by all the participants, as described in the analysis of the individual phases; however the longitudinal view shows that the pattern of recovery in the six to 12 month period falls into three potential trajectories of decline, plateau or continued improvement (following general progress in the initial six months). Regaining their previous lifestyle and the ability to return to their previous hobbies and roles within the family and community was aligned with the participant's return to their sense of self and the feeling of being back to normal.

No participants reported returning to their pre-injury status. Although on the face of it some may have returned to their previous functional and social activities, they continued to report restrictions in terms of the ease and quality with which they functioned and an emotional restriction of confidence and satisfaction and increased awareness of the ageing process.

Chapter 5: Discussion

This thesis aimed to understand the patient experience of recovery following a hip fracture over the course of a year. This included an exploration of patients' priorities in their recovery and how their recovery and priorities might change at different times following injury. The following chapter states the main findings from the study. The strengths and weakness of the study and their implications for the interpretation of the results are discussed. The possible meanings and outcome from the study are discussed, situating it within the previous literature, and suggestions for potential further study are made.

5.1 Principal findings

Three main themes of 'physical and functional recovery', 'effect on lifestyle' and 'emotional responses to circumstances' were used to recount the participants' experiences of recovering from hip fracture. The experience described by these themes varied between participants and over time. The expectation of the end point of recovery was different among the participants, mediated by their prior health experiences and personal perceptions of ageing.

Longitudinally, changes in the themes were described between interview phase one and two (two to three months and six months) showing general improvements, experienced at different levels and paces between participants but present for all. From phase two to phase three (six to twelve months) three main trajectories became apparent. Deterioration was particularly highlighted by one participant (Clare, 101) whose experience demonstrated negative change from the six month interview in all themes; associated with this was great dissatisfaction with her outcomes and lack of the progress she had anticipated. Other participants had continued to experience slight improvement within the themes across the year or had plateaued, maintaining their experience of recovery from the six month interview. These trajectories are depicted on Figure 11. Levels of satisfaction with recovery varied whichever trajectory was experienced. The findings in this study reflected a change in the focus of the participants from physical and functional recovery at the earlier stages to regaining aspects of their lifestyle at the later interview phase. This shift in focus seemed part of a process of needing to 'feel themselves again' or to regain their sense of identity as an integral part of feeling satisfied with the outcome from their fracture, enabling them to feel they had recovered.

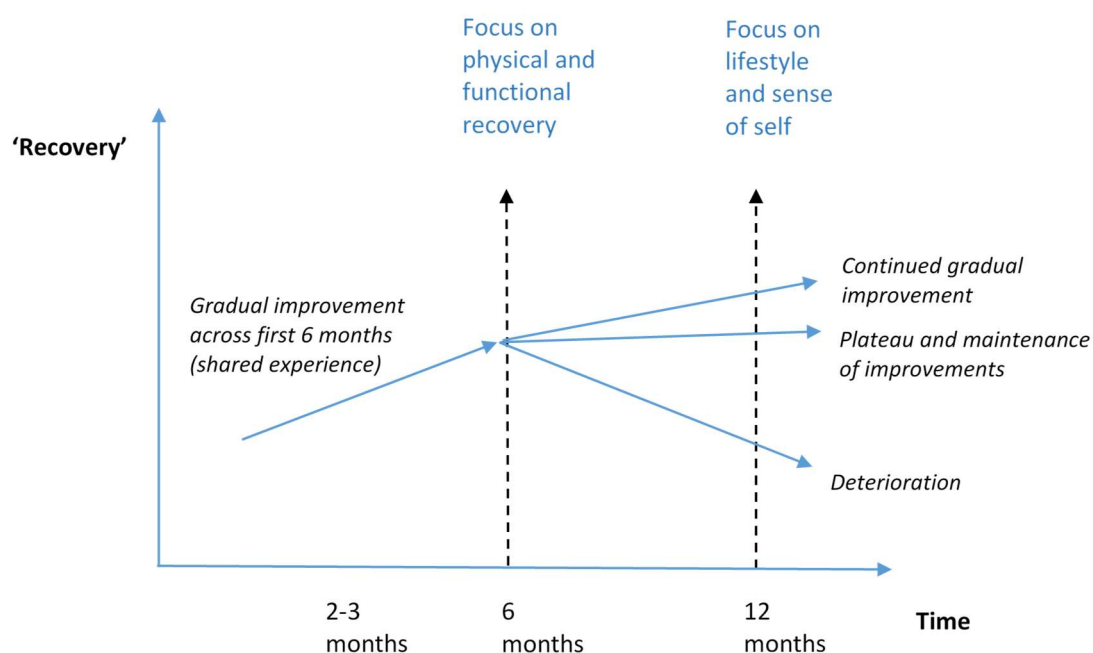


Figure 11 A temporal depiction of the trajectories of recovery described by the longitudinal qualitative analysis

Some participants strove for a complete return to their pre-fracture state and were not satisfied with anything less. However the majority of participants portrayed recovery as feeling like they were 'back to normal', however this did not have to be their full pre-fracture state. Being 'back to normal' depended on the level of satisfaction with their situation. In essence whether they had been able to accept and adapt to a 'new normal'. The experience of the three overarching themes affected the potential adaptation and acceptance which was instrumental with the recovery of their sense of self. Figure 12 illustrates these concepts where there was a positive sense of recovery from the fracture with satisfaction having achieved and accepted a 'new normal'. It is important to note that negative experience would present a lack of acceptance, adaption and difficulty rebuilding their sense of self or identity, resulting in a continued sense of having not recovered and dissatisfaction with outcomes.

As previously discussed in Chapter Four, Section 4.3 the experience of recovering from a hip fracture was individualised by the participant's specific circumstances. Medical co-morbidities, overall health and activity levels, personal perception of ageing, previous experiences of injuries and hip fracture and their home situation influenced their expectations of recovery and their approach and preparedness to accept and adapt. The 'new normal' which is

acceptable and satisfactory (and therefore sensed as 'recovered') is contextual and individual also.

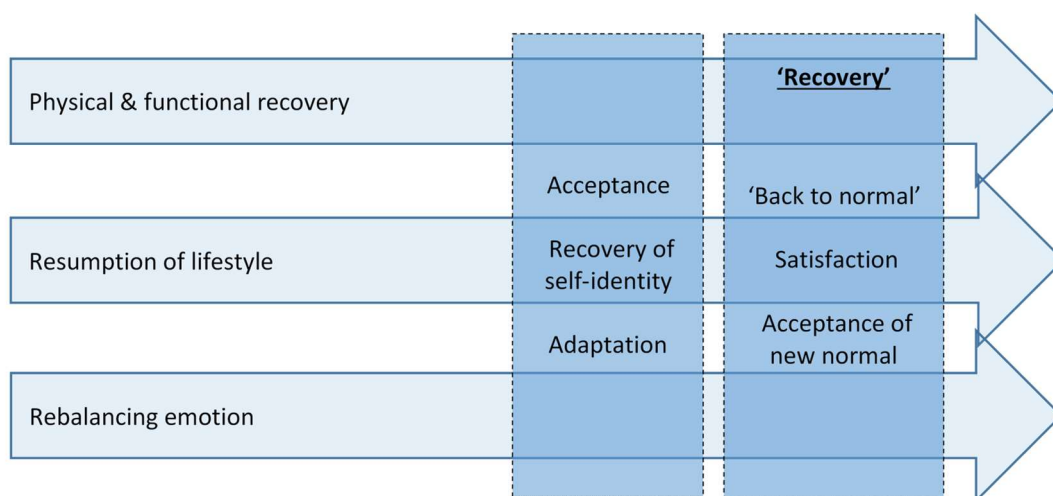


Figure 12 Conceptual illustration of recovery as accepting a 'new normal'.

5.2 Strengths and weaknesses of the study

The following sections consider the strengths and weakness of the study, focusing on the sample, the methods and study conduct. Awareness of these may affect interpretation of the findings.

5.2.1 The sample

As a realist it is important to consider how the act of sampling may impact on the potential claims that can be made from the research. This should include disclosure of the external influences beyond control of the researcher (Emmel, 2013). The sample for this study was drawn from the parent study as discussed in Chapter One, Section 1.5. This means it was restricted in a number of ways which has implications for the breadth of the hip fracture population that the experience of these participants may be transferable to. Although as a qualitative design the study does not seek to be generalisable, it is important to consider that the experience of these participants may differ from others who have a different fracture pattern or had different health needs prior to their fracture.

The parent study only recruited people who had experienced extracapsular hip fractures that were surgically repaired (Chesser et al, 2014 Appendix A) therefore the experience of these participants may differ from the other main group of hip fracture patients; those with intracapsular fractures who have either the femoral head (hemiarthroplasty) or entire hip

(total hip replacement) replaced. As discussed in Chapter One Section 1.2, Fox et al (1999) found that people with extracapsular fractures were slightly older and more likely to have four or more comorbid conditions than intracapsular fractures. They had a greater mortality rate at two and six months and were less functionally able at two months, although these differences had equalised by six months. This therefore suggests that recovery may be slower or more difficult for the extracapsular fractures, at least in the early phase, which may affect the timing of the experience related by the participants in this study. However the differences between intracapsular and extracapsular fractures having been shown to equalise by six months might support the applicability of the longer term findings of the alternative trajectories for the wider hip fracture population.

Reported in Chapter One, Section 1.5 and detailed in Appendix A the parent study also had extensive exclusion criteria due to the potential interactions of the medical intervention under investigation. This means the findings from this sample could be missing depth in understanding the effects of other medical problems. However, as listed in Chapter Four, Table 8 (page 63) only three of the 11 participants had less than four pre-existing diagnoses, suggesting the sample had a similar spread of co-morbidities when compared with those reported by Penrod et al (2008) and Fox et al (1999). Therefore the experiences of the impact of co-morbidities on the recovery from hip fracture should be comparable to the general hip fracture population. The exception to this is the experience of confusion or dementia.

Chapter One discussed the epidemiology of hip fracture and described the population that presents with hip fracture. One overwhelming feature is that a large proportion of the population with a hip fracture are living with a degree of confusion or dementia (previously diagnosed or diagnosed on admission to hospital with their fracture), or experience an acute episode of delirium associated with the circumstances around their fall and injury. The parent study and therefore this study sample did not include participants who were not able to process the information regarding the study and provide informed consent to participate. The sample therefore may relate a different experience of hip fracture compared to that experienced by those coping with confusion and dementia in their daily lives.

The participants ranged in age from 69 to 92 years which is comparable to the wider hip fracture population. 6/11 participants were male; this proportion increased to 5/7 at phase three. This is much greater than the proportion of men in the wider hip fracture population.

Depending on your epistemological standpoint this may or may not be important. All the participants were community-dwelling independently living mobile older adults prior to their fractures. All the participants returned to their own homes following the injury but they experienced a range of rehabilitation pathways including via an inpatient rehabilitation hospital, inpatient community rehabilitation centre, intermediate care team and no follow up awaiting domiciliary physiotherapy; one participant was applying to be rehoused. In hip fracture research this focus on previously independent community dwelling mobile patients is not uncommon and has been the case in other qualitative studies, for example McMillan et al (2012). An exception was the sample interviewed by Griffiths et al (2015) who came from a variety of types of residence and included those with cognitive impairment who were interviewed with their carer. The themes discussed by Griffiths et al (2015) were similar to those identified in this current study when talking about what was important to them when evaluating their recovery, but the priorities within the themes were different for people in different residential and health circumstances in their study. The similarity of the current study's findings and Griffiths et al (2015) would suggest the themes from this study may be transferable to the experience of a wider hip fracture population, particularly with the identification of a divergent case (Clare 101). However the full breadth of the potential experience within each theme may not have been explored in this study with only community-dwelling, cognitively intact participants included.

In summary, this sample could be viewed as a selective group of hip fracture patients. The implication of this on how the findings relate to the research questions and wider aims should be considered. The preceding discussion about the differences and similarities of this sample to the wider population suggests the findings of this study are sound in relation to the research questions – how recovery following hip fracture is experienced and how it changes over time. There may be implications for relating this back to the ambition to build on the existing evidence base for making decisions on outcome measures for hip fracture research. How different the experience of this study population may be in relation to the less able proportions of the hip fracture population should be considered. The participants reported individual experiences along a continuum within the overarching themes. These themes remained the same over time but their individual experience along the continuums changed. This similarity of findings with those of Griffiths et al (2015) suggests some trustworthiness of the resulting analysis, with the acknowledgement that a wider sample of the population may have identified these experiences along a wider continuum.

5.2.2 The methods

5.2.2.1 *Longitudinal design*

Longitudinal qualitative research [LQR] is ideally situated to explore the experience of recovery because following the same participants provides the opportunity to review the changes they experience during the process of recovering from the illness event. Ziden and colleagues (2010) also interviewed the same participants more than once (one month and twelve months after the fracture). They approached the two rounds of interviewing and analysis distinctly, to explore the early experience and long-term consequences of a hip fracture. This presented the outcome of the continued presence of disability and psychological distress at one year after fracture but approaching the phases distinctly limited the exploration and understanding of the change in experience over time. No other study has been identified that followed the same participant cohort longitudinally, prospectively exploring the experience of change after a hip fracture.

