Investigations on the Physiotherapy Management of People following First-Time Patellar Dislocation

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Abstract

Background: First-time patellar dislocation (FTPD) is a disabling musculoskeletal disorder. Whilst physiotherapy is considered the cornerstone treatment in FTPD, its evidence-base is limited. Three studies were undertaken to develop knowledge on this area.

Study 1: All 306 National Health Service acute hospitals with an accident and emergency and/or an orthopaedic department were sent a fourteen-item questionnaire pertaining to the management of FTPD. Physiotherapists reported they most commonly assessed this population for reduced quadriceps or vastus medialis oblique (VMO) capacity, patellar mal-tracking and excessive patellar glide. Reassurance, proprioceptive, knee mobility, quadriceps and VMO-specific exercises were the most commonly cited treatments.

Study 2: Ninety people who had experienced recurrent patellar instability completed a questionnaire which assessed the frequency with which they perceived patellar instability during various activities. Sporting and multi-directional activities were frequently associated with patellar instability. Females and those without a family history of patellar instability reported more frequent patellar instability symptoms compared to males, or those with a family history of this disorder. The results were used to construct the Norwich Patellar Instability Score.

Study 3: A pragmatic multi-centre randomised controlled trial was conducted to compare the prescription of a general quadriceps exercise and rehabilitation programme (n=15) to a VMO-specific exercise and rehabilitation regime (n=12). Whilst Lysholm Knee Score was statistically different between the groups ($p=0.02$) this was not clinically significant. The general quadriceps exercise group reported a statistically significantly greater Tegner Level of Activity Score at six weeks ($p=0.03$) but not at six months ($p=0.42$). There was no significant difference between the groups for isometric knee extension, Short Form-12 or recurrent patellar dislocation at either follow-up ($p>0.05$).

Conclusions: The studies undertaken have significantly developed the evidence-base in this field. Further investigations are recommended to further inform the clinical decision-making of physiotherapists who manage people following FTPD.

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Publications Arising from the Thesis

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Section One

Introduction

Chapter 1. Introduction

1.1 Background

The conduct of research has been attributed to the need for increased certainty in an uncertain world (Torgerson and Torgerson, 2008). For centuries people have directly or indirectly depended on research (Cleophas et al, 2009). They believe that the treatments prescribed for them will effectively improve their condition (Machin et al, 2009). This however relies on the existence of a strong evidence-base from which to justify practice (Machin et al, 2009; Cleophas et al, 2009). One area of physiotherapy research previously neglected is that of the management of people following patellar dislocation.

Patellar dislocation occurs when the patella or knee cap fully disengages from the femoral or trochlear groove resulting in a total loss of joint contact (Dejour et al, 1994). The principal mechanism of injury is commonly a combined motion of femoral internal and tibial external rotation during a quadriceps contraction when the knee is in near terminal extension (Hinton and Sharma, 2003; Bassi and Kumar, 2003). Thus, a patellar dislocation is commonly associated with football, rugby and dancing, particularly during cutting and twisting activities (Sillanpää et al, 2008a; Atkin et al, 2000; Fithian et al, 2004a). Given this aetiology, it is not surprising that patellar dislocations are most frequently seen in younger individuals. The estimated incidence of this disorder is 29 per 100,000 people per year, with a marginally greater incidence in females (Fithian et al, 2004a; Atkin et al, 2000; Rünow, 1983). Whilst this therefore affects a small proportion of the population, patellar instability is a disabling condition, limiting an individual's social and occupational aspirations especially through recurrent patellar dislocation and subluxation events (Atkin et al, 2000; Grelsamer, 2000).

Physiotherapy is considered the 'main-stay' treatment for people following a patellar dislocation (Grelsamer, 2000; Cofield and Bryan, 1977; Cash and Hughston, 1988). The literature has advocated a number of different rehabilitation modalities to treat these individuals. These have included electrotherapy treatments, taping techniques, bracing or splinting, and gait re-education (Helgeson and Smith, 2008; Osterhues, 2004; Racouillat, 2007; Palmu et al, 2008; Sillanpää et al, 2009a). Exercise prescription is considered the principal treatment strategy, with quadriceps strengthening exercises regarded as the most important type of exercise (Woo and Busch, 1998; Cofield and Bryan, 1977; Cash and Hughston, 1988). These exercises are purported to rehabilitate patellar control and stability by optimising the power and synchronicity of recruitment of all the quadricep muscles (Scudero and McCann, 2005; Solomon et al, 2001). Some authors, however, have hypothesised that the most distal portion of the vastus medialis muscle, the vastus medialis oblique (VMO), should be targeted through specific VMO exercises (Howell, 2002; Solomon et al, 2001). This was based on the premise that this muscle controls lateral patellar translation, thus reducing patellar instability symptoms (McConnell, 2007; Scudero and McCann, 2005; Solomon et al, 2001).

In the majority of cases, people treated with physiotherapy following a first-time patellar dislocation (FTPD) demonstrate a good functional outcome (Smith et al, 2010; Nikku et al, 2005; Buchner et al, 2005; Palmu et al, 2008). A large proportion of these individuals return to a comparable pre-injury functional level, with minimal pain and good range of motion (Sillanpää et al, 2009a; Palmu et al, 2008; Buchner et al, 2005; Hawkins et al, 1986). However approximately 35% experience recurrent dislocation events (Cash and Hughston, 1988; Nikku et al, 2005; Mäenpää and Lehto, 1997a; Smith et al, 2010). Surgical intervention may be considered for these people to prevent longer-term recurrent instability symptoms (Scuderi, 1995; Beasley and Vidal, 2004). Alternatively some may be re-referred to

physiotherapy to further improve patellar stability using conservative, non-surgical interventions (Andrish, 2008).

A number of knee-specific instruments have been used to evaluate outcomes following patellar dislocation. These have included the Fulkerson Patellofemoral Score (Fulkerson and Shea, 1990), the International Knee Documentation Committee Form (Hefti et al, 1993), the Lysholm Knee Score (Lysholm and Gillquist, 1982), and, most frequently within the patellofemoral literature, the Kujala Patellofemoral Disorder Score (Kujala et al, 1993). However, these instruments were initially designed to evaluate other knee disorders such as patellofemoral pain syndrome (PFPS), osteoarthritis and anterior cruciate ligament rupture rather than patellar instability (Paxton et al, 2003). At the commencement of this study, no documented scoring system had been devised to assess symptomatic patellar instability. Therefore, there was no outcome measurement which specifically assessed the predominant symptom and functional limitation for this population (Donell, 2006).

When assessed in its entirety, both the quality and quantity of the evidence-base relating to the physiotherapy management of individuals following FTPD was limited. A total of three publications, all single-case reports, had previously described the physiotherapy assessment and treatment strategies used for this population (Helgeson and Smith 2008; Osterhues, 2004; Racouillat, 2007). Based on the available evidence, three key areas were identified for further study on this topic. Firstly, it was unknown which treatments physiotherapists typically use to manage individuals following FTPD. Secondly, whilst a proportion of people who experience a FTPD continue to experience instability and dislocation symptoms, an outcome measure had yet to be devised to assess symptomatic instability. Finally, no clinical trials had been conducted to assess the effectiveness of physiotherapy treatments used to manage people following FTPD.

Accordingly, the purpose of this programme of study was to begin to address these limitations.

1.2 Study Objectives

The three broad research priorities were formalised into study objectives. These were to:

- Determine the current practices of musculoskeletal physiotherapists when managing people following FTPD.
- Devise an outcome measure to assess people's perceived patellar instability.
- Determine whether people should be prescribed general quadriceps exercises or specific-VMO exercises following FTPD.

In order to address these objectives, three specific research questions were constructed adopting two different research approaches.

1.2.1 Study One – National Survey Study

The first question posed in this study was: how do senior musculoskeletal physiotherapists working in the United Kingdom's National Health Service (NHS) manage individuals following FTPD.

Three hundred and six NHS acute hospitals with an accident and emergency and/or an orthopaedic department were surveyed using a 14 question self-administered postal questionnaire. Data collected included: grade of physiotherapist, frequency of patellar instability referrals, assessment, treatment, onward referral, and where people were typically discharged to following treatment.

After piloting this questionnaire, it was sent to superintendent physiotherapists in eligible hospitals. They acted as gate-keepers, passing the questionnaire to either the clinician with the most clinical experience of managing this population or to a senior physiotherapist with a special interest in patellar dislocation. Two reminder letters were sent to non-respondents at three-week intervals.

On completion, the survey response rate was 59%. Respondents indicated that FTPD was not a common musculoskeletal disorder managed by NHS physiotherapists, constituting an average of two percent of caseloads. The results suggested that physiotherapists most commonly assess for quadriceps or VMO capability, patellar maltracking, excessive patellar glide or effusion in their patients following FTPD. The most common treatments were reassurance, proprioceptive exercises, knee motion, quadriceps and specific-VMO exercises. Closed-kinetic chain exercises were more commonly prescribed than open-kinetic chain quadricep exercises.

The results of this survey indicated which interventions physiotherapists used. However given the previous paucity of literature, further study was indicated to assess the efficacy of these assessment, treatment and evaluative interventions. Therefore people following FTPD were managed by UK acute hospital NHS physiotherapists with interventions which have not been empirically investigated. This highlighted the need for further research.

1.2.2 Study Two – Instability Activity Survey

The second research question was: during what activities and to what frequency do people with patellar instability perceive their patella to be unstable?

Ninety individuals referred to participating orthopaedic and physiotherapy departments with symptomatic recurrent patellar instability were asked to assess the frequency with which they perceived their patellar instability. Recruitment was stratified by age and gender.

A paper questionnaire was constructed detailing 19 activities of daily living and recreational-sporting tasks which previous authors and anecdotal clinical experience had indicated as potentially associated with patellar instability. The respondents were provided with space within the questionnaire to identify additional activities not initially listed. The questionnaire was subjected to testing of face validity and intra-rater reliability prior to being more widely distributed.

The findings indicated that sporting and multi-directional twisting activities were associated with greater symptoms of patellar instability compared to lower energy, uni-planar activities. Females and those without a family history of patellar instability more frequently experienced symptoms of patellar instability compared to males, or those with a family history.

This study indicated the activities which individuals associated with patellar instability. It also highlighted that further study was necessary to determine whether these results could be generalisable to individuals with milder subluxation disorders. Additionally investigations of whether factors such as hypermobility could have an impact on perceived patellar instability in a larger cohort were indicated.

Further work allowed each of the 19 activities to be ranked and weighted to differentiate between those activities which caused the greatest compared to the least symptoms of patellar instability. Hence it was possible to construct a weighted, self-administered 19 item questionnaire to assess individual's perceived symptoms of patellar instability. This was subsequently titled the Norwich Patellar Instability (NPI) score.

1.2.3 Study Three – A Randomised Controlled Trial Assessing Quadriceps versus Specific-VMO Exercises

The final research question addressed in this thesis was: is there a difference in functional outcomes during the first six months post-dislocation between people following FTPD who are prescribed general quadricep strengthening exercises compared to specific-VMO strengthening exercises?

Twenty-seven people following FTPD were randomly allocated to receive either general quadriceps exercises and a rehabilitation regime or specific-VMO exercises and a rehabilitation regime. The primary analysis was the between-group assessment of Lysholm Knee Score at six weeks. Secondary outcomes included Tegner Level of Activity Score, Short Form-12 (SF-12), NPI score, isometric knee extension strength, recurrent patellar dislocation and duration to first recurrent dislocation. The cohort was followed-up at six weeks and six months following randomisation.

The results indicated that whilst there was a statistically significant difference between the groups with better function scores for the general quadriceps group in Lysholm Knee Score at six weeks ($p=0.02$), this was not a clinically significant difference. There was no statistical or clinically significant difference between the groups for the other outcome measurements except Tegner Level of Activity Score which was significantly greater in the general quadriceps group at six weeks. Whilst the NPI score demonstrated responsiveness to change and correlated to clinical measurements at the six week assessment, it presented with a high floor-effect for a number of questions related to less physically demanding activities.

The randomised controlled trial (RCT) presented a number of major limitations. Principally the sample recruited was underpowered with lower than expected recruitment rates and higher loss to follow-up. Further study is recommended to continue to recruit the 50 participants required for adequate power. Finally, further examination of the properties of the NPI questionnaire is warranted to explore how this outcome measure behaves for other patellar instability populations, and over a longer follow-up period.

1.3 Justification on the Staging of the Programme of Study

The development of this programme of study was iterative. Hence the findings of the national survey indicated how physiotherapists assessed the outcomes of individuals following FTPD, and found that no outcomes were adopted to evaluate symptoms of patellar instability. Thus the second study constructed the NPI score. Furthermore, the national survey indicated that physiotherapists used both general quadriceps and specific-VMO exercises. This provided the rationale for assessing this domain with a RCT as clinical equipoise had been demonstrated. The survey findings regarding the methods of identifying, assessment and treating individuals following FTPD were used to inform the design of the RCT. Hence the pragmatic design of the study enhanced the generalisability of subsequent results to UK physiotherapists. Lastly by constructing the NPI score before commencing the RCT, it was possible to assess the criterion validity of the NPI score to other outcome measurements and its responsiveness to change in the individuals recruited.

1.4 Thesis Outline

This thesis is structured to reflect the order in which studies were conducted. It consists of six sections:

Section One - Introduction (Chapter 1)

Section Two - Literature Review (Chapters 2 to 6) – This section presents the current evidence-base pertaining to patellar dislocation. After presenting the literature review's search strategy (Chapter 2), an assessment of the literature surrounding the epidemiology and pathophysiology of patellar dislocation is made (Chapter 3). The literature pertaining to the assessment (Chapter 4) and treatment (Chapter 5) of people following FTPD is critically appraised to determine the current knowledge-base on the conservative management of this condition. Finally, an evaluation of the electromyographic studies which have assessed whether the VMO can be preferentially recruited in both symptomatic and asymptomatic participants is presented (Chapter 6).

Section Three – National Survey Study (Chapters 7 to 9) – This section discusses and justifies the methodological approaches and procedures adopted, analysing the strengths and potential weaknesses for this survey study (Chapter 7). The results of the survey are presented (Chapter 8). A discussion regarding the clinical and research implications and an assessment of the methodological limitations and areas for further study is presented (Chapter 9).

Section Four – Instability Activity Survey and Construction of the NPIS (Chapters 10 to 13) – This section discusses the rationale and decision-making made during the design of the activity survey study (Chapter 10). Descriptive and inferential statistical analyses are made in the Results section (Chapter 11). The results are further interpreted in the Discussion section, considering the clinical and research implications, in addition to methodological limitations and areas for further study (Chapter 12). The final chapter of this section presents the methods and decisions made during the construction of the NPI score based on the activity survey's findings (Chapter 13).

Section Five – RCT of quadriceps versus specific-VMO exercises (Chapters 14 to 16) – In this section the concepts and decisions considered during the design of the RCT are presented (Chapter 14). The methodological approach and procedures are discussed and results of the trial presented (Chapter 15). The implications of these results are discussed and interpreted in the Discussion (Chapter 16). Clinical implications of the RCT and how these relate to previous theoretical knowledge are discussed and an appraisal of the study's methodological processes, and areas for further study are addressed.

Section Six – Thesis Conclusions (Chapters 17 and 18) - This section summaries clinical and research implications of this programme of study. An overview of the potential impact on the management of this population is presented and further recommendations for future research are also presented. Finally a protocol for the conduct of a feasibility is presented based the limitations discussed to the thesis and particularly the RCT, to take this body of work forward.

1.5 Summary

Patellar dislocation is a disabling musculoskeletal condition. On commencing this programme of study, the evidence-base surrounding the physiotherapeutic management of this disorder was sparse. The purpose of this thesis was to describe and discuss three studies which were undertaken to begin to address this dearth in the literature.

In this first section, the rationales for the study's objectives and methodological designs have been presented. The following section will examine the evidence-base on which the programme of study was underpinned. An analysis of the current evidence-base will be made to

further justify the importance of these studies and to provide a rationale for their conduct at the time of conception.

Section Two

Literature Review

Chapter 2. Overall Literature Review Search Strategy

2.1 Introduction

A comprehensive literature review is essential before embarking on any research (Egger et al, 2000). This process ensures that future studies are developed from an understanding of the existing evidence-base (Egger et al, 2000). It is therefore imperative that all relevant literature is first identified and critically appraised to fully appreciate current knowledge on this thesis's topic.

This chapter presents the search strategies used to gather the literature discussed. This has been divided into the key areas of investigation (Section 2.2), sources of literature (Section 2.3), search terms adopted (Section 2.4), eligibility criteria (Section 2.5) and methods of synthesis (Section 2.6).

2.2 Areas of Investigation

The aim of the literature review was to assess five principal areas.

- Terminology and nomenclature surrounding patellar dislocation, subluxation and instability.
- Aetiology and epidemiology of FTPD.
- Assessment method for individuals who have experienced a patellar dislocation.
- Conservative and physiotherapy treatment strategies used in the management of FTPD.
- Evaluation of the evidence pertaining to preferential VMO recruitment.

2.3 Sources of Literature

Specific search strategies were constructed using a variety of methods to identify all pertinent literature. A computerised search strategy was initially performed using all relevant electronic databases. These included the databases: Allied and Complementary Medicine Database (AMED) (1985 to December 2011), British Nursing Index (1985 to December 2011), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (1982 to December 2011), Excerpta Medica Database (EMBASE) (1974 to December 2011), Medical Literature Analysis and Retrieval System Online (MEDLINE) (1950 to December 2011) and PsycINFO (1806 to December 2011) via Ovid. Scopus, the Physiotherapy Evidence-base Database (PEDro) and the Cochrane Library were also searched on their specific search platforms. These subject-based electronic databases were appropriate given their relevance to medical and physiotherapy rehabilitation. However these electronic databases only cited published literature. In order to prevent the potential for publication bias from impacting on the literature review, a search of key unpublished or grey literature databases was also performed. These searches included accessing the databases: OpenGrey (System for Information on Grey Literature in Europe), National Technical Information Service, the World Health Organisation (WHO) International Clinical Trials Registry Platform, Current Controlled Trials, UK Comprehensive Research Network (CRN) Portfolio Database, and the UK National Research Register Archive. These latter databases of trial registers were reviewed to ensure the inclusions of studies which were either on-going or unpublished.

Conference proceedings from the British Orthopaedic Association Annual Congress, the British Trauma Society meetings, European Federation of National Associations of Orthopaedics and Traumatology meetings (EFORT), British Association for Surgery of the Knee, Physiotherapy Research Society and the World Confederation for Physical Therapy were also searched. This was to ensure that studies which may not have been published as full-texts but presented at conference in abstract form were

identified and included in the review (Centre of Reviews and Dissemination, 2008).

Additionally specialist journals were hand searched. These included: The Knee (1994-December 2011), American Journal of Sport Medicine (1987-December 2011); the British Journal of Sports Medicine (1987-December 2011); and the Journal of Electromyography and Kinesiology (1991-December 2011). This was to ensure that papers would not be missed due to citation error from the electronic databases (Centre of Reviews and Dissemination, 2008).

A review of relevant textbooks was undertaken. The libraries at the University of East Anglia, the Norfolk and Norwich University Hospital, and Addenbrooke's Hospital, Cambridge were accessed and references and bibliographies from each textbook and pertinent full-text manuscripts were scrutinised for any previously missed studies or texts which were not identified from earlier searches (Pope et al, 2007).

Finally all corresponding authors for each identified paper were contacted to identify any publications which had not been previously highlighted through the search strategies. This was essential to identify research not registered by electronic databases or through trial databases (Pope et al, 2007).

This strategy minimised the chance of omitting any important studies (Glasziou et al, 2001). Furthermore, the inclusion of studies from both published and unpublished data sources reduced the potential for publication bias (Song et al, 2010).

2.4 Search Terms

The specific search terms used were dependent on the literature review aim (Section 2.2) and the electronic database investigated. The search terms adopted for the MEDLINE databases for each literature review aim is

presented in Appendix 1. This demonstrates the search terms were constructed into 'concepts' (Centres of Reviews and Dissemination, 2008) using the Population, Intervention, Comparator, Outcomes and Design subdivisions (Pope et al, 2007). To maximise the search, a combination of text terms and MeSH headings were adopted with the Bolean operators AND, OR and NOT. This was justified in order to ensure that all potentially relevant literature was identified given the 'systematic' nature of the review process.

2.5 Eligibility Criteria

Papers were included if they: presented information regarding the anatomy, aetiology, epidemiology, natural history, assessment, treatment or evaluation of people who had experienced patellar dislocation or instability. Full-text papers printed in any language were included to prevent bias in paper selection due to language restriction. Papers presenting childhood, adult or cadaver cohorts were also included to ensure a full representation of the life-cycle of patellar dislocation in this population.

Papers were excluded if they: only assessed animal studies, or if they solely presented information pertaining to other patellofemoral disorders such as PFPS or patellofemoral joint osteoarthritis, not related to dislocation or instability events.

2.6. Method of Synthesis

The eligibility of each paper and text was determined in relation to each of the five principles described in Section 2.2. All literature was then reviewed and appraised by the author (*now referred to as the 'researcher'*) and synthesised in narrative form to inform the discussions presented in each literature review chapter (Chapter 3 to Chapter 6).

2.7 Summary

This chapter has detailed the search strategy adopted to identify the literature which informed this thesis' literature review. The following chapter will use these search results to consider the pathogenesis of FTPD.

Chapter 3. First-Time Patellar Dislocation

3.1 Introduction

A summary discussing the anatomy, embryology, function and biomechanics of the patellofemoral joint is presented as background information in Appendix 2. In this, the patellofemoral joint is described as consisting of osseous, contractile and non-contractile structures (Weber-Spickschen et al, 2011). When any one of these is impaired, damaged or developmentally compromised, individuals may experience patellofemoral joint symptoms (Trica and Alicea, 1995). This thesis examines one such pathology, patellar dislocation. In this chapter, the nomenclature (Section 3.2), epidemiology (Section 3.3), aetiology (Section 3.4) and classification (Section 3.5) of FTPD will be examined based on the current evidence-base.

3.2. Nomenclature

A patellar dislocation occurs when the patella fully disengages from the trochlear groove, with a total loss of joint contact between the patella and the femoral articular surface (Dejour et al, 1994). Patellar subluxation is defined as an abnormally located patella, where a part of the articular surface remains engaged with the trochlear groove (Inoue et al, 1988; Jafaril et al, 2008). This may be a transient subluxation, associated with a traumatic history, or a habitual subluxation, where the patella dislocates on every cycle of knee flexion (Boden et al 1997; Hutchinson and Ireland, 1995; Sillanpää, 2009). The term patellar instability is a generic term to encompass patellar subluxation, patellar dislocation or to categorise those individuals who report generalised instability symptoms (Aglietti et al, 2001; Grelsamer, 1997; Grelsamer, 2000).

A number of terms have been adopted to classify a patellar dislocation. Authors have used nomenclature such as acute, primary or recurrent without specifying

the time or frequency of injury (Sillanpää, 2009). For instance, the term acute patellar dislocation can be used to describe a first-time or secondary dislocation which occurred in the recent past. Therefore there remains debate over the specific definition of patellar instability (Holmes and Clancy, 1998; Post et al, 2002; Grelsamer, 1997). Nonetheless, there appears some consensus that the terms 'primary' or 'FTPD' represent the actual first time a patellar dislocation occurs (Sillanpää, 2009). When a dislocation has occurred previously, the subsequent dislocations can be termed 'secondary' or 'recurrent' (Sillanpää, 2009).

Throughout this thesis the term FTPD has been adopted to refer to the very first time that a patellar dislocation occurs with no previously reported or recorded episodes of patellar dislocation.

3.3 Epidemiology

The exact incidence of a FTPD remains unknown. Four studies have attempted to assess the incidence, risk factors and natural history of patellar dislocation (Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a; Hsiao et al, 2010). Atkin et al (2000) surveyed a North American healthcare service, which provided health cover for 367,335 people, over a two-year period. Surveillance was then continued over a further four-year period by Fithian et al (2004a). Sillanpää et al (2008a) investigated the incidence, nature and risk factors of FTPD with 128,714 Finnish male armed forces conscripts. They used the Finnish conscript services database and national hospital discharge registers. The final study by Hsiao et al (2010) assessed patellar dislocation with all members of the United States of America (USA) Military Service on active duty between 1998 to 2007 using the Defence Medical Surveillance System.

The overall incidence of FTPD was estimated by Atkin et al (2000) as seven per 100,000 people per year. This was lower than Sillanpää et al's (2008a)

estimation of 77.4 per 100,000 per year. Hsiao et al (2010) unusually calculated incidence by 1000 person years, reporting a risk of patellar dislocation of 13,443,448 person years. However they were unable to distinguish between the rate of recurrent and FTPD due to their retrospective database analysis methods.

All the studies reported that patellar dislocations most commonly occurred in younger age groups. Atkin et al (2000) reported the average age of a FTPD as 19.9 years (11 to 56 years). This was supported by Sillanpää et al's (2008a) population whose mean age was 20 years (18 to 23 years). Fithian et al (2004a) reported that younger people were at greatest risk of experiencing a FTPD with 29 per 100,000 in the 10 to 17 year old group, compared to one per 100,000 in the 30 plus years age group. This trend was also reflected by Hsiao et al's (2010) which reported patellar dislocation as highest in the under 20 year age group, who were 84% more likely to experience a patellar dislocation when compared to the over 40 year cohorts (Incidence Rate Ratio (IRR): 1.84; 95% CI: 0.61, 2.10).

It has been suggested that there is a greater incidence of FTPD in females compared to males (Boden et al, 1997). This is largely attributed to the increased distance between the female anterior superior iliac spines, creating a larger force vector for greater lateral translational force during quadriceps contraction (Rünow, 1983). However, such a hypothesis has yet to be substantiated with long-term, sufficiently large cohort studies (Garth et al, 1996; Fulkerson, 1997; Kasim and Fulkerson, 2000; Kujala et al, 1989). The epidemiological studies appeared inconclusive for a difference in gender. Both Hsiao et al (2010) and Fithian et al (2004a) reported an incidence of 33 per 100,000 in younger females compared to 25 per 100,000 in the comparable male group. Similarly Hsiao et al (2010) reported that females were 61% more likely to experience a patellar dislocation compared to males (IRR= 1.61; 95% CI: 1.53, 1.69). There was however an equal risk between genders in the older

age group. Since Sillanpää et al (2008a) only assessed male conscripts, the effect of gender could not be determined.

There appeared consensus that the mechanism of injury for a FTPD was associated with sporting or physically demanding pursuits. Atkin et al (2000) reported that 53 people (72%) of their FTPD cohort had experienced a FTPD during sporting activities, and 35 (66%) injuries associated with cutting or pivoting manoeuvres. In Fithian et al's (2004a) cohort, 76 people (61%) reported that their FTPD occurred during sporting activities. All subjects in Sillanpää et al (2008a) associated all their reported FTPDs to physically demanding activities. The most common mechanism of injury was a low-level fall in 21 people (29%), near-fall with valgus knee stress in 20 people (27%), collision with another person in 16 (22%) and during military exercises or sporting activities such as wrestling, climbing, weight lifting, or combat training in 16 people (22%). Sillanpää et al (2008a) reported that knee flexion with the tibia in a valgus position was the principal position of injury (93%), whilst a direct impact to the knee from falling to the ground reported in remaining individuals.

Historically, the typical description of a person who experiences a FTPD was a moderately overweight adolescent (Beasley and Vidial, 2004; Stanitski, 2003). However this notion is largely unsubstantiated by the epidemiological evidence (Stanitski and Paletta 1998; Atkin et al, 2000; Fithian et al, 2004a). Only Sillanpää et al (2008a) assessed body morphia, reporting that people who sustained a FTPD were significantly taller ($p=0.03$). Additionally those who weighed more than 77 kilograms (kgs) were significantly more likely to sustain a patellar dislocation compared to those who weighed less than 73kgs ($p=0.02$; Sillanpää et al, 2008).

These epidemiological studies presented a number of major limitations. Whilst providing useful information on the population's characteristics, both Atkin et

al's (2000) and Fithian et al's (2004a) studies only provided this information on individuals who had sufficient funds to subscribe to this health scheme. Whether socio-economic factors are important in the incidence or epidemiology of people with patellar dislocation remains unclear. Hsiao et al (2010) and Sillanpää et al's (2008a) provide important information in a higher risk age group who routinely undertook physically demanding activities. However this may not be typical of the general public. Since these military recruits are required to participate in rigorous, physically demanding activities, this may account for the higher prevalence of patellar dislocation compared to Atkin et al (2000) or Fithian et al's (2004a) results. Similarly since Sillanpää et al's (2008a) cohort consisted of males, it remains unclear whether these results were comparable to female recruits who undergo the same military training. Due to the self-selecting nature of this study, the external validity of the findings may be questioned.