Longitudinal qualitative in-depth interviewing provides prolonged contact which can enhance engagement of the participant in the research process and may encourage greater disclosure (Hermanowicz, 2013). With this greater involvement there is the risk of more intrusion into people's lives (Calman, Brunton and Molassiotis, 2013). It is possible the participants who were struggling were the ones that dropped out. The possibility of this was evident reflecting on the interview with Brianna (participant 195). Brianna withdrew from the study following the first interview. During the first interview and during the telephone call a few months later when contact was made to try and arrange the second interview, she expressed anxiety about her current situation. She had successfully applied to move to a bungalow as she found the stairs in her house difficult and was arranging her house move. In addition, her daughter was unwell and she was concerned about being a burden. She withdrew, explaining that she was 'too stressed' to continue in the study. This is an example where the causes of attrition may influence the findings of the study, as loss of those experiencing the most difficulties could lead to a limited picture of the changes experienced in the recovery process and is a challenge particularly relevant in prospective LQR studies. Despite this, diverging trajectories of recovery have been described, suggesting inclusion in the study of those who did not find recovery an easy process.

5.2.2.2 *Timing of interviews*

Considering the period of most rapid physical and functional recovery has been shown to occur in the first six months following surgery (Magaziner et al, 2000), it is possible the timing of the first interview missed a period of important change. An earlier interview, within days of surgery could have explored the aims and expectations of the participants at the start of their recovery. At the time of the first interviews, two to three months following surgery, there had often been significant progress in the few weeks just before the interview, since returning home. It is difficult to judge whether greater insight would have been gained from an earlier interview during these advances or whether interviewing when it was in the recent past facilitated the participant's ability to reflect on recent progress (for example on moving back upstairs or just starting to drive again). The timing of this first interview after discharge from hospital provided the participant with a frame of reference in time to aid reflection, was appropriate to the study aims of exploring the change in experience over time, and had practical advantages in relation to the parent study. Ethically it avoided overloading the participants in the acute phase of their recovery.

5.2.2.3 *Challenges in conducting interviews*

All participants chose to be interviewed in their own homes. There were many benefits to this, placing less demand on their mobility at a time when many found it difficult to get out of the house, and provided practicalities such as comfortable chairs, access to walking aids and reading glasses. Interviewing in someone's own home meant that family members were sometimes present at the time of the interview which presented some challenges. Particularly when interviewing one of the men whose wife was present throughout all the interviews (Jack 349) there was the impression he made light of or avoided discussing the emotional impact of the fracture and he brushed off attempts to prompt or expand on the comments he did make. The presence and inclusion of his wife though the interviews also presented practical difficulties using quotes to illustrate the points they discussed as there was not consent in place to quote her. Had the experience reported by this couple been particularly individual further ethics approval could have been sought and she could have been asked to provide her consent. This could be built into the design for a future study. The decision was made that this was not necessary in this current study as sufficient quotes were available to illustrate the findings.

A potential ethical challenge to the increased rapport built up across an LQR study is the risk of disclosure of personal and distressing information that the researcher is not in a situation to assist with (Calman, Brunton and Molassiotis, 2013). One such occasion arose during this study with Clare (participant 101) during her phase three interview (quote in Chapter Four Findings, Section 4.6.1.2 page 97) whilst discussing her struggle with her pain experience. The quote suggested that Clare was expressing suicidal thoughts in response to her pain. With greater context of the conversation before and after this quote, with the benefit of rapport and familiarity with the language and speech patterns of this participant, I was aware that this comment was intended as emphasis rather than as an indicator of suicidal intention. This participant was known to have a history of mental health problems and was in frequent contact with her Community Psychiatric Nurse (CPN). Therefore, before leaving the participant that day, I was confident that Clare was in contact with her CPN and that her son was going to be visiting her that evening.

5.2.2.4 Rigour

A number of methodological decisions were employed in this study with the aim to increase rigour and were variably successful. Over-sampling in the first phase of a LQR study is necessary when factoring in likely attrition rates (Hermanowicz, 2013). As discussed in Chapter Three (Section 3.3.1) this study aimed for data saturation rather than theoretical saturation. It took 18 months to recruit 11 participants due to the difficulties running the parent study. The original intention to transcribe and code each interview before conducting the next was not possible due to other commitments, even with these extended timeframes. Although this meant it was not possible to conduct iteration between a formal code list and ongoing data collection, I re-listened to the previous interview before a further interview with the same participant. This ensured the previous topics of discussion were recalled and established any areas where further elucidation of an emerging pattern within the interviews may have been relevant to discuss further. During the analysis process a log of code creation was maintained which demonstrated very few new codes being created in the last three interviews of each phase and in the whole of phase three, suggesting a high level of data saturation.

Second coding a portion of the data set also added to the rigour of the study design. Gaining an additional insight and view of the data can give fresh eyes to the interpretation (Barbour, 2008). In this study, although a different style of coding was observed between the researchers, the essence of the coding and experiences seen in the data was the same. Some

limitations of a second coder who was not part of the study team became apparent. The process of coding and the discussion of the outcome of the coding was extremely time-consuming, therefore further second coding was not an option. The second coder found the process extremely frustrating as she felt she did not know the project well enough to code effectively, even with discussion and a written summary of the study background and aims. The presence at the interview and rapport developed with the participants gave an understanding and interpretation of their words through familiarity with intonation, conversational style, and displays of emotion and body language which cannot be perceived through the text of a transcript, even detailed conversational analysis transcripts. This meant that at times the discussion of any differences between my coding and the second coder returned to my interpretation. Second coding by a researcher more involved in the project could have improved the time-efficiency and effectiveness of the process.

5.2.2.5 Interviewer

As discussed in Chapter Three (Section 3.3.6) open consideration and disclosure of personal sources of bias is the first defence against it. My background experience and training as a health professional will have influenced the approach to this study. A number of situations and systems have reduced the effects of this. Recent employment in clinical research rather than clinical rehabilitation meant that, during the design of the study, data collection and the majority of the analysis, I was one step removed from the day to day role of the physiotherapist. This separation from supporting patients to regain their physical function following a hip fracture assisted the recognition of the risk of, and therefore the opportunity to guard against, a narrow physically-orientated lens being applied to the study. The inclusion of some secondary coding from a non-medical social scientist acted as a further check for this influence. Clinical knowledge-base and experience may have been beneficial, as suggested by Griffiths et al (2015), as it may have provided opportunity to unpick the impact of the fracture and the influence of co-morbidities on the experiences reported.

5.3 Possible outcomes and implications

5.3.1 Sequence of recovery

Longitudinal recovery measured quantitatively by Magaziner et al (2000) showed that affective function (depression) and cognition were the first limitations to recover after a hip fracture, plateauing around four months after the fracture. Measurements of balance and gait recovered most rapidly in the first six months with slight improvements continuing after six

months but they plateaued before social function, instrumental ADLs (getting to places out of walking distance, using a telephone, grocery shopping, preparing meals, housecleaning) and lower limb extremity ADLs. These final three functions continued to improve up to one year, with instrumental ADLs continuing to improve beyond 18 months. A similar representation of plateauing is seen in the longitudinal qualitative data in the present study. Although the majority of recovery in social functioning and ADLs had largely reached their potential at the six month interview there were some continued improvements in physical sub-themes such as stamina and activities that depended on lower limb function (for example gardening) beyond six months.

Emotional or affective recovery was one of the earliest areas of function to resolve in the study by Magaziner et al (2000). Similarly, the current qualitative findings saw an initial improvement between interview phases one and two (two-three months and six months) particularly in frustration, low mood and depression. However there were two aspects of affective or emotional recovery which deviated from the sequence presented by Magaziner et al (2000). First is the finding of low level anxiety affecting participants' approaches to and confidence in tasks, with an inability to forget the fracture and trust the leg which was still apparent at 12 months. These insidious concerns were expressed by participants when asked to reflect why they continued to feel activities were not as 'automatic' or 'spontaneous' as before the fracture. It is not known whether these feelings would be identified by a score for depression such as the C-DES depression scale used by Magaziner et al (2000) or on a generic quality of life score such as the EQ-5D (either through the anxiety/depression question or the VAS for perceived health state) and yet these concerns have an impact on the participants' perceptions of their recovery. The second deviation is exemplified by Clare, participant 101, as a divergent case, where although some improvement from depression was noted at 6 months it had returned at 12 months, associated with the deterioration of her symptoms and her recovery process not meeting with her original expectations.

5.3.2 Recovery is more than regaining physical function and activities of daily living

In common with other studies the impact of a hip fracture reported went beyond the experience of physical symptoms, need for support in activities of daily living and limitations in mobility. Ziden and colleagues (2008) reported changes in the participants' relationships with others. In the current study increased dependency, especially in the early phase, was felt to

have caused changes to relationships within couples. Over the course of the year this was less of an issue as physical independence improved, but also as the context of health and ageing together continually affected the balance of roles within the couple. Relationships with others were also affected. Participants reported feeling that others' perceptions of them had changed, for example Dougal (270) feeling his son was trying to take over as 'head of the family'. The impression of others' perceptions about them influenced their sense of self and identity. Changes in relation to life situation, encompassing isolation, reduced and restricted social contact and increased caution as reported by Ziden and colleagues (2010) were also similar to the experiences related in this study by the 'effect on lifestyle' theme.

Transport, particularly driving (or ability to sit in a car) was a pivotal factor in restoring social life or lifestyle. Those who did not drive before (the women) or were now not able to drive (some of the men) required stronger support networks to regain aspects of their social life. Regaining their previous lifestyle was aligned with the participant's return of their sense of self. The ability to return to their previous hobbies, roles within the family and community restored their sense of identity. For the men with wives who did not drive there was a sense of their role within the relationship as the driver and therefore the return to driving had an additional importance in the restoration of their self-identity. This sense of identity (similar to the sense of well-being in Robinson, 1999) was a key factor in the acceptance of a new normal and therefore satisfaction with their recovery.

An important finding of this study, in common with the other qualitative studies discussed in Chapter Two, is that no participants reported they had returned to their pre-fracture status, even in this selective cohort from the hip fracture population. On a practical or functional level it could appear that some did. Five returned to walking without an aid after twelve months. A simple measurement instrument may ask if the patient is able to walk outdoors and whether they can walk without an aid. These participants would therefore be rated as having achieved the full outcome. However the qualitative data does not describe recovery as a return to their previous mobility level. The participants described lack of pace, increased effort, decreased confidence and a lack of spontaneity with their mobility. The whole process required more physical and cognitive effort than prior to the fracture. In this study the participants also communicated the concept of not being able to forget about their fracture, not being able to let go and get on, and described carrying out an internal risk assessment ahead of tasks which corresponded with the concept of "protective guarding" in the balancing of risk described by

McMillan et al (2014, 2012). As found by Paterson (2004) the tick box system rating ability to undertake tasks using 'no problems', 'some problems' or 'unable' as available in the EQ-5D-3L is unlikely to be sensitive to this repercussion from the fracture on the psychological effort involved in a physical function. It might be captured as anxiety or depression, for example question five of the EQ-5D [. However, as the participants did not consciously discuss the feelings in that way and only reflected it on further probing, self-report on such simple discrete responses is unlikely. It would possibly be reflected in a continuous scale such as the VAS for perceived health state, page three of the EQ-5D .

Other studies report fear of falling following hip fracture (Griffiths et al, 2015; Haywood et al, 2013), sometimes as a sub-theme within a wider concept for example balancing risk (McMillan, 2014), or being more insecure and afraid (Ziden et al, 2010). In this study generally the fear of falling was more focused on the circumstances or activity at the time of the injurious fall (even in others who had fallen before). McMillan et al (2014) focused their discussion on balancing risk of falling and further injury against the importance of independence and making own decisions within the wider aim to regain control. The idea of balancing risk against independent function was also present in this current study but it was a wider concept including risk of pain as well as falling and further damage and depended on the priority given to the activity. For example the risk of pain from driving was worth the risk, but the risk of falling from a step ladder whilst changing a light bulb was not. The balance of pain versus activity also encompassed embracing adaptive techniques and pacing. For example Clare (101) fought to remain independent in ADLs at twelve months through increased use of adaptive techniques and pacing despite the deterioration in her pain. Ian (146) reluctantly limited the duration of his dog walks in recognition of managing his pain levels through the day. Managing this balancing act was part of the process of taking control in McMillan et al (2012) and is a necessary step in gaining confidence in the recovery process. Balancing risk and appropriate levels of caution regarding activity limitation with respect to risk has a potentially complicated effect on evaluating rehabilitation interventions and could confound outcomes.