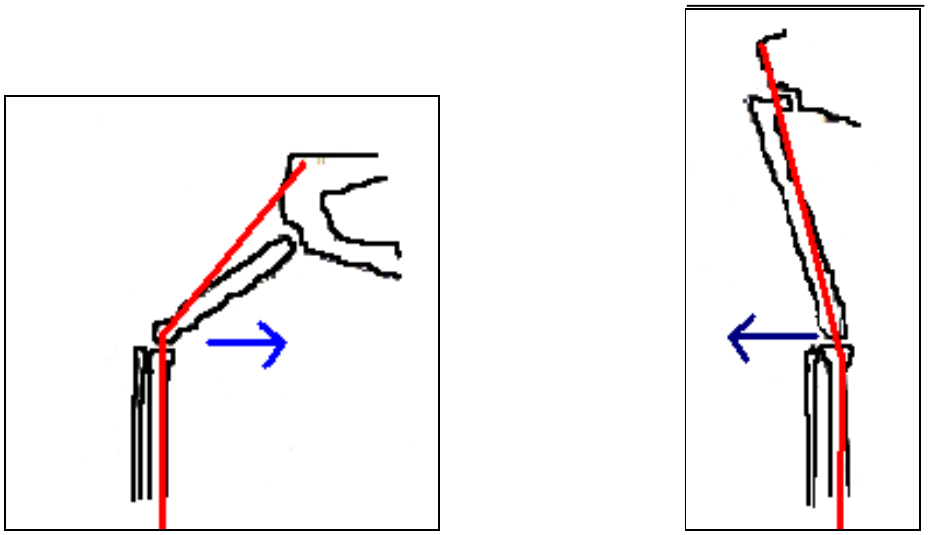
3.4 Aetiology

The patella most commonly dislocates laterally (Dath et al, 2006). This is predominantly due to proposed evolutionary changes as humans have adopted bipedal locomotion (Tardieu and Dupont, 2001; Tardieu and Trinkaus, 1994). This form of locomotion resulted in an increase in quadriceps vector, the line from the anterior superior iliac spine to the centre of the patella, down though the patellar tendon to the tibial tuberosity (Miller et al, 1997a). This angle increases in standing (Hsu et al, 1993). Through bipedal gait, the lateral vector forces the patella to translate laterally. This therefore predisposes lateral as opposed to medial patellar displacement (Figure 3.1; Woo and Busch, 1998).

Patellar dislocation occurs when the patella disengages from the trochlear groove. This may be due to a weakness of the medial soft-tissue restraints, reduced patella-trochlear groove congruency, excessive lateral soft-tissue

forces, or altered proximal or distal biomechanics to increase the lateral force vector (Dejour et al, 1994; Boden et al, 1997; Hutchinson and Ireland, 1995). Accordingly a number of anatomical structures are associated with a lateral patellar dislocation. These can be subdivided into: (1) osseous structures, (2) medial, and (3) lateral soft-tissue structures.

Figure 3.1. A schematic depiction of quadrupedial compared to bipedal femoral obliquity predisposing lateral patellar dislocation.



Quadrupedial Gait **Bipedal Gait**

3.4.1 Osseous Stabilisers

Osseous stability primarily originates from the trochlear groove. The main osseous causative factors for patellar dislocation are trochlear dysplasia and an excessive distance between the tibial tubercle to trochlear groove (Dejour et al, 1994). Secondary factors include excessive femoral anteversion, genu recurvatum and genu valgum (Van Huyssteen et al, 2006).

Trochlear dysplasia is characterised as an underdeveloped trochlear groove which is shallow or convex in shape (van Huyssteen et al, 2006; Bollier and Fulkerson, 2011; Donell et al, 2006). The reduced trochlear depth is principally derived from a reduced height in the lateral femoral condyle (Donell et al, 2006; Hing et al, 2006). In these individuals, there is an insufficient trochlear groove to restrict abnormal lateral patellar movement particularly during early knee flexion (Dejour et al, 1994; Fucentese et al, 2006; Schöttle and Weiler, 2007; Fucentese et al, 2007).

Trochlear dysplasia has been reported to present in 29% to 85% of individuals with patellofemoral instability (Dejour et al, 1994; Atkin et al, 2000). Although these case series were conducted in different countries (France and the USA), there were little methodological differences to justify this large discrepancy between the estimates. Literature has debated the aetiology of trochlear dysplasia, linking this anatomical variance to two factors (Fucentese et al, 2006). Firstly, some authors have suggested that trochlear dysplasia may have a hereditary or genetic origin (Garron et al, 2003; Tardieu and Dupont, 2001; Gray and Gardner, 1950; Fucentese et al, 2006). Others have argued that asymmetry of the femoral groove is an epigenetic developmental feature and, as such, a consequence of bipedal locomotion in some individuals (Tardieu and Dupont, 2001; Tardieu and Trinkaus, 1994). These suggestions are, however, based on anecdotal evidence rather than large epidemiological or anthropological studies which have yet to assess this.

A number of secondary osseous factors have also been suggested to predispose individuals to patellar dislocation. Lateralisation of the tibial tubercle may influence the force vector of the patella via its intimate relationship to the patellar tendon (Fulkerson and Shea, 1990; Grelsamer, 2000; Mears and Cosgarea, 2001). If the patellar tendon is naturally oblique or lateralised, the direction of the line of force on the patella is lateral, contributing to a lateral excursion of the patella (Grelsamer and Klein, 1998; Grelsamer, 2000).

Normally the trochlear groove constrains the patella from lateral transposition once it has engaged. Since the patella normally engages in the groove from 20° to 30° knee flexion, the integrity and balance of the soft-tissues from full extension to this angle is a determining factor for stability. For people who have abnormally long patellar tendons, patella alta, the patella may not engage within the trochlear groove until 40° to 60° of knee flexion (McManus et al, 1979; Lancourt and Cristini, 1975; Caton and Dejour, 2010; Simmons and Cameron, 1992; Singerman et al, 1994). Accordingly, there may be a greater predisposition for these people to experience a patellar dislocation with reduced osseous stability during typical knee motion (Fithian et al, 2004a; Grelsamer, 2000; Brattström, 1970).

The importance of the osseous structures in preventing patellar instability was highlighted by Dejour et al (1994). They reviewed 143 knees awaiting operative management for patellar instability. The authors reported that trochlear dysplasia was evident in 85% of symptomatic knees, tibial tubercle lateralisation of at least 20 millimetres was evident in 56%, whilst patella alta presented in 24% of the cohort. Whilst osseous factors may therefore appear important, the radiological measurement for the detection of these features, particularly the crossing sign and boss height for trochlear dysplasia, demonstrate limited reliability and validity (Smith et al, 2011a; Dejour et al, 1994; Kujala et al, 1989; Koskinen et al, 1993; Teitge et al, 1996; Inoue et al, 1988; Dowd and Bentley, 1986; Neyret et al, 2002; Walch and Dejour, 1989). Furthermore, anecdotally people frequently present with bilateral predisposing osseous features of patellar dislocation, but are however only symptomatic unilaterally (Simon Donell, personal communication, 2011). This finding has not been described in the literature but further complicates the interpretation of the importance of such osseous factors on the pathogenesis of FTPD.

3.4.2 Lateral Stabilisers

Little has been published on the role of the lateral retinaculum and lateral soft-tissues in individuals who have experienced a FTPD. Authors of review papers and commentaries have nonetheless suggested that people who experience lateral patellar dislocation present with a relatively tighter or shortened lateral retinaculum than normal to contribute to patellar lateralisation (McConnell, 2007; Grelsamer, 2000). It remains unclear whether atrophy of the medial contractile structures allows the lateral structures to shorten, or whether the greater mechanical advantage required to overcome this lateral translation can 'fatigue' contractile medial structures leading to muscle atrophy (McConnell, 2002). If such a mechanism occurs this could predispose an imbalance between the medial and lateral structures to contribute to patellofemoral instability. However, these are hypothetical mechanisms and future clinical trials using electromyographic (EMG) analysis and dynamic magnetic resonance imaging (MRI) are required to evaluate these relationships.

3.4.3.1 Medial Stabilisers - Passive Soft Tissue Structures

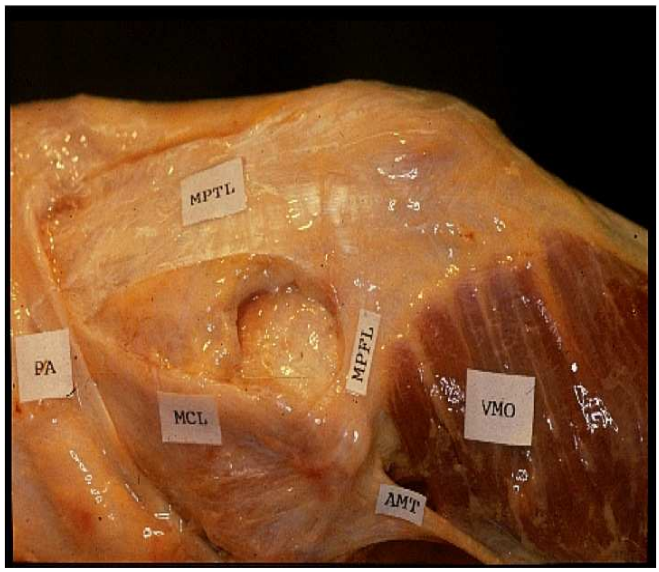
The medial structures which restrain lateral patellar displacement include: the medial patellomeniscal ligament, medial patellotibial ligament, medial patellofemoral ligament (MPFL; Figure 3.2), and the medial retinaculum (Panagiotopoulos et al, 2006; Appendix 2).

Cadaver studies have detailed the contribution of each structure in resisting lateral patellar translation. Through these, the MPFL provides approximately 50% of the tibial restraining forces, whereas the medial patellomeniscal ligament, medial patellotibial band and medial patellotibial ligament contribute 20%, 15% and 15% respectively (Conlan et al, 1993; Deie et al, 2005; Smirk and Morris, 2003; Desio et al, 1998). The MPFL has therefore been considered

the major soft-tissue stabiliser to lateral patellar dislocation (Deie et al, 2005; Smirk and Morris, 2003; Conlan et al, 1993; Desio et al, 1998).

Figure 3.2. A picture of a dissection-prepared knee, demonstrating the oblique fibres of the vastus medialis, and proximity of the MPFL to the distal vastus medialis and patella.

Distal → **Proximal**



Permission obtained for the use of this image from Dr Yrjänä Nietosvaara, the Hospital for Children and Adolescents, Helsinki University Central Hospital, Finland

The MPFL is ruptured in approximately 50% of individuals following patellar dislocations (Sallay et al, 1996; Sanders et al, 2001; Shea et al, 2006). However, recent studies have suggested that this could be as high as 90% to 100% of cases (Balcarek et al, 2010; Sillanpää et al, 2009b). These more recent estimates may be attributed to an increased awareness of this injury and improvements in MRI Tesla field-strength imaging (Balcarek et al, 2011a; Sillanpää et al, 2009b; Smith et al, 2011a). The MPFL acts as a passive check-rein. Additionally, Boden et al (1997) speculated that it may also provide

proprioceptive feedback to enhance the dynamic stability of the patella. Whilst Jerosch and Prymka (1996a; 1996b) demonstrated that knee joint proprioception is reduced in individuals following patellar dislocation, it remains unclear whether injury, principally to the MPFL, is associated with reduced sensory stabilisation.

Some authors have questioned the existence of the MPFL (Reider et al, 1981). Whilst Reider et al (1981) could not identify a MPFL in 13 of their 20 cadavers, Conlan et al (1993) identified the MPFL in 29 of their 30 cadaver knees assessed. Similarly Desio et al (1998) identified the MPFL in all nine cadavers they examined in their anatomical series. The latter reported the size of the ligament varied between knees (Desio et al, 1998). Whether the existence of the MPFL and its size or anatomical position are important as pathological indicators to patellar dislocation, remains unknown since these studies only examined healthy control knees, and not knees with a history of patellar dislocation.

Sevanongse et al (2003) assessed the force displacement relationship between medial and lateral patellar translation. In a biomechanical study of eight human cadaver knees, the quadriceps were loaded with 175 Newtons of tension replicating normal human activity whilst knees were positioned in zero, 10°, 20°, 30°, 45°, 60° and 90° of flexion. These authors reported a significant difference between passive lateral and passive medial restraining forces at 10 millimetres of displacement. For lateral displacement, the restraining forces was least at 20° flexion, but increased to 125 Newtons at zero and 90° knee flexion. Accordingly this finding would suggest that lateral patellar displacement is predisposed to occur at 20° knee flexion due to reduced medial soft tissue restraint. Whether these results can be directly generalised to living humans is questionable, and such a study would be harmful and thus unethical if performed in humans. Therefore Sevanongse et al's (2003) study may be the

best reflection of the normal relationships between force and patellar displacement.

3.4.3.2 Medial Stabilisers - Active Soft Tissue Structures

The principal contractile soft-tissue structure associated with patellar stability is the distal vastus medialis or VMO. Some authors have argued that the distinction of the VMO and vastus medialis longus (VML) to two separate anatomical structures is incorrect, suggesting that these muscles are a single entity (Glenn and Samojla, 2002; Jojima et al, 2004). Anatomists and surgeons have cited a number of factors to distinguish whether the vastus medialis is one or two independent muscles (Hubbard et al, 1997; Salmons, 1995). These factors have included the identification of different muscle fibre alignment in two distinct lines of action (Weinstabl et al, 1989), the presence of a fibrofascial plane to indicate a structural boundary between two discrete components (Javadpour et al 1991; Travnik et al, 1995), and separate innervations to allow the VML and VMO to exhibit different contraction onset timings (Glenn and Samojla, 2002; Jojima et al, 2004; Lieb and Perry, 1971; Terry, 1989).

Nineteen studies have investigated the difference in morphology between the VMO, VML and vastus medialis complex. The results of these studies are presented in Table 3.1. Twelve studies have investigated for a difference in fibre alignment within the length of the vastus medialis. All but one study reported greater obliquity in fibre alignment of the VMO to the VML. There was no clear methodological reason to account for the difference between Glen and Somojla's (2002) findings and the other eleven studies. Overall VMO fibre orientations ranged from 40° to 77°, with a mean fibre angle of 50°. In comparison the fibre orientation of VML ranged from 12° to 35°, with a mean fibre orientation of 22°.

Eleven studies investigated the presence of a fibrofascial plane. Of these, six reported the presence of this anatomical structure, although not consistently seen in all cadavers in these series. Finally, 11 studies have examined the vastus medialis' innervation. These indicated that there was no consistency in the existence of a separate innervation to the VMO and VML when MRI or cadaveric studies were assessed. Accordingly, with the exception of a definite change in fibre alignment which itself may alter the force applied to the patella from the VML, there is limited evidence to support the VMO being described as a separate anatomical entity. However only Bose et al's (1980) study assessed vastus medialis morphology in 10 knees which had experienced patellar dislocation. It is therefore unclear whether there is a difference in anatomical features between the VML and VMO in this population. Since this remains unresolved in the patellar dislocation population, this thesis will therefore continue with the assumption that the VMO is a separate anatomical entity.

Questions remain as to whether this muscle has a pathological role in patellar dislocation. Patellar malalignment associated with patellar dislocation, has been hypothesised to affect the VMO's contractile capabilities (McConnell, 1996). Grelsamer (2000) suggested that patellar instability may be related to a patella's excessively proximally or abnormally orientated VMO attachment which may create an increased vertical muscle vector than normal, thereby theoretically reducing the effectiveness of the VMO as a dynamic stabiliser (Fulkerson, 1997; Grelsamer and McConnell, 1998). However, no empirical studies have assessed the credibility of this statement using ultrasonographic or MRI images of people with or without a history of FTPD.

Table 3.1. Table representing a summary of the literature's findings on the assessment of anatomical differences between VMO and VML.

Study	Distinct difference in fibre alignment between VMO and VML		Presence of a fibrofascial plane between VMO and VML		Separate innervations to VMO and VML	
	YES	NO	YES	NO	YES	NO
Bennett et al (1993)						
Bose et al (1980)						
Farahmand et al (1998)						
Galtier et al (1995)						
Glen and Samojla (2002)						
Hubbard et al (1998)						
Javadpour et al (1991)						
Jojima et al (2004)						
Lefebvre et al (2006)						
Lieb and Perry (1968)						
Nozic et al (1997)						
Ono et al (2005)						
Özer et al (2004)						
Peeler et al (2005)						
Raimondo et al (1998)						
Reider et al (1981)						
Thiranagama (1990)						
Toumi et al (2007)						
Weinstabl et al (1989)						

McConnell (2007) suggested that the integrity of the medial retinaculum can affect the contractility of the VMO. The VMO is superficial to the MPFL as its fibres merge deep into this ligament (Panagiotopoulos et al, 2006). Through this intimate relationship, these authors hypothesised that the VMO can exhibit a dynamising effect, 'drawing-in' the MPFL during early knee flexion to maximise patellar stability (Panagiotopoulos et al, 2006). Authors have therefore suggested that strengthening the VMO may assist in the dynamic stability of the patella (McConnell, 1996; McConnell, 2007; Powers, 2003).

The lateral retinaculum may also have a similar active control. A large proportion of the lateral retinaculum arises from the iliotibial band. Accordingly, the lateral retinaculum may also be dynamised from the contractility of the tensor fascia lata and gluteus maximus from its anatomical attachments (Drake et al, 2009; McConnell, 2007; Powers, 2003). Whilst such anatomical perspectives seem appropriate, such findings have only been assessed with individuals who have experienced PFPS. Accordingly, with greater abnormal patellar displacement associated with FTPD compared to PFPS, these conclusions should be considered with some caution.

In order to determine the role of the VMO in relation to its activity and to the surrounding contractile tissues, the literature pertaining to the patellofemoral joint's anatomical morphology and EMG assessment in people following FTPD and instability symptoms was evaluated.

Only one study has investigated the anatomical composition of the vastus medialis in a cohort of people with patellar dislocation and instability symptoms. In this study, Bose et al (1980) compared the VMO attachment of the patella and its fibre alignment in 10 knees during operative patellar stabilisation to 34 cadaver knees which had no known history of patellar dislocation. The authors reported that the VMO presented with an oblique or transverse muscle fibre orientation compared to the VML in all cases. They also

reported no substantial difference in VMO attachment and fibre alignment between pathological and control knees. This suggests that these variables may not be pathological factors for patellar dislocation, although this is based on a limited sized cohort.

Although Bose et al (1980) suggested that the attachment and fibre alignment of the VMO appeared to be similar between control and pathological knees, they did not investigate whether the vastus medialis's insertion angle to the medial margin of the patella was associated with patellar instability compared to healthy controls. Koshinen and Kujala (1992) compared 10 people who had experienced patellar dislocation to 10 cadaver knees without a history of patellar instability problems, using a standardised MRI. They reported that the VMO's insertion level was significantly more proximal in those with a history of patellar dislocation ($p<0.01$). They concluded that the morphology of the VMO may be an important pathophysiological factor in people who experience patellar dislocation. However since this study only assessed 10 people, it was not possible to determine whether this result was typical of people following patellar dislocation in general, or whether this finding was a chance event (Bland, 2006). Furthermore, the authors did not categorise people as to whether they presented with severe anatomical features, such as trochlear dysplasia, or not, thus limiting the generalisability of these findings.

3.4.3.2.1 EMG Onset of the Distal Vastus Medialis and Vastus Lateralis

No studies have assessed the relative EMG onset timing of vastus medialis over vastus lateralis in people with patellar instability or following dislocation. It therefore remains unclear whether the onset timing of VMO is delayed relative to vastus lateralis in people following patellar dislocation. No evidence was identified to support or refute the concept of retraining the timing of VMO relative to vastus lateralis in people following FTPD.

3.4.3.2.2 EMG Intensity of the Distal Vastus Medialis and Vastus Lateralis

Five studies have assessed the EMG intensity of the VMO and vastus lateralis in people with patellar instability symptoms. The earliest study identified was undertaken by Mariani and Caruso (1979) who compared EMG activity of five healthy asymptomatic to eight people with patellar subluxation. Isokinetic EMG of vastus medialis and vastus lateralis muscle activity was assessed whilst participants extended their knees from 90° flexion to full extension. They reported a difference in relative EMG intensity between vastus medialis and vastus lateralis in the patellar instability group compared to the asymptomatic control, with reduced vastus medialis activity compared to vastus lateralis throughout knee range of motion in the instability group (Mariani and Caruso, 1979). This was most notable in full extension to 30° knee flexion (Mariani and Caruso, 1979). However this finding may be attributed to the specific EMG analysis approach adopted which was a simple visual inspection and classification of the raw waveform rather than an objective quantification. It was not possible to assess whether this finding differed to the other studies as population characteristics were poorly documented and the sample size of this patellar subluxation cohort was small, and not based on a power calculation. Consequentially a type II statistical error may have occurred where if a difference was evident between the groups, this may not have been detected (Portney and Watkins, 2009). This is also true in other papers on this topic where samples ranged from eight (Mariani and Caruso, 1979) to 42 (Baksi et al, 2011).

Wild et al (1982) recruited 17 people who had previously experienced a patellar dislocation. Cine-electromyography of the vastus lateralis, vastus medialis, VMO and rectus femoris under maximum isometric effort was assessed. The authors reported that there was no consistent difference in VMO and vastus

lateralis EMG activity in this cohort. However, the findings of this study were not evaluated using inferential statistics. This was a recurrent limitation, also evident in Mariani and Caruso's (1979) study. Furthermore, no authors have evaluated the precision of their findings using confidence intervals which are important in the interpretation of statistical data (Bland, 2006). Confidence intervals provide the reader with an indication of the reliability of the probability, and inform how likely the interval is to contain the parameter (Bland, 2006). By not providing this value, it is unclear as to how much confidence can be placed on a statistical finding.

Two papers were identified from the same research team (Møller et al, 1986; Møller et al, 1987). In the first paper Møller et al (1986) assessed 28 individuals, 17 with unilateral PFPS and 11 knees presented with a history and findings of patellar instability, whilst the unaffected contralateral knees acted as a control. EMG activity of the VMO and vastus lateralis was measured during isometric knee extensions performed in zero, 15°, 30°, 45°, 60° and 90° ranges of motion in a seated position. Møller et al (1986) reported that there was no statistically significant difference between VMO-vastus lateralis EMG activity ($p>0.05$). There was however a trend where lower intensity levels in VMO and vastus lateralis were exhibited in people with symptomatic patellar instability compared to their asymptomatic control knees during open-kinetic chain activities, reiterating Mariani and Caruso's (1979) earlier finding. The small sample sizes may have accounted for this statistically insignificant difference in light of type II statistical error (Bland, 2006). In the later study, Møller et al (1987) similarly reported no difference in VMO and vastus lateralis activity in their cohort ($p>0.05$). Møller et al (1987) assessed the effects of quadriceps function in a cohort divided into three groups: 50 asymptomatic knees, 15 people with patellar subluxation and 11 people with PFPS. The EMG results suggest that there was no significant difference between VMO and vastus lateralis activity in the patellar subluxation group ($p>0.05$). This finding was mirrored in the control and PFPS cohorts.

Finally Baksi et al (2011) assessed vastus medialis and vastus lateralis EMG intensity before and after patellar realignment surgery with 42 individuals who had experienced recurrent patellar dislocation. They reported reduced vastus medialis EMG intensity compared to the vastus lateralis throughout knee range of motion in all subjects pre-operatively. The authors reported that during the first post-operative year, EMG activity slowly improved to 'almost' return to equal activity between the two muscles. However, the paper provided limited information regarding the activity EMG findings and did not analyse their results using inferential statistical tests. It is therefore unclear what the magnitude of the reported difference is and whether this difference reached statistical significance. However, these results did provide some indication that EMG intensity abnormalities may be a pathological feature of patellar dislocation with altered patellofemoral joint biomechanics. However the study included only people who had experienced recurrent patellar dislocations, and it therefore remains unclear whether these findings reflect the FTPD population.

In summary, the literature suggested no evidence to support or refute a significant difference in the relative EMG onset timing of VMO and vastus lateralis between people with patellar instability or following patellar dislocation compared to asymptomatic individuals. Conflicting evidence exists to indicate whether there is a difference in EMG intensity between the VMO compared to the vastus lateralis intensity for people with patellar instability compared to asymptomatic individuals. One under-powered study was identified that suggests no significant difference in VMO to vastus lateralis EMG intensity in people following patellar dislocation.

3.4.3.2.3 VMO Muscle Fibre-Type Composition

Floyd et al (1987) conducted a study to assess VMO muscle fibre type in people with patellar instability. Muscle biopsies were taken from nine individuals who had experienced a patellar dislocation and seven who had not.

Eight of the nine people following patellar dislocation demonstrated a significantly higher number of Type IIC muscle fibres (Floyd et al, 1987). They also demonstrated a significant decrease in the proportion of Type I fibres indicating a greater proportion of fast-twitch fibres (Floyd et al, 1987). No change was detected in overall muscle fascicles pattern, shape or size of the muscle fibre between people following patellar dislocation and the healthy controls (Floyd et al, 1987). It remains unknown whether there is a causal relationship between muscle fibre type and patellar dislocation. Future larger scale longitudinal studies would be required to answer this question.

Little demographic information was provided in Floyd et al's (1987) paper detailing the frequency of dislocation, and whether the nine people assessed presented with other anatomical factors for patellar dislocation such as trochlear dysplasia. Accordingly, it is difficult to comment on the external validity of these findings.

3.4.4 Additional Factors

A number of other biomechanical and anatomical variances have been identified as predisposing factors to patellar dislocation. These have included: increased genu valgum (Fithian et al, 2001), lower extremity alignment abnormalities (Cameron and Saha, 1996; Elgafy et al, 2005; Schoettle et al, 2005), increased quadriceps angle (Mizuno et al, 2001) and foot pronation (Shea et al, 2006). People who are hypermobile have demonstrated reduced medial soft-tissue tensile strength to reduce medial stability against lateral patellar translation (Nomura et al, 2006). Finally those people with a lateral tibial tubercle or a naturally internally rotated femur in relation to the tibia are predisposed to dislocate due to their biomechanical alignment, requiring less force to cause lateral dislocation (Caton and Dejour, 2010; Fucentese et al, 2007).

Whilst review papers and textbooks have suggested that these lower extremity biomechanical factors may be important contributors to patellar dislocation, epidemiological or biomechanical assessments have yet to be performed to validate these assumptions.

3.5 Categories of Patellar Dislocation

Patellar dislocation has been described as multi-factorial (Donell, 2006; Grelsamer, 2000). The aetiological factors for patellar dislocation have been subdivided into three types: traumatic, iatrogenic, or inherited (Fithian et al, 2004a; Fucentese et al, 2006).

3.5.1 Traumatic

The mechanisms of a traumatic patellar dislocation have been subdivided within the literature into: direct, or indirect mechanisms (Shea et al, 2006).

An indirect patellar dislocation involves the action of forcing the femur into internal rotation, whilst the knee is positioned in valgus, the foot is fixed, and the quadriceps contract in near terminal extension (Hinton and Sharma, 2003; Bassi and Kumar, 2003). This position produces a significant lateral vector on the patella, exceeding the tensile strength of the medial soft-tissues to cause a lateral patellar dislocation (Amis et al, 2008). It has been suggested that turning and twisting motions whilst trying to run may be frequently cited activities for patellar dislocation (Aglietti et al, 2001; Scuderi and McCann, 2005). Hughston (1989) similarly described a forceful deceleration with a simultaneous cutting, pivoting or twisting manoeuvre as a potential cause for patellar dislocation which has been supported by the epidemiological literature (Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a). It has been argued that FTPD may only occur in individuals predisposed to patellar dislocation due to anatomical features such as hypermobility, trochlear dysplasia or lower limb mal-alignment

(Beasley and Vidal, 2004; Hinton and Sharma, 2003). In these individuals, the patella is unable to maintain it central position against lower lateral forces. McConnell (2007) suggested that in indirect patellar dislocation the patella is most vulnerable at 30° knee flexion, before the patella fully engages in the trochlea, where there is little resistance offered by the surrounding osseous conformity (Panjabi, 1992). Furthermore the trochlear groove becomes deeper distally. Therefore physical activity performed in near terminal extension may predispose to indirect patellar dislocation.

The direct mechanism for patellar dislocation is less commonly seen (Shea et al, 2006). This occurs when a laterally directed force is applied to the medial aspect of the patella to manually displace the patella from the trochlear groove (Bahr and Maehlum, 2004). Such causes usually include contact sports such as rugby or wrestling.

3.5.2 Iatrogenic

Although the patella most commonly dislocates laterally, medial dislocation can also occur (Boden et al, 1997; Shannon and Keene, 2007; Richman and Scheller, 1998). This is largely considered an iatrogenic event following overzealous lateral release to reduce lateral soft-tissue stability to allow excessive medial displacement (Hughston and Deese, 1988; Shannon and Keene, 2007).

Although regarded as rare, superior intra-articular dislocation has also been reported within the literature (Wajid et al, 2006; Maripuri et al, 2008; Joseph et al, 2005; Choudhary and Tice, 2004). The superior intra-articular patellar dislocation presents as clinically distinct from a lateral patellar dislocation with such individuals presenting with a locked, flexed knee, more indicative of a meniscal tear (Maripuri et al, 2008; Joseph et al, 2005). Whilst many lateral patellar dislocations self-reduce, these dislocations frequently require surgical

reduction (Dimentberg, 1997). No studies have examined the actual incidence of medial or superior intra-articular patellar dislocation in the population.