5.3.3 Meaning of recovery

The experience of repetitive strain injury in Beaton et al (2001) (discussed in Chapter Two Section 2.1.1) identified codes of symptoms, functional limitations, emotional and social limitations, and role limitations which are reflected in the three main themes in this study. The

three states of perceived recovery - resolution, readjustment or redefinition suggested by Beaton et al (2001) are represented in the longitudinal view of the data in this study. Resolution as a construction of being better in Beaton et al (2001) was described by either a magnitude of change, for example in symptoms or functional ability, or by achieving a threshold, for example return to a valued activity which enabled the participants to see themselves as 'better' or 'recovered'. The concept of magnitude of change may not have been observed in this study, however acceptable thresholds were evident. A threshold could be achieving a certain level of independence in day to day life (Gillian 239) or ability to return to a core activity, for example driving (Dougal 270), the ability to care for a spouse (Collum 284), or social participation (Jack 349) and may be integral to the idea of regaining self-identity as part of viewing oneself as 'recovered'.

There is a more subtle difference between the other states of recovery in Beaton et al (2001) which are not as clearly observed in the findings of the present study. 'Readjustment' is the adjustment to life to work around the disorder and 'redefinition' is adapting to living with the disorder. The eldest participant (Jamie 110) described elements of readjustment and redefinition. Beaton's term 'resolution' infers acceptance of the threshold reached as satisfactory. Jamie did not appear satisfied with his outcome but by 12 months he was more accepting of it. He had changed his routines and support systems to enable him to function at home which were both readjustments and redefinitions. This aligns with the concept of adaptations as part of the process towards a new normal suggested in Figure 12. However in the case of Jamie, perhaps a limitation to the extent he regained his self-identity and accepted the changes in his situation made it difficult for him to be satisfied and perceive himself as having recovered (although he did appear to have accepted his new normal).

Beaton et al (2001) discussed that the state of recovery was influenced by factors such as coping styles, comparators and the perceived legitimacy of the disorder. The impact of the fracture on the sense of self, entwined with perceptions of age and health on the experience of recovery reported in this and other studies (Griffiths et al, 2015; Brett, Tutton and Staniszewska, 2013; McMillan et al, 2012, Ziden, Schermann and Wenestam, 2010) presents an interesting comparison with Beaton's concept of 'perceived legitimacy'. Following hip fracture the participants in this study and Griffiths et al (2015) discussed their recovery bound up with the process of ageing and within the wider circumstances of their general health and existing co-morbidities. The perception of self or construct of their self-identity was also influenced by

and encompassed their perception of their health and age. It appears that if the impact of the hip fracture was 'legitimate' within the individual's perception of their age and health then the consequent disability and limitations may have been more acceptable. This may mean that in Beaton's terms 'resolution' is an easier state to reach with lower 'thresholds', or as depicted by Figure 12 may have assisted them to be satisfied with and accept a 'new normal'. Those that did not perceive themselves as 'old' or having any limitations due to a pre-existing co-morbidity may have continued to hold high expectations of recovery and therefore struggled more to reach 'resolution' or their 'new normal'. For example Clare (101) and Ian (146) were two of the younger participants in this study with no significant limitations on their physical participation and social activities prior to the fracture (although both had significant pre-existing conditions). Both participants continued to look for resolution of the impact of their fracture at 12 months, for example being able to wear high heels or have unlimited stamina for walking the dog, when other participants had accepted restrictions and made adaptations or adjusted their lifestyles and expectations.

"Cause I don't want to be like this, I I really want to be normal, wear my high heels and (laughs) you know, but it is an horrible injury it really is" [Clare 101]

The differences in the disorder and population involved may explain why there is reduced evidence of readjustment in the present study when compared with Beaton et al (2001). The younger working population with repetitive strain injury in Beaton et al (2001) presents a different type and circumstances of an illness event, which has been shown to be relevant in the recovery trajectory experienced in older patients by Godfrey and Townsend (2008). Godfrey and Townsend (2008) identified four types of recovery trajectory in their grounded theory study of older adults receiving intermediate care. The illness event leading to the need for intermediate care varied including hip fracture, elective orthopaedic surgical procedures, stroke, cardiac events and exacerbations of long-term conditions. Of the four types of recovery identified ('cure and restoration', 'adjusting to discontinuity and establishing markers of continuity', 'getting back and keeping going', and 'managing uncertainty'), they reported hip fractures as either following 'cure and restoration' or 'getting back and keeping going'. Cure and restoration has similarities to 'restoration' in Beaton et al (2001) although, because Godfrey and Townsend focused on older adults, age is contextual throughout and the alternative types or meanings of recovery are different. The experience of this recovery was typified by a 'younger' older adult, previously active who had an illness crisis. These

participants expected a return to an active lifestyle from the outset and experienced a generally upward process, with mobility tempered by pain. 'Getting back and keeping going' in comparison referred to those of advanced old age with multiple health problems who had an illness crisis such as a fall or fracture or who were gradually deteriorating. This group was more likely to be restricted before the crisis and their recovery aims focused on returning home. They were experiencing an ongoing process of adjustment to age, illness and disability and tried to sustain their sense of self through adjustments to their situations. The views of recovery in Godfrey and Townsend (2008), coming from a study of older adults, have a strong resonance with the versions of recovery evident in this current study. The experiences of Ian (146) and Jamie (110) who were difficult to place in the types of recovery in Beaton et al (2001) fit with these two types of recovery ('cure and restoration' and 'getting back and keeping going').

'Managing uncertainty' pertained to older adults with long-term illness or disabilities whose experiences of recovering from acute exacerbations were not related to the recovery from a crisis such as a hip fracture. The remaining type of recovery identified by Godfrey and Townsend (2008) was 'adjusting to discontinuity and establishing markers of continuity'. This was presented as the recovery experienced following a life-threatening illness (for example a brain tumor or cancer) or the start of a chronic illness (for example stroke). Hip fracture recovery was not perceived to take this trajectory which included the phases 'early days coming to terms with loss', 'accommodation' (reappraisal of selves as 'old') and 'provisional normality'. However these phases and the description of the experience as a disruption of self-image and previous lifestyle (biographical disruption) certainly depicts some of the longitudinal experiences reported in this MPhil study.

5.3.4 Measuring recovery

Ziden and colleagues (2010, 2008) argued that hip fracture has an impact on psychological and social health as well as bone and therefore multidisciplinary healthcare should also include this in rehabilitation. If healthcare acknowledges the emotional, psychological and social impact of the fracture demonstrated by this MPhil study, Ziden and colleagues (2010, 2008) and others and endeavours to support the recovery of this with its care provision (whether directly or indirectly), then evaluation strategies should also seek to be in a position to measure the impact of the care provided. Whether this is pertinent for inclusion in a core outcome set or

whether it should be acknowledged and included for evaluation when relevant to the research question can be debated. The acceptance of these as important outcome domains to measure may depend on the philosophical standpoint of the individual researcher. The complexity of the perception of recovery presented in this MPhil study challenges the effort to measure domains representing the patient view of 'recovery' in a succinct core outcome set. The change in focus or priority through time, balancing risk, caution and levels of conscious effort during physical function, the differing individualised requirements to regain the sense of self (entwined with their personal perception of age and health) and the variance in thresholds for acceptance of a new normal are examples of the emotional and psychological complexity which are difficult to grasp with defined outcome domains. However, acknowledging the drive towards improving outcome measurement in trials and reducing potential for bias and heterogeneity in reporting, the case for developing core outcome sets stands. The primary aim for a 'core' set with trials including additional outcomes relevant to the research question as required remains an important distinction. Development of core outcome sets should continue to aspire to include the outcomes important to patients (and carers) alongside other stakeholders though further work is required to consider options for encompassing some of the complexity of the patient experience of recovery.

To identify whether the current measurement tool recommended by Haywood et al (2014) as the basis for a core outcome set for hip fractures, the EQ-5D-3L, does capture the themes described by the participants as important in their recovery, a comparison was undertaken. An overview of the themes identified through all phases of this study was mapped to health domains using the terminology of the two-level classification from the ICF (WHO, 2001) and to the dimensions covered in the EQ-5D and is presented in Table 10.

Table 10 Themes mapped to health domains (ICF two-level classification) and EQ-5D

Theme	Sub themes	Health domain (ICF two-level)	EQ-5D dimension
Physical and functional recovery	Physical symptoms and limitations	X ¹	X
	• Pain	Sensation of pain b280 ²	Pain/discomfort
	• Stiffness and swelling	Mobility of joint b710	X
	• Balance	Involuntary movement reaction functions b755	X
	• Limp	Gait pattern functions b770	X
	• Stamina	Muscle endurance functions b740	X
	• Sleep	Sleep functions b134	X
	• Walking	Walking d450 ² ,	Mobility
		Moving around in different locations d460 ²	Mobility
		Moving around using equipment d465	Mobility
	• Standing	Maintaining a body position d415	X
	• Bending / kneeling	Changing basic body position d410 ²	X
	• Stairs	Moving around d450	X
	• Tiring	Exercise tolerance function b455	X
	Environment	Physical geography e210, climate e225	X
	• Equipment	Products and technology per personal use in daily living e115, indoor and outdoor mobility and transportation e120	X
	Functional activities	X ¹	Self-care / usual activities
	• Activities of daily living	Lifting and carrying objects d430	Self-care / usual activities
		Washing, dressing and toileting oneself d510, d520, d530, d540 ²	Self-care
		Acquisition of goods and services (shopping) d620	Usual activities
		Household tasks (preparing meals d630, doing housework d640, caring for household objects d650)	Usual activities
	• Social support / need help	Support from immediate family e310, extended family e315, friends e320, neighbours e325, personal care providers e340	X
	• Coping strategies	?Higher-level cognitive functions b1640	X
	• Alternative strategies	X	X
	Take it steady	X	X

Theme	Sub themes	Health domain (ICF two-level)	EQ-5D dimension
Effect on lifestyle	Getting out of the house	Moving around in different locations d920 ²	?Usual activities
	• Informal social interactions	Informal social relationships d750 ³	?Usual activities
	• Transport	Using transportation d470, driving d475	X
	• Visiting family and friends	Moving around in different locations d460 ²	Usual activities
	• Being part of society	Community life d910	?Usual activities
	• Hobbies	Recreation and leisure d920	Usual activities
	Change in role and relationships	X	X
	• Family relationships	Family relationships d760	X
	• Change in role	X	?Usual activities
	• Looking after others	Assisting others d660	?Usual activities
	Want to be back to normal	X	VAS
	• Spontaneity	X ⁵	X
	• Independence	X	X
	• Ability to forget	X	X
Emotional response ⁴	Prisoner	X	?Anxiety / depression
	Burden	X	?Anxiety / depression
	Mood change	X	Anxiety / depression
	• Frustration and boredom	X	X
	• Building confidence	X	X
	Fear of falling and doing further damage	X	?Anxiety /depression
	Unable to forget	X	?VAS
	Want to be back to normal	X	?VAS
	• Perseverance	X	X
	• Is it part of a permanent decline?	X	X
	• Don't want to be like this	X	X
	Acceptance	?Higher-level cognitive functions b1640	X

Notes:

¹ The main sub-themes of physical symptoms and activities and functional activities are too broad to be classified by the ICF which is more suited to the various 3rd level themes.

² The domains of pain, walking, washing oneself, dressing, changing basic body position and moving around in different locations as proposed as the core outcome domains by Haywood et al (2014) are highlighted.

³ A code such as 'Informal social relationships d750' is given but is not an ideal fit. The third level theme relates the opportunity to have informal social interactions, whereas the ICF code d750 relates to the ability to create informal social relationships.

⁴ The experience of emotions and attitudes that were reported such as perseverance, feeling a burden and confidence would be 'personal factors' in the ICF and are not currently classified. There is a code 'Emotional functions b152' which relates to experiencing emotions as a function rather than the feeling, interpretation and changing of emotions and therefore does not describe the experience related by the participants.

⁵ The concept of time or effort to complete a task in the ICF would be coded with a qualifier (for example no, mild, moderate, severe or complete limitation or difficulty) therefore there is no code or category to an experience like the loss of spontaneity.

Method:

ICF linking rules from Cieza et al (2005) were consulted in the approach to this mapping process. These rules were created for the purpose of linking to outcome measures and with interventions at detailed 3 level categories. The general process outlined by Cieza et al (2005) was followed to link or map to the qualitative themes but at the two-level classification as successfully undertaken by Bagraith, Hayes and Strong (2013) mapping to patient generated goals in lower back pain. The use of an 'X' identifies a domain which is not coded at this two-level classification. A '?' has been used to indicate where there is potential to map a domain but it is not immediately clear at this two-level classification and further clarification and exploration would be required to confidently confirm a link. There has not been an attempt to identify between the 'pf' patient factors and 'nc' not covered as suggested in the ICF linking rules (Cieza et al, 2005).

As illustrated by Table 10, both the ICF classification and the EQ-5D have insufficient conceptual detail to capture the complex experience of hip fracture presented by the themes from this study. The core outcome set proposed by Haywood et al (2014), as discussed in Chapter Two Section 2.1.3, included the domains of sensations of pain, walking, washing oneself, dressing, changing basic body position and moving around in different locations (highlighted on Table 10). Re-grouped as pain, ADLs and mobility these domains were supplemented with mortality and QoL with the suggestion they should be measured by the EQ-5D, mortality and indoor and outdoor walking status. The mapping presented in Table 10 demonstrates that the EQ-5D maps well onto the domains suggested for the core set. However it also illustrates the diverse experience of recovery from hip fracture not included in this set of outcome domains. It is possible that the themes of social and emotional recovery (for example regaining valued lifestyle activities in pursuit of 'being normal', confidence, and ability to forget) are accessed by the EQ-5D VAS but this would benefit from being verified by further investigation.