3.5.3 Heredity

Carter and Sweetnam (1958) first acknowledged a genetic link to patellar dislocation when they presented a case series of familial joint laxity causing recurrent dislocation. The authors concluded that there were probably genetic determinants associated with recurrent dislocation, speculating that joint laxity may be one associated factor. It has been estimated that between nine to 15% of people may report a family history of patellar instability (Fulkerson, 1997; Atkin et al, 2000; Stanitski, 2003). Atkin et al (2000) also assessed whether there was a familiar link with the incidence of patellar dislocation. Seven people (nine percent) of their cohort reported a family history of patellar dislocation. Fithian et al (2004a) commented that those with a family history of dislocation were twice as likely to dislocate when they reported a family history of patellofemoral dysfunction or treatment for lower extremity problems. However, this latter estimate was based on the author's anecdotal experiences (Fithian et al, 2004a). Although Carter and Sweetnem (1958) published their findings over 50 years ago, there has yet to be any epidemiological studies or genetic investigations to determine whether there is a genetic link or pattern to patellar dislocation. Further studies are therefore warranted to answer this question.

3.6 Summary

This chapter has introduced the aetiology and epidemiology of FTPD. Furthermore the anatomical abnormalities which may predispose people to a patellar dislocation have been identified. The following chapters will now focus on determining how people following FTPD are assessed and treated by physiotherapists.

Chapter 4. Assessment of Patellar Dislocation

4.1 Introduction

The importance of a thorough assessment of a patient's history, though a subjective assessment or history taking, and a systematic clinical examination or objective assessment is well understood (Hengeveld and Banks, 2005). Only after such a careful examination, can clinical decisions be appropriately constructed to devise an optimal treatment programme (Petty and Moore, 2009). In clinical trials, the accurate identification of specific groups of individuals, using valid and reliable assessment methods, is essential when screening potential participants for study eligibility (Chow and Liu, 2004). If not rigorously performed the ability to generalise findings to a specific population is diminished (Friedman et al, 1998).

This chapter will examine the literature pertaining to the clinical examination of people following patellar dislocation. The processes involved in the subjective (Section 4.2) and objective assessment (Section 4.3), differential diagnoses (Section 4.4) and concomitant injuries (Section 4.5) will be considered.

4.2 Subjective Assessment

No clinical studies have been undertaken to assess the items included in a subjective examination. Nonetheless, a number of textbooks and review papers have provided commentary on this aspect of examination.

The available literature suggests that the most important question to ask during a subjective assessment is to determine whether the individual can describe a convincing report of a dislocation event (Aglietti et al, 2006; Woo and Busch, 1998). A sudden, palpable, bony protuberance of the knee, with the patella "popped out" is frequently reported (Woo and Busch, 1998). Most patellar

dislocations, especially recurrent dislocations, spontaneously reduce on knee extension (Burk, 1992). When this does not occur, people seek medical attention in an accident and emergency department where manual reduction under analgesia is performed. Such people frequently present with a flexed knee as a result of hamstring spasm associated with pain (Woo and Busch, 1998). However, these clinical descriptions have only been anecdotally reported. No qualitative studies have reported the specific experiences of individuals immediately following a patellar dislocation. Similarly, no epidemiological studies have been conducted examining the characteristics of those individuals whose patella spontaneously reduce compared to those who require manual reduction.

The literature suggests that people who experience a patellar dislocation frequently describe a diffuse parapatellar tenderness and visual effusion within three hours post-injury (Boden et al, 1997). A palpable defect in the medial retinaculum has also been reported (Dath et al, 2006). It has been hypothesised that this is a result of disruption to the medial capsule and retinaculum following lateral patellar dislocation (Aglietti et al, 2006; Brukner and Kahn, 2010).

Authors have recommended that following patellar dislocation, people should be asked about a family history of patellar instability (Stefancin and Parker, 2007). Literature has attributed a family history of patellar instability to either hypermobility syndrome or trochlear dysplasia (Palmu et al, 2008; Carter and Sweetnam, 1958; Fithian et al, 2004a; Garron et al, 2003; Fucentese et al, 2006). Whilst Palmu et al (2008) reported that a family history of patellar instability is an important prognostic indicator, it remains unclear whether the hereditary link is associated with benign joint hypermobility syndrome or another genetic factor.

4.3 Objective Assessment

The physical examination immediately following a patellar dislocation has been reported as particularly difficult to undertake due to the presence of overt soft-tissue swelling, pain and muscle spasm (Sanders et al, 2001; Frobell et al, 2007). Consequently textbooks recommend that such people should be immobilised for three to five days post-injury and return for a second examination once swelling and pain have subsided (Frobell et al, 2007; Aglietti et al, 2001; Woo and Busch, 1998; Dath et al, 2006). Whilst this appears a sensible recommendation to minimise the potential for these symptoms to confound the examination, no empirical studies have been undertaken to evaluate the importance of this suggestion.

The literature describes 18 different diagnostic tests which could be used in the assessment of individuals following a patellar dislocation. These include: the apprehension test and modified apprehension test, Bassett's sign, the gravity subluxation test, the J-sign, patellar glide test, patellar tilt test, Q-angle, quadriceps pull test, an assessment of lower limb alignment, gait, hypermobility, patellar positioning, tibial tubercle to trochlear groove (TTTG) positioning, and quadriceps definition, and palpation of the medial retinaculum. The methods used for these tests are summarised in Appendix 3. However diagnostic accuracy has only been assessed for four tests with this population. These will now be examined.

4.3.1. Apprehension Test and Bassett's Sign

The apprehension test is the most frequently cited test in textbook and review papers to assess patellar dislocation (Petty and Moore, 2009; Magee, 2008; Brukner and Kahn, 2010; Malanga et al, 2003; Scudero and McCann, 2005). The Bassett's sign is a patellar dislocation-specific test, devised for the assessment of MPFL injury (Boden et al, 1997). It is sometimes referred to as

'pain on palpation of the medial retinaculum' (Fithian et al, 2001; Arendt et al, 2002; Mäenpää et al, 1997).

Sallay et al (1996) compared the apprehension test and Bassett's sign (index texts) to MRI findings (reference test) with 23 people following an acute patellar dislocation. Nineteen individuals also underwent an examination under anaesthesia and arthroscopy, whilst 16 patients also underwent open surgical exploration of the medial soft tissues. The sensitivity was reported as 70% for the Bassett's sign and 39% for the apprehension test. A limitation to this study was that the authors did not state the level of experience each assessor had prior to commencing the study. Furthermore limited information was provided on the exact technique used to assess each test. Consequently, it was unclear whether prior training was important and whether the techniques used were similar to normal clinical practice, thus reducing external validity.

4.3.2 The Quadriceps Angle or Q-Angle

The Quadriceps or Q-angle has been historically used during the assessment of individuals with suspected PFPS (Ando et al, 1993). Some authors have advocated its use for people following patellar dislocation. The Q-angle is cited as normal or non-pathological at a value of 10° to 15° in men, and 15° to 20° in women (Kantaras et al, 2001). A Q-angle greater than these values has been considered abnormal (Omololu et al, 2009; Hvid et al, 1981; Horton et al, 1989).

The Q-angle is proposed to indicate risk of patellar dislocation where an increased Q-angle suggests greater patellar lateralisation (Sheehan et al, 2010). Variables which influence the Q-angle can include position (standing or supine) or whether the quadriceps were relaxed or contracted (Smith et al, 2008). Ando et al (1993) assessed the Q-angle in individuals following patellar dislocation. They compared the conventional clinical method of assessing Q-angle using a

goniometer against computer tomography (CT). The study sample comprised of 43 individuals with a history of recurrent patellar dislocation compared to 26 healthy, asymptomatic people with no history of patellar dislocation or knee pain. There was no statistically significant difference between the clinical and CT assessment of the Q-angle ($p>0.05$) and no difference between the patellar dislocation or asymptomatic cohorts ($p>0.05$). The mean Q-angle clinically measured in the asymptomatic group was 13°; this was 14° in the patellar dislocation group. Assessment of sensitivity or specificity of the Q-angle was not performed. However the findings did not support the adoption of the Q-angle due to its inability to distinguish between pathological and non-pathological knees in this study.

4.3.3 Tibial Tubercle to Trochlear Groove Distance

The tibial tubercle to trochlear groove (TTTG) distance indicates the position of the tibial tubercle relative to the patella and trochlear groove. A lateralised tibial tubercle increases the lateral force on the patella, enhancing the risk of dislocation (Balcarek et al, 2011b). Traditionally, the TTTG has been assessed as part of a radiological examination using CT or MRI (Shakespeare and Fick, 2005). However, a clinical method of assessing this distance was devised by Shakespeare and Fick (2005) who compared the clinical to the MRI method of assessing TTTG distance with 24 knees in individuals awaiting patellar realignment surgery. Fifteen knees presented with patellar instability and no history of dislocation, whilst nine individual's had experienced one or more previous dislocations. Findings demonstrated that whilst 15 of the knees which had previous instability demonstrated good correlation between clinical and MRI measurements, the clinical TTTG measures of the nine people with a history of patellar dislocations were consistently underestimated, with the mean difference between clinical and MRI measurements being 11 millimeters (Shakespeare and Fick, 2005). The authors concluded that this difference was greater than measurement error and questioned the appropriateness of this test

with the more severe patellar dislocation patients (Shakespeare and Fick, 2005). This paper clearly defined the methods used to assess TTTG, additionally providing adequate information as to who undertook the assessment procedures. However this information was not provided in the other studies which have assessed this domain. By not providing sufficient information regarding the assessors, it was not possible to determine how much previous assessor experience or training had impacted on the findings of the other studies reviewed. In this instance, the reliability of a test cannot necessarily be attributed to the results obtained, but may be related to specific assessment techniques and familiarity with the test.

4.3.4 Medial Patellar Subluxation Test

Although medial patellar subluxation has been previously acknowledged as a rare event (Chapter 3; Section 3.5.2), one study has assessed the sensitivity of a test used to evaluate this phenomenon: the gravity subluxation test (Nonweiler and DeLee, 1994). Nonweiler and DeLee (1994) evaluated this test on five people with a history of medial subluxation post-lateral release, all demonstrated positive test results. This correlated to surgical findings where all five presented with a detachment of the vastus lateralis from the superior pole of the patella. The authors appropriately concluded that the gravity subluxation test had a sensitivity of 100%. They then reviewed the gravity subluxation test on 25 people who presented with bilateral knee joint hypermobility without knee pathology. In this cohort the gravity subluxation test was negative in all 25 cases, indicating a specificity of 100%. However, since the assessors were not blinded to the participant's medical history, this may have biased the outcomes of this test. Medial patellar dislocation is an uncommon clinical pathology with very different aetiological features to lateral patellar dislocation (Hughston and Deese, 1988; Shannon and Keene, 2007). Thus the results of this study cannot be transferred to individuals who have experienced a lateral FTPD.

4.3.5 Other Physical Examination Tests

One study has assessed the intra- and inter-rater reliability of the physical examination test used for people following recurrent dislocation (Smith et al, 2011b). In this study Smith et al (2011b) assessed the reliability of examination tests between five orthopaedic surgeons with a specialist interest in patellofemoral disorders. These clinicians assessed five individuals who had experienced recurrent patellar dislocation and had received or were waiting for surgery. The results indicated that there was moderate to substantial intra-rater reliability for each orthopaedic surgeon. Physical tests which demonstrated high agreement between the surgeon's first and second assessments included the assessment of tibial torsion (Kappa=0.84; 95% confidence interval (CI): 0.68, 0.97), popliteal angle (Kappa=0.80; 95% CI: 0.61, 0.93), and the Bassett's sign (Kappa=0.79; 95% CI: 0.60, 0.90). Inter-rater reliability was however consistently poor. Most notably this included assessments such as hip flexor flexibility (Kappa=-0.20; 95% CI: -0.45, 0.05), medial apprehension test at 30° knee flexion (Kappa=-0.19; 95% CI: -0.44, 0.05) and iliotibial band (ITB) flexibility (Kappa=-0.18; 95% CI: -0.37, 0.02). Whilst these results provided an indication that the physical examination for patellar instability may be limited, they can only be generalised to individuals following recurrent dislocation. Similarly the reliability of a physiotherapist's assessment cannot be assumed from the results of this cohort of specialist surgeons.

4.4 Differential Diagnosis

The most commonly exhibited patellofemoral joint pathology is PFPS (Tenforde et al, 2011; Myer et al, 2010). As with patellar instability this pathology can be associated with patellar mal-tracking, tilting and lateralisation (Donell, 2006). The condition is differentiated from patellar dislocation through its clinical history. Patients with PFPS report pain as their principal symptom particularly during activities such as prolonged sitting and stair descent

(Grelsamer, 2000), unlike people following patellar dislocation (Boden et al, 1997). In addition people with PFPS rarely report severe instability during functional activities (Collado and Fredericson, 2010).

Tibiofemoral instability can mimic patellar instability through its symptomology (Donell, 2006). In both cases, people have anecdotally reported their knees to "pop out". Tibiofemoral instability can originate from damage to various intra-articular structures (Hughes and Watkins, 2006). For instance a meniscal tear can be a source of similar symptoms. The literature has demonstrated superior clinical diagnostic abilities using joint line tenderness over other tests such as a positive McMurry's test (Malanga et al, 2003). Secondly, anterior cruciate ligament rupture may be a source of tibiofemoral instability (Hughes and Watkins, 2006). This can be differentiated from a patellar dislocation through a positive pivot shift test or a Lachman test (Stanitski, 2003; Atkin et al, 2000), both of which have demonstrated favourable positive and negative predictive values on meta-analysis (Scholten et al, 2003). Additionally, both anterior cruciate ligament rupture and patellar dislocation are frequently associated with a valgus torsion injury, with the foot fixed during a twisting task whilst running or accelerating (Grelsamer, 2000; Brukner and Khan, 2010). Both injuries can also exhibit immediate overt knee effusion (Brukner and Khan, 2010). Consequently, there may be major similarities in a patient's history and initial presentation between a patellar dislocation and these intra-articular tibiofemoral joint injuries.

Due to the mechanism of injury, a medial collateral ligament injury may also be a differential diagnosis (Quinlan et al, 2010). This can be specifically excluded from patellar dislocation through the assessment of a valgus stress test during the clinical examination (Malanga et al, 2003). Two studies have assessed the sensitivity of the valgus stress test (Garvin et al, 1993; Harilainen, 1987), both reporting support for this test in detecting medial collateral ligament injury. Garvin et al (1993) reported a sensitivity of 96% in 23 individuals who

underwent surgery for medial collateral ligament rupture. Harilainen (1987) also reported sensitivity of the valgus stress test of 86%, but specificity of 25% based on a cohort of 72 individuals following knee trauma. This study indicated that whilst the valgus stress test was appropriate in detecting a medial collateral ligament injury, there was a high possibility of detecting a false positive outcome.

Additional pathologies acknowledged as potential differential diagnoses to patellar dislocation also include osteochondral dissecans, symptomatic plica, Sinding-Larsen-Johansson Syndrome, infrapatellar tendonitis, prepatellar bursitis and fat pad impingement syndrome (Woo and Busch, 1998; Dath et al, 2006). Although rare, tumours such as chondroblastoma and inflammatory arthritis may also be a source of chronic patellofemoral joint symptoms which would require differentiation both clinically and through further radiological investigations such as MRI (Woo and Busch, 1998).