Current practice and guidelines for measurement of recovery (including the hip fracture core set proposed by Haywood et al, 2014) conceptually consider all outcome domains as equally important when measured longitudinally in prospective evaluations. There should be consideration of how the change in focus or priority over time identified in this study could be interpreted with regard to sequential outcome measurement and the duration for which outcome measurement is continued. The current recommended core set does not include a recommendation for timing of outcome assessment. An observational study by Griffin et al (2015) reported minimal recovery in health related QoL measured by the EQ-5D and walking ability extending beyond four months after fracture which could be construed as indicating that measurement of outcomes beyond four months is not necessary. At this time point however, many facets of the recovery experience reported in this study had not stabilised. The potential importance of this is emphasised by the different meaning of recovery for individuals, as discussed in Section 5.3.3, the variety in recovery trajectories experienced beyond six months and the shift in focus in the participants view of their recovery as discussed in section 5.1 and is highlighted by the breadth of health domains identified which are not represented in the EQ-5D (Table 10). This suggests that there may be continued change in experience in the recovery from hip fracture which may be useful in the evaluation of care but is not measured by the EQ-5D.

Beaton et al (2001) suggested that evaluating treatment and measuring recovery should be managed with measurement tools where the patients specify the items to be measured, for example using goals such as the Measure Yourself Medical Outcomes Profile [MYMOP] (Paterson, 1996), Canadian Outcome Performance Measure [COPM] (Law et al, 2005) or Goal Attainment Scaling [GAS] (Turner-Stokes, 2009). They felt that only this way can the complexity of the variation and meaning in how recovery is experienced be encompassed. Godfrey and Townsend (2008) suggested that outcomes of intermediate care should be evaluated by how far towards a patient's goals they have come because the needs and circumstances of the patients are so varied. These concepts are highly relevant to the heterogeneous hip fracture population. Both these studies were making recommendations pertaining to the measurement of outcomes and evaluation in clinical care. Individualised outcome measurement tools have previously been successfully incorporated in rehabilitation trials in other older adult populations (COPM; Sturkenboom et al 2014, MYMOP; Wylde et al, 2012, GAS; Rockwood et al, 2003). Whether they would be accepted in the hip fracture research setting is unclear, particularly during the current drive for core outcome sets to give comparable outcomes across trials. However the inclusion of such individualised tools as supplementary to the current core set may be beneficial in capturing a broader evaluation of recovery.

5.3.5 Summary

Recovery from hip fracture was described as a sequence of experience in core areas of physical, functional, social, emotional and psychological health following the initial injury. For the majority this sequence was progressive, with adaptations as required, supporting the return of the sense of self. This was achieved through resumption of valued activities and lifestyle to an individual threshold at which point a patient could accept and be satisfied with a new normal. This occurred within an individual's context and perception of their age and wider health. Where an individual's experience of recovering from their hip fracture did not progress to a situation which enabled them to 'feel themselves' again to a satisfactory level, they continued to seek further recovery, and in some cases further support from healthcare professionals.

The complex experience and interpretation of what recovery means and how it is represented across the large spectrum of health states within the hip fracture population presents a challenge in how to measure the aspects of recovery important to the patients. Adopting a health related quality of life score such as the EQ-5D may overcome the variations and

complexity by focusing on the key domains of pain, ADLs, mobility and the overarching concept of quality of life (Fernandez, Aquilina and Costa, 2016) but the detail of the experience of hip fracture against which patients may judge their recovery may be missed. Sanderson et al, (2010b) managed to create a patient core set of domains that encompassed the breadth of rheumatoid arthritis with mild and advanced disease, recent diagnosis and long term treatment, which would suggest a more detailed core set could be developed to encompass the recovery experience across the variety of the hip fracture population. However there is some suggestion that inclusion of individualised measurement tools may be the alternative (Godfrey and Townsend, 2008; Beaton et al, 2001; Carr and Higginson, 2001).

5.4 Implications for rehabilitation

Management of expectations

As no participants returned to their previous state even in this selective group, it may be beneficial for clinicians to temper patients' expectations to help them be more realistic at the outset and therefore increase their chances of achieving a recovery of an acceptable new normal. However this could have a negative effect on the mind-set for rehabilitation. Further discussion on this point is not in the scope of this study and would need further investigation.

Pain

Those participants with more pain initially continued to be the participants with the greatest pain experience throughout the longitudinal analysis and in some cases continued to seek further intervention from health professionals at 12 months. There are multiple potential mechanisms which could be responsible for their pain experience. Pain may be explained by failure of fracture fixation however the need for revision surgery is reported in a only small proportion of the population (3.8 – 5.5% in extracapsular fractures depending on type of fixation; NICE, 2011) and yet pain after 12 months continued to be reported by 59% patients in a review of the Norwegian hip fracture register (Gjertsen et al, 2016). Alternative mechanisms for the pain experienced and whether early identification of those more likely to have continued limitations due to their pain should be considered to provide the opportunity for targeted interventions.

Psychological support

The multidisciplinary care package needs to include psychological support to encourage the patient to move on from the injury. Participants reported continued risk assessment, looking to balance achievement and independence with self-limiting against risk. This carries associated risks of reducing physical activity or lead to maladaptive changes recognised within the falls literature (WHO, 2007). Psychological support could also address fear of returning to location or mechanism of injury. This is beyond the scope of this study but further discussion would be interesting for consideration in a longer term rehabilitation package.

Limp / leg length

Leg length and limp was a significant limiting symptom for almost half the participants at twelve months. Lack of formal follow up in Orthopaedics relies on patients discussing it sufficiently with their GP, which may become overshadowed in the midst of other health problems. Healthcare professionals should remain aware and open to the identification of options for managing leg length discrepancy to promote the beneficial impact of interventions such as built-up shoes on quality of life.

Evaluations in clinical care

The experience of recovery reported in this study identifies domains against which the participants judged their recovery. The domains (as illustrated linked to the ICF in Table 10) may be useful to guide the choice of measure for use in evaluating clinical care. Alternatively individualised outcome measurement strategies (such as Goal attainment Scaling, COPM or MYMOP) may be useful due to the diversity of the patient group and their complex contextual versions of recovery.

5.5 Future research

Further mapping of the themes produced from this study to a higher level classification of domains than currently presented in Table 10 may facilitate comparison to additional measures and would provide further critique of the EQ-5D as the basis for a hip fracture core outcome set. Findings from this MPhil study suggested that the domains mortality, pain, ADLs, mobility and QoL (the current recommended core set by Haywood et al, 2014 in agreement with the international consensus by Liem et al, 2013) may oversimplify the experience and recovery following a hip fracture from a patient perspective, at least over a longer duration

and for the previously active and independent patients with high expectations and potential for recovery. Additional mapping akin to those undertaken for various ICF core sets (Grill et al, 2005; Scheuringer et al, 2005) might clarify the potential to identify a more detailed core measurement set.

Further quantitative data collected during the execution of the parent study included prospective outcome scores for the EQ-5D, the SF36 (Ware and Sherbourne, 1992) and the Short Physical Performance Battery [SPPB] (Guralnik et al, 1994). A future study comparing the longitudinal qualitative thematic experience related by the participants against their outcome scores would give an opportunity to explore whether the same longitudinal recovery trajectory is demonstrated by the quantitative data. This could provide interesting evidence for the content validity and sensitivity to change of these scores and provide further insight into the role of evaluation beyond the current apparent recommendation of four months.

Acknowledging the selective proportion of the hip fracture population represented in this study, further longitudinal studies of the experience of recovery in patients with intracapsular fractures, patients who are less able, more dependent, care home dwelling and with lower cognitive function would be beneficial. This would establish whether the trajectories of change over time found in this study are representative of the wider hip fracture population. Adaptations to the methodology such as carer/patient dyad interviews (as used by Griffiths et al, 2014) performed longitudinally or longitudinal ethnographic observations may be required to gain understanding of the recovery of those with impaired cognitive function.

5.6 Conclusion

This study has explored patients' experiences of a hip fracture longitudinally over the course of one year. The findings show that a hip fracture impacts all aspects of a person's life. Recovery from a hip fracture is experienced physically, functionally, socially, emotionally and psychologically, described through three main themes of 'physical and functional recovery', 'effect on lifestyle' and 'emotional response to circumstances'. The longitudinal insights from this study suggested that there is a sequential experience in recovery. Early focus on progress with physical and functional recovery stimulated recovery from the biographical disruption caused by the impact of the fracture. Later this focus shifted to resumption of important aspects of lifestyle and emotional acceptance of the injury at the individual's threshold (in the

wider context of their perceived health and age) which supported the regain of control and perception of self, facilitating the sense of return to a 'new normal'.

The breadth of situation and complexity of health conditions involved for the spectrum of hip fracture patients means the development of a single PROM for hip fractures is unlikely. The core domains represented by the main themes from this MPhil study and others are partially reflected by the domains included in the EQ-5D (a generic quality of life score) and therefore support its use as the primary score in a hip fracture core set. However evaluating with only the EQ-5D may oversimplify the patient's experience of and priorities in recovery following a hip fracture. The present study suggests additional domains that should be considered when choosing outcomes for research questions aimed at promoting recovery; for example some rehabilitation studies, surgical trials or when evaluating multi-disciplinary rehabilitation processes.

The current study presents findings which return to the debate that outcomes over a time frame greater than four months may be relevant to establish the extent of recovery of self, satisfaction with outcome and achievement and acceptance of a 'new normal', within a patient's individual perception of their health and age. This may be particularly relevant in the evaluation of psychological recovery in the patient groups who were more active and independent prior to their fracture. The potential for developing a more detailed core set or adopting a personalised approach to outcome measures as is more common in clinical care, for example the use of Goal Attainment Scaling or MYMOP in evaluation research should be considered.

Words: 51 956

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Appendix A: Parent study protocol publication

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Protocol

BMJ Open The administration of intermittent parathyroid hormone affects functional recovery from pertrochanteric fractured neck of femur: a protocol for a prospective mixed method pilot study with randomisation of treatment allocation and blinded assessment (FRACCTT)

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ABSTRACT

Introduction: Pertrochanteric hip fractures occur in an elderly population and cause considerable morbidity and loss of functional ability as the fracture heals. Recently, parathyroid hormone (PTH), which is licensed for the treatment of osteoporosis, has been shown to potentially accelerate bone healing in animal and human studies. If its administration could allow a faster functional recovery after pertrochanteric hip fracture, then a patient's hospital stay may be reduced and rehabilitation could be potentially accelerated. PTH can currently only be administered by subcutaneous injection. The acceptability of this intervention is unknown in this elderly population. The aim of this pilot study is to inform the design of a future powered study comparing the functional recovery after pertrochanteric hip fracture in patients undergoing standard care versus those who undergo administration of subcutaneous injection of PTH.

Methods and analysis: The study is an open label, prospective, randomised, comparative pilot study with blinded outcomes assessment to establish feasibility of the trial design. Patients will be randomised to receive a 6-week course of PTH or usual treatment. Functional outcomes will be assessed at 6 weeks and 12 weeks. Blinded assessment will be used to minimise the effect of bias of an open label study design. A nested qualitative study will investigate the patient experience of, and expectations following, hip fracture and the patient important aspects of recovery compared with the outcome measures proposed.

Results: Results will be analysed to establish the potential recruitment, compliance and retention rates using 95% CIs, and trial outcomes quoted with SDs and 95% CIs for the effect size.

Ethics and dissemination: The study has been

Strengths and limitations of this study

- Blinded assessments.
- Multicentre, randomised controlled trial.
- Validated outcome measures used.
- Qualitative interview of patient experience.
- Open label study.
- Pilot study.
- Multiple questions.
- Vulnerable elderly population.

approved by the South West 2 Research Ethics committee (reference 10/H0206/34). The findings of this study will be disseminated to the medical community via presentations to orthopaedic, orthogeriatric and osteoporosis societies, and their relevant specialist journals.

Trial Registration: ISRCTN Register reference number: ISRCTN03362357.
Eudract Number: 2010-020081-22

INTRODUCTION

In the UK, an estimated 70 000 people are admitted to hospital per year due to a hip fracture. The recovery from hip fractures, in terms of outcome for the patient and time-scales, requires extensive resources from the health and social services and has great implications on the quality of life and social support for the individual, despite the current treatment options available.¹ Patients

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in this population rarely recover their preinjury mobility and independence.^{2,3}

Parathyroid hormone (PTH) is licensed for the treatment of osteoporosis but there is a growing number of animal studies suggesting it can aid fracture healing.^{4,5} What is currently unknown is the effectiveness of this for patients who have sustained hip fractures. A short-term medical addition of PTH to the current management of these patients has the potential to improve the rate of functional recovery and as a consequence to reduce the risks of longer hospital stays, period of dependence on services and potentially quicken functional recovery.

PTH has been shown to improve bone mineral density and reduce risk of refracture in osteoporotic humans.⁶ Preclinical studies have shown PTH to have a beneficial effect on callus formation, in terms of quality, with regard to trabecular formation, and acceleration of the remodelling phase.^{7,8} The proposed mechanism for these effects is thought to be via increasing osteoblast-induced bone formation and proliferation of mesenchymal cells when mediated by insulin-like growth factor 1 (IGF-1). IGF-1 is thought to be stimulated by the inflammatory mediators following a fracture.⁹ Therefore, PTH influences the amount of bone laid down, and the rate at which the bone is remodelled, achieving an increased amount of bone tissue, including increases in trabecular thickness.⁷ This is thought to lead to accelerated healing of fractures. Despite the evidence from animal studies regarding the benefits in treatment of fractures,¹⁰⁻¹⁴ the dosage, duration and cost-effectiveness of treatment remain in question.⁹ Presently, subcutaneous injection remains the only licensed administration route¹⁴ and although there are other potential delivery systems under investigation these are not yet licensed for use.¹⁵

The number of publications, expert reviews and animal studies discussing the role of intermittent PTH in fracture healing in orthopaedic, gerontology and endocrinology literature demonstrates the high level of interest and belief in this new application of PTH. Currently, the impact that this treatment may have on patients and their recovery is unknown. The use of a daily injection therapy in elderly acutely injured patients can be viewed as difficult to implement. This pilot study is necessary to investigate how reasonable it is to expect this population to be able to cope with the injection therapy and whether, due to the number of unknown circumstances within the study design, including the proposed outcome measures, it will function appropriately for a full-scale, appropriately powered study which will answer the question of efficacy.

Primary objectives

- To establish the potential recruitment, compliance and retention rates for this intervention and trial design to inform sample size calculation, feasibility and design for the full study.

- To trial the outcome measures intended for use in the future full study—to test for time and ease of completion in follow-up clinics and tolerance of participants and to explore the validity and appropriateness of the suggested measures from the patients' perspective.

- To clarify and define 'standard' medicinal care for osteoporotic fractures received by the comparison group.

- To establish the feasibility and acceptability of injection therapy over 6 weeks in the elderly and acutely injured population.

METHODS

This is an open label, prospective, randomised, comparative pilot study with blinded outcomes assessment to trial the study design. Patients will be randomised to receive PTH or normal treatment. A nested qualitative study will investigate the patient experience of, and expectations following, hip fracture and the patient important aspects of recovery compared with the outcome measures proposed (figure 1).

Sample

Sample size

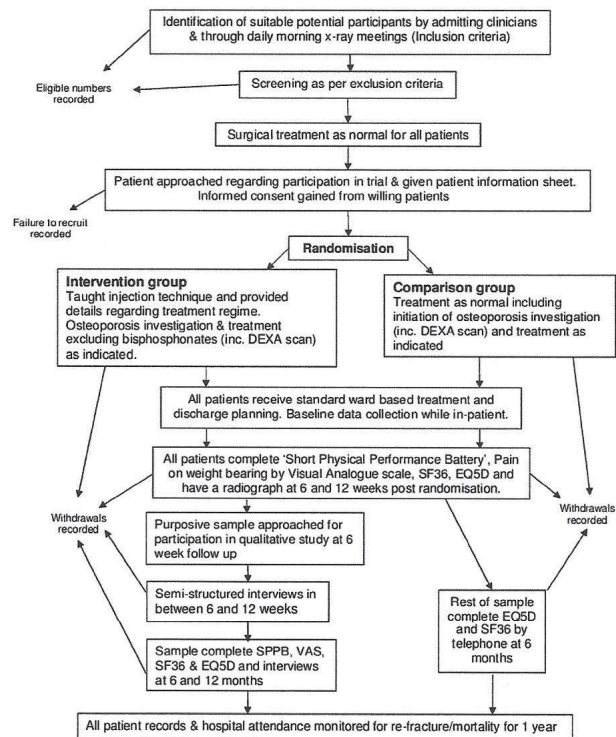
This study is intended to be a pilot study to determine whether the methodology is appropriate for a main study with adequate power. As such, a suitable sample size for the pilot study was deemed to be 20 per group. Forty patients will be sufficient to provide estimates of SD alongside published literature and 20 patients will be sufficient to estimate compliance levels to inform a larger adequately powered study. This should also provide sufficient participants for the nested qualitative study (a purposive sample of up to 30 participants) to reach saturation of responses¹⁶ in semistructured interviews.

Recruitment

Consecutive patients admitted with a pertrochanteric femoral fracture over the age of 60 years will be identified from the orthopaedic trauma units in six UK acute care National Health Service (NHS) hospitals. Exclusion criteria included the contraindications for the use of PTH detailed in the product literature and those fractures not treated by fixation (box 1).

Appropriate patients will be approached regarding the study as per International Conference on Harmonisation-Good Clinical Practice (ICH-GCP) guidelines. They will be provided with a written patient information sheet and the trial will be discussed, including the concept of randomisation and an explanation of the treatment and follow-up included in both arms of the trial (including potential side effects of the intervention and potential

Figure 1 Trial flow diagram.



participation in the qualitative substudy). The patient will be given a minimum of 24 h to discuss their participation with whomever they choose. They will also be given contact information of the research team during this time for any further information required. Where possible, potential patients will be given as long as required to consider their participation. However, consent will need to be gained and randomisation performed within 7 days of surgery, permitting initiation of the intervention within 10 days postsurgery. Randomisation will be performed using the secure online service provided by Sealed Envelope (<http://www.sealedenvelope.com>).

Interventions

PTH intervention arm

The intervention arm will administer a subcutaneous injection of 20 µg recombinant PTH (teriparatide, Eli Lilly, Indiana, USA) from a prefilled pen daily for 6 weeks (42 days). The current research suggests a treatment regime of daily subcutaneous injection, between 21 and 56 days,^{13 17 18} which closely matches the requirement for subcutaneous injections of low molecular

weight heparin for thromboprophylaxis advised for this patient group.¹⁹ As a consequence, a 6-week period of treatment was decided for this study due to matching the current requirements for subcutaneous injections for thromboprophylaxis. Additionally, if 6 weeks do not give a significant benefit, then the clinical improvement anticipated is unlikely to lead to functional improvement of the patient.

A recent study completed by Eli Lilly¹⁸ looked at the effect of intermittent PTH on distal radial fracture healing. Measuring the time to radiographic healing, the results showed a reduced healing time in the 20 µg/day treatment group. The results did not show a significant reduction in time to healing measured by cortical bridging on radiograph for the 40 µg/day group compared with the placebo group and no dose response was observed between the 20 and 40 µg/day groups (given for 8 weeks). This supports the intention to trial 20 µg/day. A greater functional difference should be demonstrable in hip fracture healing compared with the upper limb healing due to the role in weight-bearing, essential in activities of daily living. There may be a greater

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Box 1 Exclusion criteria

Exclusion

- A. Fracture not as a result of a low-energy injury/fall, for example, fall from standing height
- B. Patients whose fracture is managed conservatively
- C. Surgical fixation with total hip replacement (THR), haemiarthroplasty or cannulated screws
- D. Previous treatment with parathyroid hormone (PTH) or other PTH analogues
- E. Hypersensitivity to the active substance or to any of the excipients
- F. Previous intravenous bisphosphonate (eg, zoledronic acid) in the previous 12 months
- G. Strontium therapy for osteoporosis within the past 12 months
- H. Current medications for breast and prostate cancer (eg, tamoxifen, anastrozole, Zoladex and Prostaject) or other hormone therapies such as testosterone and hormone replacement therapy
- I. Decreased capacity to understand the risks of participating in the trial
- J. Pre-existing metabolic bone disease, for example, Paget's disease and hyperparathyroidism other than primary osteoporosis or glucocorticoid-induced osteoporosis
- K. Pre-existing hypercalcaemia or high or low corrected calcium which requires investigation
- L. Severe renal failure (epidermal growth factor receptor <30) or urolithiasis
- M. Current unexplained raised alkaline phosphatase
- N. Active cancer diagnosis or skeletal malignancies or bone metastases, or prior external beam or implant radiation therapy to skeleton within the past 5 years
- O. Premenopausal
- P. Pregnancy or lactation
- Q. Sustained use of oral steroids
- R. Wheelchair users, bed bound or transferring only prior to fracture
- S. Other current injuries (including fractures) that will affect ability to mobilise at 6 weeks
- T. Physically incapable to carry out treatment protocol or appropriate social circumstances (eg, needle phobia, other severe disabilities limiting manipulation of injection pen and without appropriate carer willing and able to assist).
- U. Patient consents to study >7 days postsurgery
- V. Current participation in any other clinical trial of medicinal product

demonstrable effect in the hip fracture population if the extent of osteoporosis is greater. It is recognised by the study group that there is discussion regarding the potential reduction of effect of PTH if there is vitamin D deficiency²⁰ and this will therefore be monitored in all patients.

Prescription of calcium and vitamin D will continue as per standard treatment. Prescription of other osteoporosis medications such as bisphosphonates and strontium will be stopped or delayed until following the 6-week PTH treatment time. Teriparatide is licensed for the treatment of severe osteoporosis and the prevention of further fragility fracture; therefore, delaying the

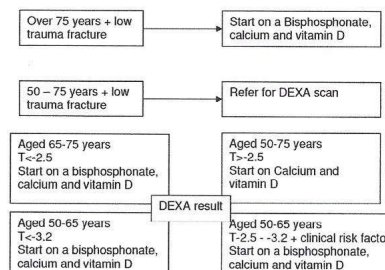


Figure 2 The National Institute for Health and Care (NICE) guidelines for osteoporosis treatment.²¹

initiation of bisphosphonate therapy does not present any risk to the patients. A review of osteoporosis medication would be indicated as standard care if a patient has been receiving a bone protection medication and has suffered another fragility fracture. After completion of the 6 weeks PTH treatment time, the patient may begin or continue normal osteoporosis treatment which will be prompted by a letter to the participant's general practitioner (GP).

The participants randomised to the intervention arm will be assisted with the injection in the immediate post-operative phase. They will receive training to administer the injection individually from the clinical or research team prior to discharge and provided with written supporting information. The option of a carer administering the injection will be discussed as appropriate when the situation occurs.

Participants will be asked to return the injection pens to the research team at the 6-week follow-up. This will enable a calculation of compliance to be performed.

Normal treatment arm

The normal treatment arm will continue with standard treatment regimens including continuation of or initiation of osteoporosis investigations/medications as per the National Institute for Health and Care Excellence (NICE) guidelines (figure 2).²¹

Participants in the pilot study will continue to be referred for Dual-energy X-ray Absorptiometry (DEXA) scans in line with normal care standards, for example, as stipulated above in the NICE guidelines²¹ or if further investigation is clinically indicated. Both arms of the study will undergo operative fixation, postoperative rehabilitation and discharge planning as provided as standard care.

Data collection

Details regarding eligibility will be recorded during the screening process. Further information regarding questions and concerns posed by those approached will be retained to inform the recruitment information for the



full trial and the content of the patient information for the full trial as part of the primary objective. Numbers of patients fulfilling the inclusion criteria but not recruited, and where possible, reasons for this will be recorded and monitored to ensure against selective entry and to inform the recruitment process and estimates for the future full trial. Recruitment estimates in the full trial will be based on the recruitment rate from the pilot study in combination with data records of the total eligible patients in each site.

Baseline data (including prefracture social circumstances, concomitant illnesses and medications) will be collected following participant recruitment to allow comparisons between groups. The patients' health records/attendance to hospital (and primary care records if required) will be monitored up to 1 year for incidence of further fracture and mortality, results of DEXA scan and initiation of osteoporosis treatment.

Outcome measures

The Short Physical Performance Battery (SPPB),²² 36 item, Short Form health survey, V.I (SF-36), EuroQol (EQ-5D) and visual analogue scale (VAS) for pain on weight-bearing measures will be performed by a blinded trained assessor during outpatient clinic visits at 6 weeks and 3 months postoperation. The assessor will be trained by the trial coordinator to ensure consistency and adherence to the trial protocol. Radiograph and compliance information will also be completed as part of their consultation. Patients participating in the nested qualitative study will be asked to repeat all of these assessments during their interviews at 6 and 12 months. Those not participating in the interviews will receive a telephone call to complete the quality of life questionnaires (SF-36 and EQ-5D) at 6 months (figure 3).

Compliance

Patients deviating from any prescribed intervention (intervention or comparative care group) will be encouraged to discuss this with the research team at the 6-week and 3-month follow-ups. The patients in the intervention group will be asked to return their injection pens to the research team at the 6-week follow-up. The remaining

contents of the returned pens will be measured, enabling an assessment of compliance.

Monitoring adherence to prescribed medications will continue for the comparison and intervention groups until the 12-week follow-up to allow an improved definition of 'normal treatment' for the full study. This will include recording which medications, time of starting medication, timing and results of DEXA scan and tolerance and compliance with their treatment at each follow-up stage.