4.5 Concomitant Injuries

Due to their mechanism of injury, anterior cruciate ligament and medial collateral ligament rupture can accompany patellar dislocations, particularly in the sporting knee (Brukner and Khan, 2010; Stanitski, 2003). Combined patellar dislocation with disruption of the anterior cruciate ligament from relatively low-energy athletic injuries have been reported in Simonian et al's (1998) case series of nine patients. Although rare, they, and Mills and Nowinski (2001), both suggested that disruption of the medial retinaculum, MPFL and medial collateral ligament with anterior cruciate ligament injury may predispose patellar dislocation. The specific incidence of this injury has however yet to be determined within the literature.

Osteochondral fracture of the medial border of the patella or lateral femoral condyle has been estimated to present in 50% to 72% of individuals following

patellar dislocation (Vainionpää et al, 1986; Nomura et al, 2003; Stanitski and Paletta, 1998; Dainer et al, 1988, Hawkins et al, 1986; Harilainen and Myllynen, 1988; Nomura and Inoue, 2004). Other authors have suggested a much lower incidence with approximately five to 30% of acute patellar dislocations (Frandsen and Kristensen, 1979; Rorabeck and Bobechko, 1976; Hammerle and Jacob, 1980; Hutchinson and Ireland, 1995). On assessment of these study populations, there remains no obvious reason to account for this discrepancy in estimated incidences. Nonetheless, osteochondral fractures are regarded as a cause for the failure of conservative treatment regimes due to their associated increased pain and symptoms related to fissuring from the osteochondral defect, principally in the central dome of the patella (Nomura and Inoue, 2004; Stanitski and Paletta, 1998).

The diagnosis of osteochondral fractures is made through radiographic investigations or by aspiration to detect fat droplets (Boden et al, 1997). These are regarded as difficult injuries to diagnose (Hutchinson and Ireland, 1995; Woo and Busch, 1998). In Stanitski and Paletta's (1998) case series, eight out of 28 osteochondral loose bodies were radiographically identified. The authors recommended that a low threshold should be adopted for arthroscopic investigation with people who respond poorly to conservative treatment.

4.6 Summary

The present literature provides some evidence to support the use of the Bassett's sign, gravity subluxation test for medial patellar dislocation, but little support for the clinical assessment of the TTTG and Q-angle in people following patellar dislocation. Although most commonly recommended in textbooks, the apprehension test demonstrates questionable sensitivity and whilst not validated by empirical evidence, the most commonly cited method of diagnosing a patellar dislocation is through a convincing report of dislocation. However current literature examining the assessment of patellar dislocation

exhibited a number of limitations and no published literature has assessed the sensitivity, specificity, reliability or validity of the different diagnostic tests used in the examination of this population by physiotherapists.

Having identified the assessment methods used to diagnose a patellar dislocation, the following chapter will examine treatment strategies prescribed to manage individuals diagnosed as having experienced a FTPD.

Chapter 5. Treatment of First-Time Patellar Dislocation

5.1 Introduction

Previous chapters have examined the aetiological factors and assessment methods for FTPD. This chapter will consider how people following FTPD are treated. Consistent with the aims of this thesis, the literature pertaining to the operative management of this population will not be reviewed. Instead, the non-surgical and physiotherapeutic management of people following FTPD will be examined. This chapter will therefore evaluate the initial immobilisation (Section 5.2), the different physiotherapy treatments reported (Section 5.3), outcomes of these physiotherapy programmes (Section 5.4) and methodological limitations to the current evidence-base (Section 5.5).

5.2 Initial Immobilisation

Historically following FTPD people have been initially immobilised before commencing a rehabilitation programme (Cosgarea et al, 2002). Recommendations regarding the form, duration and position of immobilisation have varied throughout the literature.

There is no consensus in the literature regarding the optimal position of immobilisation. Hutchinson and Ireland (1995) advocated the use of a knee extension splint with a lateral buttress pad to reduce lateral patellar translation. Others have recommended immobilising the knee in a full-leg brace or cast, or using a knee sleeve with a patella cut-out (Woo and Busch, 1998; Bahr and Maehlum, 2004). Each form has been hypothesised to promote the healing of disrupted medial soft-tissues by minimising patellar lateralisation throughout knee motion (Woo and Busch, 1998; Bahr and Maehlum, 2004).

Scuderi and McCann (2005) suggested that knee range of motion should be restricted to less than 90° of flexion. Sillanpää et al (2009a) recommended limiting knee range from zero to 30°. Immobilising the knee in zero to 30° flexion has been hypothesised to reduce excessive contact pressures within the patellofemoral joint (Sillanpää et al, 2009a; Norris, 2000; Brukner and Khan, 2010). Throughout this range the patella is not constrained within the femoral trochlear (Senavongse et al, 2003). Therefore the minimal tension placed on the medial soft-tissues compared to when constrained in the femoral trochlear groove, may aid the formation of well-organised collagen during the soft-tissue remodelling phase (Waldman et al, 1999; Evans, 1980).

Similarly there appears little consensus regarding the optimal duration of immobilisation. Textbook and review literature have recommended immobilising from two to six weeks post-injury (Woo and Busch, 1998; Solomon et al, 2001; Hutchinson and Ireland, 1995). Shea et al (2006) acknowledged that immobilisation could lead to arthrofibrosis and atrophy of cartilage, muscle, ligaments and bone (Akeson et al, 1987; Booth, 1987; Kannus, 1992). In the light of this, a number of other authors have advocated early range of motion and rehabilitation to reduce the risk of such complications (Buchner et al, 2005; Hinton and Sharma, 2003; Järvinen, 1997).

Two randomised controlled trials have assessed initial immobilisation of people following FTPD. Kiviluoto et al (1986) compared the clinical outcomes in 47 individuals immobilised in a plaster cylinder cast compared to 30 placed in a semiflexible pressure bandage during the initial three weeks post-FTPD. All were permitted to fully weight-bear and were instructed to do isometric quadriceps exercises during the immobilisation period. There was no significant difference between the groups regarding the incidence of recurrent dislocation ($p>0.05$) during the first 12 months. However those in the semiflexible bandage reported a shorter duration of sick leave (median 22 days) compared to the

plaster cast immobilisation group (median 34 days). The authors did not document whether this was statistically significant.

In the second study, Mäenpää and Lehto (1997b) allocated participants into three groups. Sixty people were immobilised in a full extension plaster cast, 17 in a full extension cardboard posterior splint, and 23 were provided with an elastic knee sleeve with a lateral buttress pad. All were fully weight-bearing, whilst unrestricted knee motion was permitted for those allocated to the sleeve group. At a mean 13 year follow-up, there was no statistically significant difference between the groups in range of motion, incidence of retropatellar crepitations, apprehension test or in Kujala Patellofemoral Disorder Score ($p>0.05$). There was however a difference in re-dislocation rate. Those allocated to the sleeve group reported a statistically significant higher re-dislocation rate of 0.29 per follow-up year, compared to 0.08 in the posterior brace group and 0.12 in the plaster cast group ($p<0.05$). The authors did not discuss whether this difference was clinically significant. Participants who received the cast or posterior splint were immobilised for three weeks whilst those who wore the sleeve were instructed to wear this for two weeks. It is therefore unclear whether the duration of immobilisation rather than its form accounted for the difference in findings. Furthermore, the authors did not determine whether there were differences in the rehabilitation programmes of participants whilst wearing their allocated interventions. It is therefore not possible to determine how these immobilisation methods were enforced and whether the ability to remove the posterior splint or sleeve during rehabilitation was a factor which may account for these differences.

Whilst both Mäenpää et al (1997) and Kiviluoto et al's (1986) studies provided useful information pertaining to recurrent dislocation rates, they only evaluated a small number of outcome measures with insufficient sample sizes. It is unclear whether the form of immobilisation can influence the speed with which individuals return to work or recreational activity. It is also unknown whether

the form or duration of immobilisation can influence physiological variables such as quadriceps or hamstring strength, perceived patellar instability or treatment satisfaction. Based on this literature it therefore remains unclear whether methods of immobilisation impact on outcome.

5.3 Physiotherapy Interventions

No trials have compared different individual physiotherapy interventions in the treatment of FTPD. However, 27 papers have presented the outcomes of physiotherapy programmes following FTPD. The demographic and interventional characteristics of these studies are presented in Table 5.1.

Of the 27 papers identified, nine studies were clinical trials of operative versus non-operative treatment strategies. Of these seven were formal randomised controlled trials (Christiansen et al, 2008; Camanho et al, 2009; Nikku et al, 1997; Nikku et al, 2005; Palmu et al, 2008; Sillanpää et al, 2008b; Sillanpää et al, 2009a). Fourteen studies were case series whilst three were single-subject case-study designs. This latter design has some limitations since although case studies can provide interesting data regarding an individual, their findings cannot be generalised to the wider population (Zhan and Ottenbacher, 2001).

Thus larger studies are considered more robust and clinically important than single case study papers (Moher et al, 1994). However to avoid publication bias, all study designs were included (Song et al, 2010; Song et al, 2000).

Table 5.1. Table to summarise the population characteristics and interventions used as part of physiotherapy programmes in the twenty-seven papers assessing the rehabilitation of people following FTPD.

Study	Knees (n)	Mean age years (range)	Diagnosis and how made	Physiotherapy programme	Mean duration from dislocation to treatment	Av. Follow-up period (years)
Atkin et al (2000)	74	19.9 (11-56)	Convincing history of primary patellar dislocation with haematosis/effusion; medial retinaculum tenderness; positive apprehension test.	Knee immobiliser permitting weight bearing as tolerated using crutches. Patients encouraged to begin resisted closed-chain exercises and passive range of motion exercises in the brace as tolerated. Neoprene sleeves encourage for pivoting activities and sports.	Less than 4 weeks.	24 weeks
Buchner et al (2005)	63	21.1 (10-52)	Reported primary patellar dislocation; knee effusion; positive apprehension test; tenderness on medial retinaculum.	Neoprene knee orthotic for 4 weeks permitting all FWB and range of motion as able.	N/S	8.2 (2-15)
Camanho et al (2009)	16	26.8 (12-74)	Primary patellar dislocation requiring manipulation for reduction	Knee immobilisation in cast. Regime of VMO and quadriceps strength exercises, hamstring and lateral retincular stretched.	3-4 weeks	36.3 months
Cash and Hughston (1988)	103	21.7 (9-72)	Presented as a primary patellar dislocation.	Knee aspiration if required. Lateral padded foam and bandage applied in extension and immobilised in plaster cast or splint with commence of quadriceps exercises, SLR, progressive resistance exercises. Immobiliser used for 2 to 6 weeks. Physiotherapy commenced until normal strength and stability was obtained.	14 days	8.1 (2.0-26.7)
Christiansen et al (2008)	35	19.9 (13-39)	Locked dislocation of history of knee trauma, intra-articular haematoma, tenderness of the medial epicondyle and positive apprehension test.	Brace immobilisation 0 to 20 degrees for first 2 weeks. Week 2 to 6 free range of motion, quadriceps exercises and general physiotherapy.	N/S	2
Cofield and Bryan (1977)	48	17.6 (10-54)	Convincing history of patellar dislocation.	Conservative management. 43 patients immobilised, 42 known to be immobilised for 3.5 weeks average.	N/S	5
Garth et al (1996)	79	16.4 (7-35)	Positive apprehension test.	Six patients had knee aspiration. Ice from day 0 to 2. Analgesics and NSAIDs. SLR exercises. Electrical stimulation; neoprene knee sleeve used until pain subsided (approximately 3 to 8 weeks). Immediate passive, active-assisted and active stationary bike begun. Isometric and isotonic quadriceps and VMO exercises. WBAT.	0	2
Hawkins et al (1986)	20	19 (13-39)	Evident or suspected patellar dislocation.	Immediate cylinder cast or splint immobilisation in 11 patients for average 3 weeks. Aggressive physiotherapy.	Approx. 4 to 5 days	40 months (6-174 months)

Study	Knees (n)	Mean age years (range)	Diagnosis and how made	Physiotherapy programme	Mean duration from dislocation to treatment	Av. Follow-up period (years)
Helgeson and Smith (2008)	1	23	Convincing report of patellar dislocation. MRI. Positive apprehension test.	Immobilised in full extension (3 weeks) and neoprene sleeve (not stated duration).Gait re-education. Cryotherapy. Knee flexion limited to 80° for 2 weeks. Passive knee flexion stretched begun from 3rd week. Isometric quadriceps contraction with audio and visual feedback. Isometric quadriceps with co-contractions of hamstrings and hip extensors in standing with knee at 15° flexion. Single leg balance exercise progressed with multi-directional perturbations with an exercise band. Dynamic control of hip, knee and ankle alignment during standing, stepping, hopping, squatting, lunging exercises performed.	4 weeks	12 weeks
Hvass et al (1988)	37	18 (8-32)	N/S	Immobilisation in cast, followed by a physiotherapy programme which was not specified.	N/S	31 months (15-64)
Kiviluoto et al (1986)	77	23	N/S	Knee joint aspiration. Rigid plaster cast used in 47 cases, 30 knees immobilised in a semi-flexible pressure dressing from mid calf to mid thigh. Immobilised for 3 weeks in cast. Immediate quadriceps setting and FWB. Isotonic exercises when immobilisation abandoned. Jogging and return to light sports being at 6 weeks.	N/S	1
Larsen and Lauridsen (1982)	79	18.7 (6-52)	Convincing history of patellar dislocation.	Immobilisation in plaster case (22) or elastic bandage (57). All provided quadriceps exercises.	N/S	5.9 (1-31)
Mäenpää and Lehto (1997a)	100	23 (10-64)	Convincing history of patellar dislocation with positive clinical diagnosis on evaluation.	N/S	N/S	13 (6-26)
Mäenpää and Lehto (1997b)	85	21 (10-64)	Convincing report patellar dislocation.	Aspiration. Immobilised in either a plaster cast, posterior spilt both in full extension, or knee bandage or brace permitting some knee motion. All instructed quadriceps exercises.	N/S	13 (6-26)
Mäenpää et al (2000)	82	36	N/S	Immobilised for 3±2 weeks.	N/S	13±5
Mäenpää et al (1997)	75	N/S	N/S	Knee joint aspiration; Conservative treatment.	N/S	11 (6-24)
McManus et al (1979)	33	N/S	Patellar dislocation with convincing account/ signs of patellar dislocation.	Immobilisation in case, followed by a physiotherapy programme consisting of quadriceps strengthening exercises.	N/S	31 months (6-61)
Nikku et al (2005)	57	20	Observed locked primary patellar dislocation or dislocatable on EUA.	N/S	Less than 14 days	7.2 (5.7-9.1)