Participants will be made aware throughout that they may withdraw from the study at any stage. In the occurrence of withdrawal from the study, the patients will be asked if they would inform the research team why they are withdrawing—this is due to the need to establish acceptability of treatment. This would be included in the patient information sheet, and patients would be made aware from the outset. Patients withdrawing/not complying with the injection therapy will be asked if they would continue to participate in follow-up for outcome data collection. Patients withdrawing from attending for follow-up, unless explicitly withdrawing consent, will continue to be monitored for DEXA scan results, further fragility fractures and mortality for 1 year (via hospital or primary care records).

Any participant withdrawing from the study who is part of the qualitative group would be asked if they wished to continue to participate in the semistructured interviews. This is necessary to establish a true picture of acceptability and success of outcome measures and study design. Patients will be made aware that it is their choice whether to take part at each stage.

Safety reporting and monitoring

Participants will be asked to report adverse events (AEs) at each follow-up. The research team will inform the participant's GP of the person's inclusion in the trial on discharge from hospital and encourage timely communication of any AEs experienced during the study. All AEs will be recorded in the study paperwork. The trial coordinator will maintain a log of AEs and inform the chief investigator (CI). All AEs and adverse reactions for both groups will be collated in a document

	Screening	Randomisation ≤ 7 days post #	End of In- pt stay	6 weeks	12 weeks	6 months	12 months
Informed consent	x						
Review inclusion and exclusion criteria	x						
Participant ID assigned	x						
Randomisation		x					
Baseline data set		x	x				
Radiological assessment # fixation				x	x		
Compliance measurement				x			
Collection of osteoporosis investigation treatment data			x	x	x		
SPPB				x	x	Qual group	Qual group
VAS pain				x	x	Qual group	Qual group
SF-36				x	x	x	Qual group
EQ-5D				x	x	x	Qual group
Qualitative interview					Qual group	Qual group	Qual group
Monitoring for further fragility fracture			x	x	x	x	x
Lost to follow up or withdrawal of consent recorded			x	x	x	x	x
Adverse event recording			x	x	x	x	x
Mortality		x	x	x	x	x	x

Figure 3 Participant timeline.

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to enable comparison. The CI and trial coordinator will jointly collate reports for submission to the sponsor, Medicines and Healthcare Regulatory Agency (MHRA) and Research Ethics Committee (REC) as required.

All serious adverse events and serious adverse reactions will be reported to the Sponsor via the Research & Development office and the regulatory authorities as per the North Bristol NHS Trust standard operating procedure as soon as the research team is aware of it (within 24 h) and a written report will follow within 7 days as per ICH-GCP guidelines.

The study will be monitored by the North Bristol NHS Trust Research & Innovation office as the sponsor of the study according to their standard operating procedures.

Blinding

The study will be open label due to the complexities of placebo injections in a frail elderly population (the invasive nature of the intervention and the need to withhold or account for the normal osteoporosis medications for the placebo group). This is the plan for the full study. Blinded assessment of an objective functional score has been included to minimise the bias effect this design may have.

Data management

All data collection forms are anonymised. The coordinating centre will check for any missing data or anomalies that can be addressed by the recruiting site. All data will be coded and manually entered into a Microsoft Access 2003 database. Data validation will occur in 10% of all data entry to minimise transcription error. In the event that there is a >2% error overall, the validation will be extended to 20%.

Analysis

Analysis of the feasibility aspects of the pilot study will focus on proportion of patients who were recruited and compliant using 95% CIs calculated using the binomial method.

Statistical analysis for the trial outcomes will be similar to that for the main study, but reporting SDs of outcome variables and CIs of effect sizes, not investigating statistical significance. The two groups will be compared by tabulating information available at baseline (prior to randomisation). Comparisons of outcome variables following randomisation will be carried out using an intention-to-treat methodology and an appropriate methodology will be used where follow-up outcome data are not available. In the full study, this may mean data imputation using regression techniques, but in the pilot study, there will be insufficient data to carry out the regressions robustly and last observation carried forward may be used to prevent omission of patients. Treatment effects between the groups will be calculated and CIs calculated. In the full study, in the unlikely event of large differences between the groups at baseline, regression techniques may be employed to demonstrate the treatment effect before and after controlling for these differences.

Thematic analysis of the qualitative data will be undertaken.¹⁶ Interview transcripts will be coded and themes produced from those codes will be used to recommend domains which describe the process of 'recovery' or 'getting better' from the patients' perspective and priorities.

The interviews will be audio-recorded and fully transcribed to allow coding and analysis in an ongoing and iterative manner.²³ Interview transcripts will be anonymised using the participants' trial ID. The researcher will code the transcripts according to themes that emerge from the data with supervision from the university supervisors. Data management will be assisted using NVivo software.

ETHICS AND DISSEMINATION

We will comply with the Medical Research Council Good Clinical Practice guidelines, and the trial will run under the standard operating procedures of North Bristol NHS Trust. An independent data monitoring committee will meet annually, with an option to increase if specific concerns arise. The findings of this study will be disseminated to the medical community via presentations to orthopaedic, orthogeriatric and osteoporosis societies and their relevant specialist journals. The protocol amendments to date are listed in table 1.

Table 1 Protocol amendments

30 March 2010	Original protocol (approved as a single site study)
18 January 2011	Amendment 01: at request of MHRA for authorisation incorporated changes to wording of exclusion criteria to align these more closely with contraindications to PTH as listed in the SmPC and addition of participant timeline
4 April 2011	Amendment 02: non-substantial changes to data collection forms
30 August 2011	Amendment 03: protocol amended to incorporate an additional four recruiting sites due to lower potential participant numbers than anticipated
14 December 2011	Amendment 04: change to Oxford PI and addition of three further sites
1 February 2012	Amendment 05: non-substantial amendment. Minor changes to Participant Info Sheet
2 March 2012	Amendment 07: non-substantial amendment. Minor changes to qualitative Participant Info Sheet
16 April 2012	Amendment 08: extension to study timescales and revision of target recruitment rate. Addition of recruiting site and removal of recruiting site.
24 June 2012	Amendment 09: change to Bath PI

MHRA, medicines and healthcare regulatory agency; PI, principal investigator; PTH, parathyroid hormone; SmPC, Summary of Product Characteristics.

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Author affiliations¹Department of Orthopaedic Surgery, Frenchay Hospital, Bristol, UK²University Hospitals Bristol NHS Foundation Trust, Level 3 Education Centre, Bristol, UK³NIHR Biomedical Research Unit, Nuffield Department of Orthopaedic Surgery, Nuffield Orthopaedic Centre, University of Oxford, Oxford, UK⁴Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Kadoorie Critical Care Research Centre, John Radcliffe Hospital, University of Oxford, Oxford, UK**Acknowledgements** The authors would like to thank North Bristol National Health Service (NHS) Trust for agreeing to sponsor the study.**Contributors** TC and RF conceived the original study and developed the protocol with RH, SB, RG, KH, KJ, SL and KW. Statistical advice was provided by RG. TC led the writing of the first draft of the manuscript, with contributions from RH, SB and RF. All authors contributed to the editing and redrafting.**Funding** This is a summary of independent research funded by the National Institute for Health Research (NIHR)'s Research for Patient Benefit Programme (Grant Reference Number PB-PG-0408-16292).**Competing interests** None.**Ethics approval** South West 2 Research Ethics Committee.**Provenance and peer review** Not commissioned; externally peer reviewed.**Data sharing statement** No additional data are available.**Open Access** This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 3.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/3.0/>**REFERENCES**

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APPENDIX B: Topic guide

FRACTT study: nested qualitative study

Patient perceptions of what happens after hip fracture.

Interview topic guide

This is an interview overview to guide the interview topics. The interviewer may also ask additional questions or use prompts to clarify information following answers from the interviewee.

Prior to the start of the interview

Interviewer to explain:

- The aim of the interview is to explore your experiences of getting better following your broken hip.
- The interview will be recorded, all transcriptions will use your code or number from the study not your name. Our discussions are confidential and you will be anonymous to anyone other than me.

Prompts ideas:

Can you tell me more about that?

Can you give me an example of that?

How did you feel then?

What was important to you in that situation?

What effect did that have on you?

What did that mean to you?

Warm up topics:

Collect basic biographical details – education, employment, living arrangements

Perceptions and expectations

1. How have you been managing since we last saw you?
2. Can you describe what you have been doing this week?
3. Do you feel like you are getting better?
 - If so - what has changed / improved?
 - If not - why not?
 - What were you like before?
 - What would help make things better?
4. What is important to you – in terms of your health and getting back to normal?

Experience of outcome measures in pilot study

1. What did you think of the *questionnaires* you did last time / today?
2. What about the *walking and balance* test?
3. In research we often use things like those *questionnaires* – Do you think they are a good idea?
4. What about the timed walk etc?

Experience of injection therapy (for intervention group participants only)

1. Tell me about the injection...?

Wrapping up

Is there anything you would like to add?

At 3rd timepoint - Would you like us to send you a summary of what we find? ☐

Thank you very much for your time and valuable contribution.



University of the
West of England



FRACTT study: nested qualitative study

Patient perceptions of what happens after hip fracture.

Interview topic guide

This is an interview overview to guide the interview topics. The interviewer may also ask additional questions or use prompts to clarify information following answers from the interviewee.

Prior to the start of the interview

Interviewer to explain:

- The aim of the interview is to explore your experiences of getting better following your broken hip.
- The interview will be recorded, all transcriptions will use your code or number from the study not your name. Our discussions are confidential and you will be anonymous to anyone other than me.

Warm up topics: basic biographical details – education, employment, living arrangements

Can you tell me about your household / your family / who you live with at the moment.

Perceptions and expectations

HOW

1. How have you been managing since you left the hospital/I last saw you?

WHY

2. Could you describe what you have been doing this week?

WHAT

3. Do you feel like you are getting better?

- ◆ What has changed / improved? ◆ Why not?
- ◆ What were you like before? ◆ What's difficult about getting about?
- ◆ What would help make things better? ◆ Why won't you ask others for help?
- ◆ What does your pain stop you from doing? ◆ What does your doctor say?
- ◆ What do you mean by.....? ◆ You said.... Can you explain...?
- ◆ Why is that difficult? ◆ How do you manage with that?

4. What is important to you – in terms of your health and getting back to normal?

Experience of outcome measures in pilot study

1. Do you remember filling in lots of questions on a question sheet when you came to the hospital? What did you think of the *questions*?
 - ▲ What did you think the questions were about?
 - ▲ How was the questionnaire for you to do?
2. What about the *walking and balance* test?
 - ▲ How did you feel being asked to do that?
 - ▲ How did it go?
3. In research we often use things like those questionnaires and walking tests – Do you think they are a good idea?



University of the
West of England



Experience of injection therapy (for intervention group participants only)

1. Tell me about the injection...?
 - ★ What did you think when they showed you the injection at the hospital?
 - ★ How was the injection for you to do? ★ How have you found it storing them?

Wrapping up

The things you've said have been really interesting. What else should we talk about? Do you have something to add? / Is there anything you'd like to add?

At 3rd timepoint - Would you like us to send you a summary of what we find? ☐

Thank you very much for your time and valuable contribution.

Prompts ideas:

- | | |
|---|--|
| Can you tell me more about that? | What did that feel like? |
| What was that like? | Can you give me an example of that? |
| How did you feel then? | What was important to you in that situation? |
| What effect did that have on you? | What did you think at that time? |
| What was it about x that was so good/bad? | What did that mean to you? |
| So you said xxxx happened..? | |
| Echo – you were telling me about.....? | |

APPENDIX C: NHS ethics approval

NHS
National Research Ethics Service

South West 2 Research Ethics Committee

Royal Devon & Exeter Hospital (Heavitree)
 Room TH5
 Gladstone Road
 Exeter
 Devon
 EX1 2ED

Telephone: 01392 405272
 Fax: 01392 405270
 Email: Barbara.Inger@nhs.net
www.nres.npsa.nhs.uk

03 November 2010

Mr Timothy Chesser
 Consultant Orthopaedic Surgeon
 North Bristol NHS Trust
 Department of Orthopaedic Surgery
 Frenchay Hospital
 Bristol
 BS16 1LE

Dear Mr Chesser

Study Title:	The administration of Parathyroid hormone affects functional recovery from pertrochanteric fractured neck of femur: A prospective randomised comparative pilot study with blinded objective functional outcome assessment.
REC reference number:	10/H0206/34
Protocol number:	R&D 2185
EudraCT number:	2010-020081-22

Thank you for your letter of 20 October 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority
 The National Research Ethics Service (NRES) represents the NRES Directorate within
 the National Patient Safety Agency and Research Ethics Committees in England



The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Investigator CV	2	25 May 2010
Protocol	3	30 March 2010
GP letter Appendix 8a	1	17 March 2010
GP Letter 1 Appendix 3	2.1	28 July 2010
National Institute for Health Research letter		25 March 2009
Summary of Product Characteristics Forsteo*		
CV for Rebecca Fox		02 January 2007
REC application		25 May 2010
Covering Letter		25 May 2010



Covering Letter		20 October 2010
Questionnaire: EQ-5D Health Questionnaire		
Participant Information Sheet: Pilot Study Appendix 2	3	28 July 2010
Participant Consent Form: Interview Study Appendix 9	3	28 July 2010
Response to Request for Further Information		20 October 2010
Participant Information Sheet: Interview Study Appendix 9	3	28 July 2010
Participant Consent Form: Pilot Study Appendix 2	3	28 July 2010
Questionnaire: SF-36 (tm) Health Survey		
GP letter Appendix 8b	1	17 March 2010
Reviewers 1 2 3 comments		

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

APPENDIX D: University ethics approval

Our ref: SE/lt

10 September 2016

Mrs Rebecca Fox
Department of Orthopaedic Surgery
Frenchay Hospital
Bristol
BS16 1LE

Dear Rebecca

Application number: HSC/11/1/11

Application title: The administration of Parathyroid hormone affects functional recovery from pertrochanteric fractured neck of femur: a prospective randomised comparative pilot study with blinded objective functional outcome assessment

NHS Application Number: 10/H0206/34

Your NHS Ethics application and approval conditions have been considered by the School Research Ethics Sub-Committee on behalf of the University. It has been given ethical approval to proceed with the following conditions:

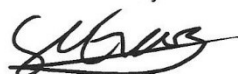
- You comply with the conditions of the NHS Ethics approval.
- You notify the School Research Ethics Committee of any further correspondence with the NHS Ethics Committee.
- You notify the School Research Ethics Sub-Committee in advance if you wish to make any significant amendments to the original application.
- Please note that all information sheets and consent forms should be on UWE headed paper.
- If you have to terminate your research earlier than planned, please inform the School Research Ethics Sub-Committee within 14 days, indicating the reasons.
- Please notify the School Research Ethics Sub-Committee if there are any serious events or developments in the research that have an ethical dimension.
- Please be advised that as principal investigator you are responsible for the secure storage and destruction of data at the end of the specified period a copy of the guidelines are enclosed for your information.

Please note that your study should not commence at any NHS site until you have obtained final management approval from the R&D department for the relevant NHS care organisation. A copy of the approval letter(s) must be forwarded to Leigh Taylor in line with Research Governance requirements.

We wish you well with your research.

-2-

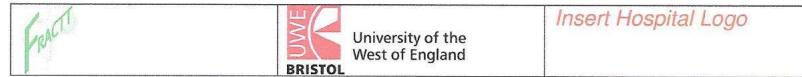
Yours sincerely

A handwritten signature in black ink, appearing to read 'Simon Evans', with a stylized flourish at the end.

Simon Evans
Chair
Faculty Research Ethics Sub-Committee

c.c. Shea Palmer

APPENDIX E: Participant information sheet



Enquiries to: Rebecca Fox
Trauma researcher
Email: Rebecca.fox@nbt.nhs.uk
Telephone: 0117 3402801
Department of Orthopaedic Surgery
Frenchay Hospital
Bristol
BS16 1LE

Information about the research

Parathyroid hormone in the recovery from hip fractures – a pilot study Interview study

(Study reference number: R&D 2185)

Researcher
Mrs Rebecca Fox

We would like to invite you to take part in an additional part of this research study. Before you decide whether to take part we would like you to understand why it is being done and what it will involve for you. One of our team will go through this information with you and answer any further questions you have. Take time to consider before deciding whether to take part. You may wish to discuss taking part with family and friends.

The study is exploring how can we measure what happens after a hip fracture.

Thank you for taking the time to read this.



What is the purpose of the study?

We would like to invite you to take part in the section of the study that looks at the patient experiences of their broken hip. We are interested in finding out what it is like after a broken a hip and its impact on your daily life. A better understanding of your experiences will be used to develop practice and further research.

Why have I been invited?

You have been invited because you are taking part in the parathyroid hormone pilot study. We are asking 20-30 of the patients in that study to take part in some interviews.

Do I have to take part?

No. It is up to you whether to take part in this section of the study. The study will be explained to you, including what will happen at each stage and what it will involve. If you do not wish to take part this will not affect your care or your involvement in the pilot study.

What will happen to me if I take part?

If you agree to take part in the study we will arrange a time convenient to you for the researcher to come and talk to you.

We would like this to happen either before or at your next appointment. The researcher can come to your house if that is the easiest option for you.

In the discussions the researcher will ask you a few questions about your experiences of breaking your hip. For example they may ask you to describe how you are managing and what aspects of recovery are important to you. We would also like to know what you think about the questionnaires and the measurements that you are doing as part of the pilot study.

The interview will take about approximately 60 minutes. However if you would like to finish the interview early, or meet several times for a shorter duration, we can arrange this. If you feel tired or want to stop at any time you may do this.

The researcher needs to be able to go back over the conversation afterwards and therefore will ask to tape record the discussion so it can be typed out and analysed later. You may like to have a copy of your transcript. Anonymous quotes from your transcript may be used to illustrate themes that come from the interviews. Copies of the transcripts will be kept in a secure place for 15 years in keeping with current guidance. You will not be identifiable from these transcripts.

We would like to repeat these interviews at 6 months and 12 months after your hip operation. Again, this will be arranged at a time and place convenient to you.

When the researcher comes to talk to you at 6 and 12 months she will also ask you to repeat the measurements of your walking and balance and questionnaires.

**What will I have to do?**

If you agree to take part in the study we will ask you to sign another consent form to say that we have discussed the study with you fully, that you have had an opportunity to ask questions and that you understand what it involves for you.

We will also arrange the time for the first interview and discuss where you would like this to happen and telephone you to confirm nearer the time.

During this study we would encourage you to be honest with us about how you are managing, your experiences, your thoughts about the study, the medications, the questionnaires and measures that you do.

What are the alternatives to taking part?

If you choose not to participate in the study your care will NOT be affected and you will continue with the plans for the original study. This includes a further appointment in 6 weeks time (3 months after your hip operation) and a telephone call 3 months after that (6 months after your hip operation).

What are the possible disadvantages or risks of taking part?

Discussing what you have been through with your broken hip and how you are getting on may be upsetting or emotional for some people. You can take a break or stop the discussions at any point if you need to.

If you wish to talk to someone other than the researcher the senior staff in clinic or the other members of the research team will be available.

What are the possible benefits of taking part?

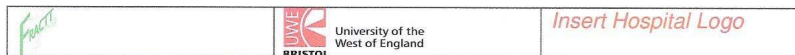
Although we do not expect that taking part will give you any direct benefits some people find talking about experiences helpful.

What if I go into the study but then change my mind?

If you decide not to continue with the study, you can make this decision at any time. You can withdraw at any time without giving a reason, withdrawing from the study will not affect your care in anyway.

Will my taking part in this study be kept confidential?

Yes. All information collected about you during the course of the study would be kept strictly confidential. A study number will be used instead of your name so that information about you will be confidential. All information will be stored in a password protected computer and locked filing cabinet in a secure office.



What if there is a problem or I want to make a complaint?

In the first instance we would encourage you to discuss any problems with us. If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint through the usual NHS process. Details about this are available from the research team or *Insert Hospital complaints team name*. *Insert name* can be contacted at *Insert location by telephone or fax on Insert contact details*.

You may have grounds for legal action if you are harmed during the study. In this case, you may have to pay your legal costs. The normal NHS complaints mechanisms would still be available to you.

Who will know that I am participating in this study?

The doctors responsible for the care of your broken hip, looking after you as part of the study and your GP will know you are taking part.

What will happen to the results of the research study?

The information gained during this study will be used by the research team to develop the design of a larger trial. These discussions will give information about what is important to patients during the time after a broken hip. This will assist researchers to decide the best ways to measure recovery after a broken hip in future research.

At the end of the study the results will be written up by the researcher as part of her postgraduate degree at the University of the West of England. Outcomes from the study will be published in the medical press and presented at conferences to share the knowledge gained. The written work for the University and any publications in the medical press may use quotes from the discussions as examples of the topics discussed. You will not be identifiable from any of the quotes used. You will not be identified in any publication or presentation produced.

Who is organising and funding the research?

This study is sponsored by North Bristol NHS Trust. The study is funded by the National Institute of Health Research (Research for Patient Benefit scheme).

The research staff involved in this study do not receive any payment other than what is required to cover expenses. The study is independent of any commercial organisation.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been considered and approved by 'South West 2' Research Ethics Committee. The Research Ethics Committee has the responsibility for scrutinising proposals for medical research on humans, has examined this proposal and has raised no objection from the point of view of medical ethics.

**Further Information and contact details**

For further general information and advice about research participation please contact the Research and Innovation Department at Southmead Hospital on 0117 323 6468. Although staff at this department are employees at the hospital they are independent of the research team.

Further information about medical research is available through the NHS Direct website (www.nhsdirect.nhs.uk) and search for the term 'clinical trials'

If you have any questions or you wish to obtain further information about this study, you may contact

Rebecca Fox, Researcher

Telephone: 0117 3402801

Address: Department of Orthopaedic Surgery, Frenchay Hospital, Frenchay, Bristol, BS16 1LE

Email: Rebecca.Fox@nbt.nhs.uk

Shea Palmer, University Supervisor

Address: School of Health and Social Care, University of the West of England, Blackberry Hill, Bristol, BS16 1DD

What do I do now?

If you want to take part, a time for the interview will be arranged. If you do not want to take part you do not have to do anything further.

Thank you for considering taking part in this study and for taking time to read this sheet.

	 University of the West of England BRISTOL	Insert Hospital Logo
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Participant Consent Form

Centre	
Study Number	R&D 2185
Patient Study ID	
Title of project	Qualitative study supplementary to: Parathyroid hormone in the recovery from hip fractures – a pilot study Patient perceptions of what happens after hip fracture
Researcher	Mrs Rebecca Fox

	Please initial
1. I confirm that I have read and understand the information sheet dated 16/04/2012 Version 4.3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I agree to the researcher audio-recording the interview	
4. I agree to the study publishing anonymous quotations from the interview	
5. I understand that the information I give will be kept confidential and used only for the purposes of this study, and that my consent is conditional upon the researchers complying with their duties and obligations under the Data Protection Act.	
6. I agree to the researchers recording and processing information about for research purposes.	
7. I agree to take part in the above study	

Name of patient	Signature of patient	Date
Name of person taking consent	Signature of person taking consent	Date

When completed: 1 for interviewee; 1 for researcher site file; 1 (original) to be kept in medical notes

APPENDIX F: Code list and descriptions

Code	Description
Able Ability to carry things	Discusses difficulty with carrying things or now being able to carry things (often related to 'walking aid')
Acceptance	<p>Realisation continued improvement may not happen. Feeling like they have plateaued and no longer progressing. Might be acceptance of long term need for walking aid, no longer driving, now needing help in the garden etc or might just be happy with their lot, they've done ok and don't feel the need to push on (might relate back to their age?).</p> <p>Also acceptance because other priorities but would always say would like somethings to be better even if think it's not realistic.</p> <p>Different levels of acceptance – some happy, some begrudging, not quite there yet</p>
Adaptation of environment	Discusses a change to their environment to facilitate function
Adherence to treatment	Discusses adherence to treatment – OP meds or exercises or use of equipment
Attitude	<p>Suggestion that their attitude may be affecting how they are recovering. Or may infer that an attitude was required or enforced by situation e.g. having patience.</p> <p>Or reflection on personality / attitude may differ to others</p>
Balance	Discuss balance - may use actual word balance or other words to describe it. 'Not so steady'
Bending kneeling	Relate difficulty with bending or kneeling normally when discussing a functional task that requires it
Being part of society	<p>Describe desire too, importance of, progression which enables them to do things that help them feel part of society. Has overlap with prisoner, getting out and about, informal social interaction.</p> <p>E.g. being able to vote, participate at church,</p>
Boredom	Relates feeling bored or gives example
Building confidence	Getting over milestones – was worried to that but then did it and its ok now
Burden	Discusses concern of being a burden on others
Change in role	Mentions that injury has affected their role – either actually or perceived by them. Different to just being able to do something physically – more emotional feeling of what 'role' they have lost.
Change to plans	e.g. moving holiday dates
Communication with medical professionals	Include all medical professionals
Comparing self to others	Compare their progress to others they know, or comparing self to other people generally
Coping strategies	Discusses ways round difficulties (may relate to adaptation of environment, alternative method) may include emotional, psychological solutions as opposed to 'alternative method' which is physical alternatives. Also included dividing tasks with another person – team work.