Study	Knees (n)	Mean age years (range)	Diagnosis and how made	Physiotherapy programme	Mean duration from dislocation to treatment	Av. Follow-up period (years)
Nikku et al (1997)	55	19.1	Reported or observed in clinic unreduced patellar.	Thigh muscle exercises.FWB permitted. Immobilisation in knee extension in a cylinder cast in adults and plastic splint in children (3 week duration). Neoprene sleeve used from week 3 to 6 when range of motion exercises begun, and worn during sport for the first 6 months.	≤ 14 days	25 (20-45) months
Osterheus (2004)	1	49	Convincing report of patellar dislocation.	Restricted weight-bearing. Ice, elevation, ankle pump exercises. Taping technique in a 'Y' configuration worn 24 hours a day. Static and dynamic balance training, stationary cycling, self-massage, range of motion, quadriceps exercises and core stabilization training.	3 days	5 weeks
Palmu et al (2008)	28	13	Clinical evident or suspected patellar dislocation.	For patellar dislocatable under anaesthesia, a removal knee extension orthotic (week 0 to 3) followed by a neoprene sleeve (week 3 to 6). Otherwise, neoprene sleeve was used immediately. Thigh muscle exercises and FWB as comfortable immediately permitted. Neoprene sleeve encourage during first 6 months post-injury.	< 2 weeks	14 (11-15)
Pedersen and Pedersen (1989)	26	22 (11-74)	Primary patellar dislocation with convincing history and clinical signs.	Immobilisation in cast, followed by a physiotherapy programme consisting of quadriceps strengthening exercises.	N/S	35 months (17-54)
Racouillat (2007)	1	16	Reported primary patellar dislocation	Crutches for 1 week, WBAT with neoprene brace. Open and closed chain quadriceps strengthening exercises and core strengthening exercises. At 3 weeks, once "base strength obtained" plyometric exercises with McConnell taping method were begun for 6 weeks.	10 days	9 weeks
Savarese and Lunghi (1990)	17	N/S	Primary patellar dislocation with convincing history and presentation.	Immobilisation in cast, followed by a physiotherapy programme of isometric quadriceps exercises.	N/S	3 (11 month-6 years)
Sillanpää et al (2009a)	22	20.0 (19-21)	Reported or observed traumatic primary patellar dislocation.	Knee aspiration. Knee immobiliser worn to permit ROM exercises of from 0 to 30° ROM permitted (week 0-3) and 0 to 90° then permitted (week 3-6). Then removed for muscle strengthening programme.	1 day (0-7 days)	7 (6-9)
Sillanpää et al (2009b)	53	20.0 (19-23)	Primary patellar dislocation confirmed by physical examination and MRI	Knee immobilisation protocol as per Sillanpää et al (2009). Followed by a quadriceps strengthening exercise programme. Full weight-bearing gait re-education throughout.	<21 days	6.9 (4-10)
Sillanpää et al (2008b)	76	20.0 (19-22)	Reported primary patellar dislocation and evidence of physical examination.	Aspirated knee if required. Brace used to permit 0 to 60° for mean 4 weeks (3-6) permitting WBAT. Guided range of motion, quadriceps strengthening exercises after initial 4 weeks immobilisation.	1 day	7.5 (6-11)

± - Standard deviation; Approx – Approximately; Av – Average; EUA – Examination under anaesthetic; F – Female; FWB – Full weight-bearing; M – Male; N/S – Not stated; Pat Dis – Patellar Dislocation; Pts – Patients; SD – Standard deviation; WBAT – weight bearing as tolerated

Sixteen papers were prospective studies, four were retrospective, and in the remainder, this was unclear. Whilst retrospective data provides useful results when assessing a cohort, such research may present with inherent methodological weaknesses (Clark, 2008; Weinger et al, 2003). These can include: bias through the limited reporting of outcomes, self-selection of only compliant patients, or only reporting complete data (Egger et al, 2000). Accordingly prospective data is considered of greater rigour than retrospective publications (Clark, 2008).

Since the literature only presented the findings of overall treatment programmes, it was not possible to ascertain whether one specific physiotherapy treatment was superior to another. However, it was possible to determine how effective such treatment regimes have been for people following FTPD.

5.3.1 Quadriceps Strengthening Exercises

The most commonly cited treatment in the physiotherapy programmes reviewed was quadriceps-related muscle exercises. Textbooks have suggested that exercises are the 'keystone' treatment for this population (Mears and Cosgarea, 2001; Beasley and Vidal, 2004; Solomon et al, 2001; Aichroth, 1983; Howell, 2002). Quadriceps-related exercises have been subdivided within the literature to general-quadriceps strengthening and specific-VMO strengthening exercises.

General Quadriceps Exercises

The treatment regimes of 13 of the 27 studies included general quadriceps exercises. These specifically included isometric and isotonic exercises, functional and sports-related quadriceps exercises. These exercises have been recommended by textbook and review papers (Mears and Cosgarea, 2001; Beasley and Vidal, 2004; Solomon et al, 2001; Aichroth, 1983; Howell, 2002).

Specific-VMO Exercises

Two papers reported that specific-VMO exercises were included in treatment regimes (Camanho et al, 2009; Garth et al, 1996). However they did not specify what types of VMO exercises were prescribed. This limited use of VMO exercise was in stark contrast to textbook and review literature which provides considerable support for the use of these (Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001). Yet none describe which specific exercises should be taught (Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001).

The pathophysiological justification for VMO exercises is based on the assumption that the VMO acts as the patella's primary dynamic stabiliser (McConnell, 1996; Grelsamer, 2000). Thus by strengthening this muscle, the VMO may develop greater tension to withstand laterally directed forces from vastus lateralis and lateral retinaculum. Accordingly the patella can be centralised throughout range, thereby reducing the potential for re-dislocation and instability symptoms (McConnell, 2007; Grelsamer, 2000). Additionally Panagiotopoulos et al's (2006) cadaveric study reported that the VMO can 'dynamise' the MPFL through its attachment to this ligament. Therefore, as the VMO contracts, the MPFL may generate greater tension to further resist lateral patellar translation (Panagiotopoulos et al, 2006). Nonetheless both these suggestions remain speculative until further clinical trials are undertaken to investigate the role of the VMO in FTPD cohorts using EMG and dynamic MRI assessment.

McConnell (2007) suggested that people who experience a FTPD may present with abnormal VMO onset timing compared to the vastus lateralis. She hypothesised that exercises targeted to recruit the VMO may correct such

abnormal muscle activity (McConnell, 2007). However, there is insufficient literature to support this hypothesis and McConnell (2007) did not acknowledge which exercises should be prescribed to achieve this. Further research is therefore required to validate this hypothesis in this population. VMO exercises can only preferentially bias the VMO over the other quadricep muscles if it can be selectively activated and strengthened. Since this is an important concept to this thesis, this will be specifically examined in Chapter 6.

5.3.2 Stretching Exercises

One paper reported prescribing lateral retinaculum stretching exercises as part of their physiotherapy programme (Camanho et al, 2009). This was based on the concept that by lengthening these tissues, the tension placed on the patella to laterally translate can be reduced (Camanho et al, 2009). For this same reason, a number of textbook and review papers have also suggested the inclusion of flexibility exercises to address tight soft-tissue groups including the quadriceps, ITB, hamstrings and gastroc-soleus complex (Post et al, 2003; Cherf and Paulo, 1990; Morelli and Rowe, 2004; Howell, 2002). However the efficacy of the different stretching regimes for this population remains unknown.

5.3.3 Proprioception and Balance Exercises

Although the use of lower limb proprioceptive exercises was advocated in Shea et al (2006) and Morelli and Rowe's (2004) commentary papers, none of the studies identified from the literature search included proprioceptive exercises as part of their physiotherapy regimes. Therefore, whilst previous authors have suggested that this population can exhibit proprioceptive deficits (Jerosch and Prymka, 1996a; Jerosch and Prymka, 1996b), no evidence is currently available to support or refute the prescription of proprioceptive exercises.

5.3.4 Taping

The use of taping was documented in two case-studies. Osterheus (2004) used a 'Y' configuration taping technique for five weeks, whilst Racouillat (2007) taped using the McConnell protocol for a six week period. The use of taping has been more widely cited within textbook and review papers. Taping has been theoretically justified to correct patellar mal-tracking and tilt, to promote vastus medialis function through enhanced proprioceptive feedback, and to decrease pain (Gilleard et al, 1998; Beasley and Vidal, 2004; Woo and Busch, 1998; McConnell, 1986). However Gigante et al (2001) refuted this claim. They assessed 16 individuals with PFPS who were assessed using CT imaging after performing quadriceps loading exercises with patellofemoral joint tape (Gigante et al, 2001). They reported that taping did not significantly medialise the patella, and that a biomechanical mechanism for any change in symptoms remains unclear. Given this uncertainty, authors have suggested that taping should be regarded as an adjunct rather than a mainstay treatment (Boden et al, 1997; Howell, 2002; Post et al, 2003; Scuderi and McCann, 2005).

5.3.5 Bracing

Bracing may also be considered an adjunct to rehabilitation (Howell, 2002). Six papers described the use of neoprene and bracing devices as part of their physiotherapy regimes (Atkin et al, 2000; Buchner et al, 2005; Hawkins et al, 1986; Mäenpää and Lehto, 1997b; Nikku et al, 2005; Palmu et al, 2008; Racouillat, 2007). Authors have suggested that bracing, in the form of neoprene sleeves and thermoplastic braces, may be useful during the transition from formal to no immobilisation (Racouillat, 2007; Palmu et al, 2008).

Bracing is suggested to benefit people by controlling the degree and orientation of lateral patellar translation. Shellock et al (1994) assessed the effect of a

patellar stabilisation brace using dynamic MRI. They reported that 11 out of 15 people included in the trial demonstrated a radiological improvement in patellar alignment using the brace. The four individuals who demonstrated no improvement were either overweight or exhibited patellar alta in their trial. These authors did not assess the effects of bracing on clinical outcomes such as recurrent dislocation rates or patient satisfaction which may have been more clinically meaningful. Nonetheless, textbook and review authors have suggested that bracing may provide some symptomatic relief (Cherf and Paulos, 1990; Post et al, 2003). Given these conflicting recommendations, further research is warranted to assess the clinical outcomes of bracing with people with different physical characteristics such as patellar alta or a higher weight following FTPD.

5.3.6 Provision of Walking Aids

Two case-studies reported the prescription of gait re-education for people following FTPD (Helgeson and Smith, 2008; Racouillat, 2007). These authors suggested that walking aids can be used to reduce the associated discomfort of walking during the initial phases of recovery post-FTPD (Helgeson and Smith, 2008; Racouillat, 2007). However no studies have specifically assessed the pathophysiological or psychological benefits of using walking aids with this population.

5.3.7 Ice

Ice was incorporated into the treatment programmes reported in two papers (Osterheus, 2004; Helgeson and Smith, 2008). This treatment has also been supported by textbook and review papers (Shea et al, 2006; Norris, 2000). Ice has pathophysiological justification through its ability to reduce swelling and inflammation from capsular and medial retinacular disruption associated with FTPD (Bleakley et al, 2011). Pain from inflammatory bradykinins and

substance-P release may also be reduced though ice's vasoconstriction capabilities and its afferent stimulation on the pain-gate mechanism (Godfrey, 2005).

5.3.8 Electrotherapy

No textbooks or research studies have recommended the use of common electrotherapy agents including ultrasound, interferential therapy, biofeedback or pulse electromagnetic energy for people following FTPD. Three of the 27 papers identified included muscle stimulation in their physiotherapy programmes (Sillanpää et al, 2009a; Garth et al, 1996; Helgeson and Smith, 2008).

The prescription of electronic stimulation is theoretically based on its ability to recruit slow- and fast-twitch muscle fibres to recruit motor units during voluntary muscle contraction (Robertson et al, 2006; McDonough and Kitchen, 2002). Using these principles, muscle stimulation has been applied to the vastus medialis and VMO to hypothetically enhance medial patellar stabilisation (Sillanpää et al, 2009a; Garth et al, 1996; Helgeson and Smith, 2008). Since none of these studies have compared the rehabilitative outcomes of people who have used electronic stimulation compared to those who did not using a RCT design, the efficacy of this intervention remains unknown for the management of FTPD.

5.3.9 Lower Limb Biomechanical Correction and Orthoses

No studies were identified which treated lower limb biomechanical abnormalities as part of their physiotherapy treatment programme. This contrasts to textbooks which recommend that biomechanical issues should be addressed to optimize lower extremity imbalance, strength and function in this population (Bicos et al, 2007; Cherf and Paulos, 1990). They suggested that

glutei and hip external rotator weakness should be addressed, based on the assumption that improvements in gluteal control should decrease excessive femoral internal rotation to minimise patellar lateralisation. In light of this, Howell (2002), Cherf and Paulos (1990), Post et al (2003), King (2000) and Woo and Busch (1998) also suggested that foot orthoses should be considered to correct leg length discrepancy or excessive foot pronation and tibial rotation which may present in FTPD cohorts. However, since these recommendations are not evidence-based, the role of orthoses remains unclear in those following FTPD.

5.4 Outcomes Following Physiotherapy

A variety of different outcome measurements were reported in the 27 papers reviewed to evaluate the results of their physiotherapy regimes. The specific outcomes of the regimes are considered below.

5.4.1 Functional Outcome Scores

Ten different functional scores were used to evaluate outcomes. These outcomes are listed in Table 5.2. Overall, people treated with a physiotherapy programme following FTPD regained acceptable or excellent functional results. The findings pertaining to the Kujala Patellofemoral Disorder Score, the Lysholm Knee Scoring Scale and the Tegner Activity Scale can be viewed with particular confidence given that these have previously demonstrated to be reliable (test re-test) and valid (criterion validity) for individuals following FTPD (Paxton et al, 2003).

There was no substantial difference in the individual outcomes presented in Table 5.2 between studies with the exception of the Tegner Activity Score. For this outcome, two studies reported a decrease in activity level post-rehabilitation by 0.7 out of 10 (Nikku et al, 2005) and 2.2 out of 10 (Buchner et

al, 2005). One study reported an increase in Tegner Activity Score by one point (Palmu et al, 2008). Whilst there was no substantial difference in the treatment strategies adopted between these studies, Palmu et al's (2008) sample consisted solely of adolescents, whilst Nikku et al (2005) and Buchner et al's (2005) cohorts were adult participants. In addition, Palmu et al's (2008) follow-up was almost twice the duration of Nikku et al (2005) and Buchner et al's (2005) studies (Table 5.1).

Table 5.2 Table to list the functional outcome scores which have been used to evaluate the clinical outcomes of physiotherapy for people following a patellar dislocation.