	<div> <div>Alternative non physical activities</div> <div>Discuss alternative ways they occupy themselves if not able to do what they used to e.g. reading, DVDs</div> </div> <div> <div></div> <div>Also coping strategy for boredom. This might or might not have changed much since fracture</div> </div> <div> <div>Alternative method</div> <div>Relates having found an alternative way of completing a task or returning to 'normal' / previous way of completing a task.</div> </div>
Disbelief	Relate feeling something hasn't been addressed- eg misdiagnosed or missed at time of break. Not accepting that break was cause of current problems/pain
Don't want to be like this	Expresses dislike of current situation/abilities Emotional distress at state or situation. May relate feeling depressed.
Driving	Discussion of driving – whether has been able to or not, expectations, importance of driving
Effect on other leg joints	need it more, makes other leg ache – phase 2, changed to other joints – discuss effect on knees/ other hip etc
Environment	How environment affects function – eg steep steps to door, weather
Equipment	Assistive devices – may be provided by hospital or found themselves. Helpful or hindrance, changing needs. May combine with 'walking aids'?
Exercises	May refer to exercises advised by physio or rehab team, suggested by family or friend, previous experience. May feel they are essential or pointless, unsure why or how much. Currently keep separate from 'Walking'
Fall	Relates a fall since their hip fracture. Or talks about fall history, being referred to falls clinic.
Family relationships	Effect of injury on relationships with family (?could also come up with friends I suppose). In 270 overlaps with change in role. 239 – 2 family keeps her going
Family Social support	Previously 'family support' – participants discuss assistance and support offered, needed, accepted, essential from family, partner, friends, neighbours.
Fear of falling and doing further damage	<div> <div>Fear of falling – closely linked with fear of further damage. May combine?</div> <div> <div>Fear of doing further damage</div> <div>Fear of doing further damage affecting way doing things now, restrictive, interfering with general life</div> </div> </div>
Frustration	Describe frustration. May use actual word. Causes varied (pain, slow recovery, limitations – physical, social, reliance on others.

	Some overlap with 'Boredom'	
Further surgery	Relate feelings about need for further surgery	
Functional activities	ADLs	Eg W&D, cooking, making cup of tea. ?will include shopping and house work. Consider emotion attached to it – are they frustrated at what they can't do, please with what they can do, thing nothing of it, feel progress has been made...
	Gardening	Describes / refers to gardening in any form (may combine with ADLs or house work – consider also hobby)
	House work	Should this be part of ADLs? Discuss ability, desire, importance of being able to do jobs around the house e.g. vacuuming, making beds, laundry, hanging pictures, painting walls
	Shopping	Discuss solutions for shopping – whether can or can't do it, how get round it
Got used to it	Got used to something – so reaction to situation has tempered	
Getting out of the house	Desire to, difficulty, importance or achievement in getting out of the house	
Hobby	Describes desire to, importance of, difficulty with or achievement of a function that is more than an ADL – their hobby or preferred or favourite activities/ past time.	
Home	The desire or importance of being in own home	
Inactivity	Describe feeling of being inactive with examples of things unable to do, may relate dislike of being able to do things. Or express concerns about inactivity	
Independence	Describe what they are aiming for, what want to be able to do without having to rely on other people. Relate what they are becoming able to do i.e. regaining their independence	
Independent	Describe determination to do something themselves now eg through an alternative method	
Informal social interaction	Describe spontaneous, informal or unstructured social interactions that they miss or want to get back to e.g chatting to other dog walkers, shop assistants, Are they describing the limitation on activities that results in a feeling of isolation? ?drop informal – encompass different types of social interaction. +/- of different types	
Leg length	Leg length difference or feeling of reported	
Is it part of a permanent decline (age)	Are things going to get better (wider picture of other medical problems cropping up as well) would things have happened anyway.	
	Is it just age?	Discuss whether a change is just due to age, may discuss whether they should just accept it. May have been expecting the change.
Limp	Describe feeling that way they are walking is not normal –may use word limp or describe having to hop from one leg to other or use words such as 'waddle'. May discuss desire to walk without	

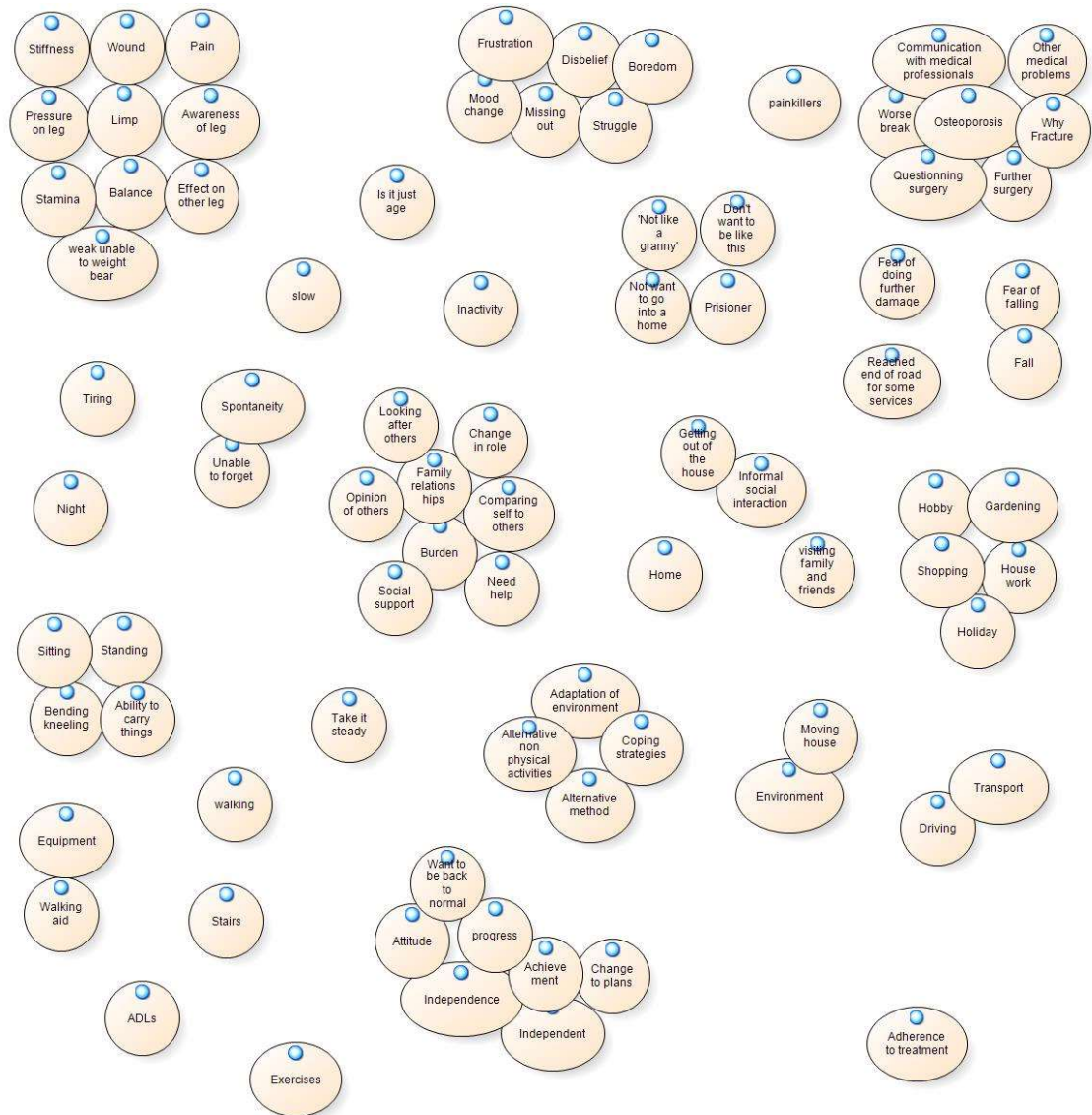
	a limp again
Looking after others	Discuss their role to look after others (e.g. partner, grandchild) e.g. difficulties or impact on ability to do it.
Loss of appetite	Not wanting to eat and losing weight - may be pain related, ?mood related, physically difficult to stand to prepare food
Missing out	Describe feeling they are missing out on things others are doing (may explain why)
Mood change	Describes a change in mood e.g. being fed up / down / depressed by situation or happier / boosted by achieving something
Moving house	Relates wanting to or having to move
Need help	Describes tasks that they need help with (overlap with family support, ADLs, shopping)
Night	Discuss experiences of night time – e.g. pain, getting to the toilet, sleeping, getting in and out of bed, positioning in bed. (some potential cross over with 'tiring')
'Not like a granny'	Refer to age or culture – e.g. social stigma of a walking aid, not being old enough yet
Not want to go into a home	Or not wanting to not be able to look after self
Opinion of others	Relate what they are told by others witnessing their recovery (non-healthcare)
Osteoporosis	Discuss or refer to bone health
Other medical problems	Discuss other medical problems – prior to or along side hip fracture. May relate effects of these on experience of hip fracture, may discuss timing of diagnosis or deterioration
Pain	References to pain – lots of it, not much, worse than expected, better than expected, what it stops them doing, how to manage it, how/whether they expect it to change. Whether it is changing.
painkillers	Discuss use of painkillers – how managing, how feel about taking them, what told to do with them
Perseverance- not there yet	discuss an activity that there are continuing to try to do, maybe building up, or practicing
Pressure on leg	Refer to feeling unable to put pressure on leg or unable to create pressure with leg. At present also include feeling heavy
	Awareness of leg Describes being more aware of leg, may be more cautious because aware of it. ?May combine with 'pressure on leg' including it feeling heavy
Prisoner	Describe being a 'prisoner', 'being stuck', 'trapped', or wider discussion of activities being limited to a restricted environment, restriction could refer to physical limitations eg walking, transport difficulties, environment e.g. steps that are difficult, weather (wind/ice) medical e.g. other health problems, mental e.g. confidence/anxiety
Problem with original surgery	Relate problems with surgery, may have been seen on xray
progress	Describe what they have seen themselves do as progression from where they were or what they will see as progress.

	Describing actual tasks (potential overlap with achievement although this is more the feeling of achievement rather than practical task based – may need revisiting) Also used where a feeling of lack of progress is related – overlap with struggle?
	Achievement Relates feeling of achievement e.g something they hadn't been able to do accomplished
Questioning surgery medical management	Questioning the surgery they had, whether it was the right thing, whether they would have been better off with a hip replacement.. Or questioning rehab they had / didn't have, questioning decision to take the parent study intervention on reflection (Overlap with comparing self to others (or media) here)
Reached end of road for some services	As sounds – relates services having stopped e.g. physio, OT, DN
Sitting	Sitting painful, unable to sit for long, sitting easier than it was...
slow	Relate that recovery seems slow, has taken longer than they expected (be aware my overlap with progress – currently feels different)
Sought review from surgeons as not happy	Relate having seen or planning to be seen by doctors because not happy with outcome – reasons may vary.
Spontaneity	Discuss not being to just do something – having to think about it, consider carefully, plan before doing something. Consider leg before doing something ?Freedom 110 (101 phase 3 freedom)
Stairs	Managing stairs – easy, difficult, solutions, progress. Difficulty or limitations because of stairs, different techniques or changing ability
Stamina	Discuss being able to do something but not for long, or want to be able to do more of something (overlap with walking and ADLs)
Standing	Ability to or inability to stand, duration, support or limitation of activities due to standing tolerance.
Stiffness and swelling	Refer to stiffness in hip or leg (currently include swelling or heaviness in leg also) may be re-named to include 'symptoms' but what about pain.
Struggle	Describe being able to do things (i.e. able to complete the task) but it being a struggle / awkward / difficult / painful / afraid while doing it
'Take it steady'	Refer to not rushing or doing something steadily. Doing things slower. Also when describing pacing themselves. Want to be able to get with things and not have to take it steady
Tiring	Refer to being tired – its limitation on being able to do things. Can now do things but they are tiring
Transport	Refer to being able to use public transport / taxi's / getting lifts / dial-a-ride / public buses (currently excluding driving themselves)
Unable Ability to forget	Memory of break and the impact of it limits their feeling of being able to be 'back to normal' Being careful because of leg – overlap with awareness of leg,

	<p>fear of doing further damage</p> <p>Phase 2 – able to forget occasionally, ?a sign of moving on. Seen as a sign of progression (& phase 3)</p>
visiting family and friends	Difficulties, desire, unable, importance (overlap with missing out)
walking	<p>Difficulties, desires, importance. What they need to be able to walk to do, how managing, references to speed, pain (overlap with balance, limp, pain, walking aid, stamina, etc etc)</p> <p>Changes to walking</p> <p>May discuss Walking outdoors specifically – kerbs, ice, wet, leaves, wind, being able to control dog on lead</p>
Walking aid	Need them, dislike them, like them, reliance on, want to get rid of, difference uses for, progression through
Want to be back to normal	Describe desire to be normal or ordinary again (with examples) – may include/ overlap with mobility, social activities, ADLs, independence, pain . Is on spectrum with 'don't want to be like this'.
Weak unable to weight bear	Possible overlap with 'awareness of leg', may describe lack of trust in leg of feeling like it might buckle under them.
Will not give up	As it sounds!
Worse break	Questioning whether it was a worse break than their previous one or their friend/neighbour or worse than they realised, or worse than they were told. (overlap with comparing with others)
Wound	Talks about wound – awareness of it, problems with it

APPENDIX G: Example of mind map

Example of early grouping of codes from phase one



APPENDIX H: Thematic map

Example of a thematic map in working progress from phase one.