Functional outcome score	Frequency of use	Studies which used this score
Kujala patellofemoral disorder score (Kujala et al, 1993)	9	Camanho et al, 2009; Sillanpää et al, 2009b; Sillanpää et al, 2009a; Palmu et al, 2008; Mäenpää et al, 1997; Mäenpää and Lehto, 1997a; Christiansen et al, 2008; Sillanpää et al, 2008b; Nikku et al, 2005
Tegner level of activity score (Tegner and Lysholm, 1985)	6	Nikku et al, 1997; Palmu et al, 2008; Sillanpää et al, 2009b; Sillanpää et al, 2008b; Buchner et al, 2005; Nikku et al, 2005
Hughston VAS knee score (Flandry et al, 1991)	3	Nikku et al, 1997; Palmu et al, 2008; Nikku et al, 2005
Lysholm knee score (Lysholm and Gillquist, 1982)	2	Nikku et al, 1997; Buchner et al, 2005
Crosby and Insall assessment tool (Crosby and Insall, 1976; Heywood, 1961)	1	Laren and Lauridsen, 1982
Lower Extremity Functional Scale (LEFS) (Binkley et al, 1999)	1	Helgeson and Smith, 2008
Hall assessment (Hall et al, 1979)	1	Savarese and Lunghi, 1990
Cox rating system (unable to cite original reference)	1	Hvass et al, 1988
A unspecified patellar instability score (unable to cite original reference)	1	Christiansen et al, 2008
Knee Injury and Osteoarthritis Score (Roos et al, 1998)	1	Christiansen et al, 2008

5.4.2 Muscle Strength and Torque

Muscle strength and torque were reported in eight papers using four methods: Medical Research Council (MRC) muscle rating system, isokinetic strength and torque, thigh girth and observational quadriceps bulk.

One study assessed muscle strength using the MRC observational grading system (Medical Research Council, 1981). This case-study reported an improvement in quadriceps strength from two to four out of five during a nine week period (Racouillat, 2007).

Thigh girth measured was assessed in three cohorts with varying results (Osterhues, 2004; Nikku et al, 1997; Sillanpää et al, 2009a). Whilst Osterhues (2004) reported a three centimetre deficit, Nikku et al (1997) only reported a 0.3 centimetre deficit between the injured and uninjured limbs at final follow-up ($p=0.50$). Sillanpää et al (2009a) also reported no statistically significant difference in thigh girth measurement between the injured and uninjured limb ($p>0.05$). Whilst all studies incorporated a period of immobilisation and exercises in their interventions, as Table 5.1 illustrates, the follow-up periods varied between the studies (5 weeks to 7 years), which may have accounted for this difference in findings.

Two studies assessed isokinetic knee torque following their cohort's rehabilitation (Atkin et al, 2000; Mäenpää et al, 1997). Atkin et al (2000) reported that isokinetic knee extension torque was greater than 80% of the contralateral limb in 60 out of 74 people 24 weeks after commencing their physiotherapy programme. Whilst Mäenpää et al (1997) demonstrated a 10% deficit in quadriceps muscle strength at a mean of 11 years follow-up when assessed at 60° knee range. However neither this parameter at 60° nor 0° reached statistical significance to the contralateral limb ($p>0.05$). However, the

duration of rehabilitation received was not documented in either paper. The generalisability of this latter paper was further complicated since the authors did not specify what physiotherapy interventions were prescribed to their cohort (Mäenpää et al, 1997).

Three studies assessed observed quadriceps atrophy at final follow-up (Osterhues, 2004; Hawkins et al, 1986; Savarese and Lunghi, 1990). Osterhues (2004) observed minimal quadriceps atrophy in their single-subject case-study at five weeks after commencing their physiotherapy programme. Hawkins et al (1986) reported that 20% of their cohort presented with observable quadriceps atrophy at a mean 40 month follow-up. However Savarese and Lunghi (1990) reported that 76% of their cohort exhibited quadriceps atrophy at three years. This difference in outcomes may be attributed to the structured exercises prescribed to Osterhues' (2004) case, whilst, according to their academic paper, Hawkins et al's (1986) participants did not receive physiotherapy exercises as part of their intervention. It remains unclear why Savarese and Lunghi's (1990) cohort presented with such a high incidence of quadriceps atrophy. However these authors did not state the intra- or inter-rater reliability of their method of assessing this outcome. Potential measurement error should be considered as a major limitation in the assessment of strength or torque since no studies have evaluated the reliability or validity of these measurements in the FTPD population. This may account for the poor consistency of muscle strength and girth measurements in these papers.

5.4.3 Range of Knee Motion

Knee range of motion was reported in seven papers (Osterhues, 2004; Helgeson and Smith, 2008; Sillanpää et al, 2009a; Atkin et al, 2000; Mäenpää et al, 2000; Mäenpää and Lehto, 1997a). Two case-studies reported that their participants regained full range of motion post-physiotherapy (Osterhues, 2004; Helgeson and Smith, 2008). Conversely, five papers reported some loss of knee range of

motion post-physiotherapy (Sillanpää et al, 2009a; Atkin et al, 2000; Mäenpää et al, 2000; Mäenpää and Lehto, 1997a; Savarese and Lunghi, 1990). Sillanpää et al (2009a) and Atkin et al (2000) reported that mean total motion ranged from 132° to 140° at two and seven years post-rehabilitation respectively. Furthermore Mäenpää et al (2000) and Mäenpää and Lehto (1997a) reported that a flexion deficit was evident in 23% and 21% of their cohorts respectively. They also reported an extension deficit in 15% and 13% respectively (Mäenpää et al, 2000; Mäenpää and Lehto, 1997a), whilst Savarese and Lunghi (1990) reported that total knee range of motion was limited in 12% of their cohort.

When assessed by treatment strategy, Osterhues (2004), Helgeson and Smith (2008) and Atkin et al (2000) incorporated range of motion exercises into their rehabilitation programmes, whereas Savarese and Lunghi (1990), Mäenpää and Lehto (1997a) and Sillanpää et al (2009a) solely prescribed muscle strengthening exercises. This may account for the difference in outcome, with limited information presented on the rehabilitation protocols of Mäenpää et al (2000) and Mäenpää and Lehto's (1997a) studies. The difference in range of motion may also be attributed to a variation in follow-up duration, ranging from 12 weeks (Helgeson and Smith, 2008) to 13 years (Mäenpää and Lehto, 1997a). Finally whilst goniometry has demonstrated an acceptable level of intra- and inter-rater reliability (Bellamy et al, 1999; Brosseau et al, 2001), the assessment this measurement's reliability has only been conducted in cohorts with osteoarthritis and other knee pathologies and not FTPD.

5.4.4 Pain

Pain was assessed in five papers (Hawkins et al, 1986; Buchner et al, 2005; Pedersen and Pedersen, 1989; Savarese and Lunghi, 1990; Hvass et al, 1988). There was some variability in the method used to record this outcome. These included subjective assessments using Likert-styled responses, yes/no responses to the presence of pain, and visual analogue scale (VAS) scores.

Whilst no studies report pre-rehabilitation pain scores, there appeared consensus that at follow-up, ranging from 2.5 to eight years post-FTPD, a proportion of people continued to experience pain following rehabilitation. Thirty-five percent of Pedersen and Pedersen's (1989), 41% of Savarese and Lunghi's (1990) and 22% of Hvass et al's (1988) cohorts reported pain at their final follow-up assessments. Buchner et al (2005) reported a mean VAS pain score of three out of 10 in their cohort at a mean of 8.2 years post-patellar dislocation. Finally Hawkins et al (1986) reported the highest incidence of pain where five people (25%) reported mild pain, six (30%) reported moderate, whilst four people (20%) reported severe pain at a mean follow-up of 40 months. However no studies have assessed the reliability of measuring pain in people following FTPD. Previous studies have indicated that the VAS method of estimating pain severity is both valid and reliable in individuals with PFPS (Crossley et al, 2004; Laprade and Culham, 2002; Harrison et al, 1995). No studies have however assessed the reliability of Likert responses to pain following FTPD.

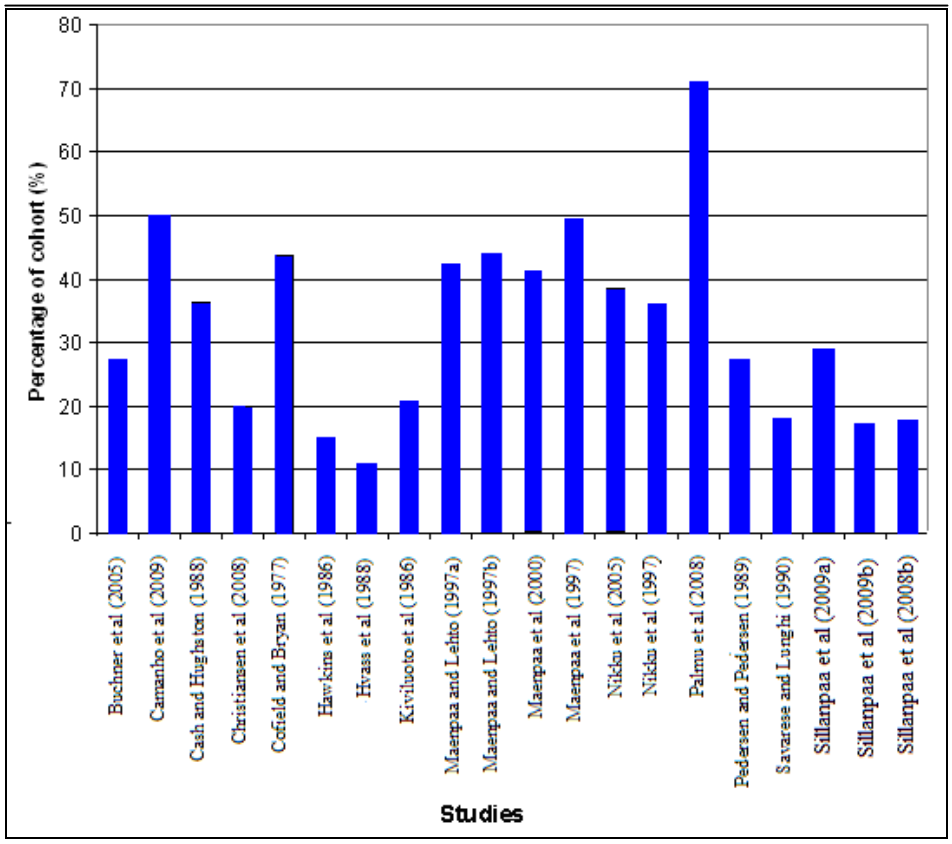
5.4.5 Effusion and Swelling

Atkin et al (2000) and Savarese and Lunghi (1990) assessed residual knee effusion in people following FTPD. Whilst there was no substantial difference in cohort characteristics or in the physiotherapy regimes prescribed, Savarese and Lunghi (1990) reported more than double the incidence of knee effusion (12%) compared to Atkin et al (2000; five percent) at final follow-up. However, as Table 6.1 demonstrates, both studies recruited small samples, thus this finding may have been a chance event and not typical of the FTPD population due to sampling error (Chow and Liu, 2004). In addition, the assessment of knee effusion has demonstrated high inter- and intra-rater reliability in those with knee osteoarthritis (Cibere et al, 2004; Johanson et al, 2004) but this outcome has not been assessed in people following FTPD.

5.4.6 Recurrent patellar dislocation

The most frequently cited outcome reported in the studies identified was frequency of recurrent patellar dislocation; reported in 20 papers (Figure 5.1).

Figure 5.1. Bar chart to illustrate the frequency of recurrent patellar dislocation post-rehabilitation of the 20 studies which evaluated this outcome measurement.



The incidence of recurrent dislocation ranged from 11% (Hvass et al, 1988) to 71% (Palmu et al, 2008) following physiotherapy. Palmu et al (2008) reported a considerably higher incidence of recurrent dislocation compared to the other studies. However this study solely recruited people younger than 16 years

(Palmu et al, 2008). When assessed by intervention there was no substantial difference in the physiotherapy regimes described in the five studies which reported an incidence of recurrent dislocation of less than 15% (Sillanpää et al, 2009a; Sillanpää et al, 2008b; Savarese and Lunghi, 1990; Hvass et al, 1999; Hawkins et al, 1986), compared to the seven studies which reported recurrent dislocation rates of greater than 40% (Palmu et al, 2008; Mäenpää and Lehto, 1997b; Mäenpää and Lehto, 1997a; Mäenpää et al, 1997; Mäenpää et al, 2000; Camanho et al, 2009; Cofield and Bryan, 1977).

5.4.7 Recurrent Patellar Instability

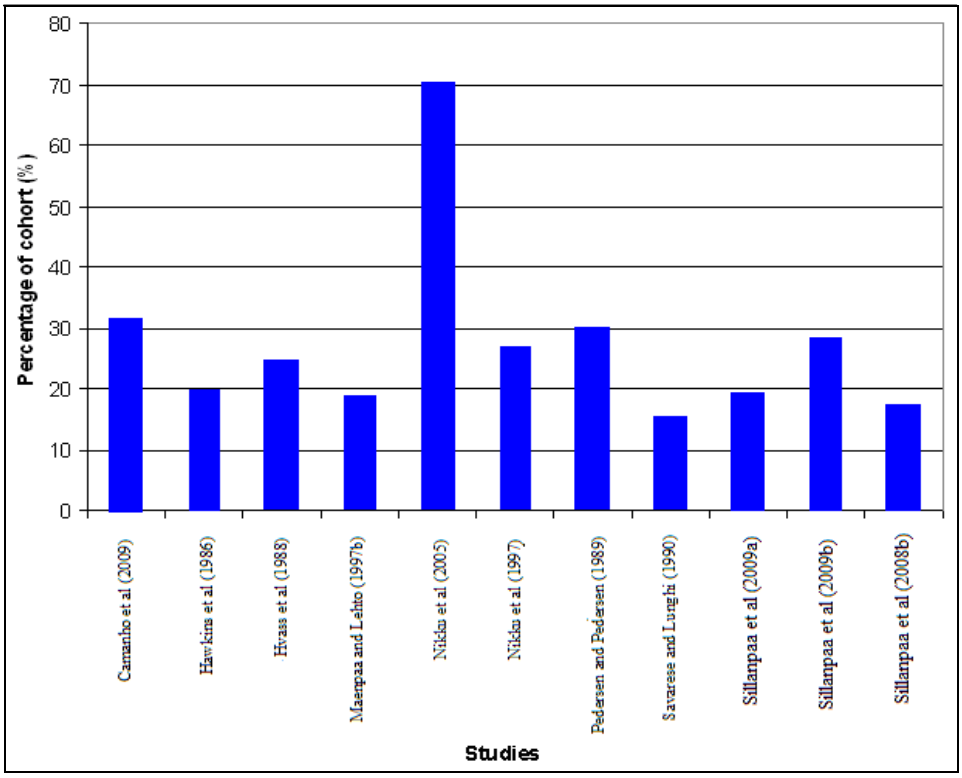
Eleven papers assessed the frequency of instability or subluxation symptoms in the absence of frank dislocation post-physiotherapy. Recurrent instability symptoms were reported in 15% (Savarese and Lunghi, 1990) to 70% (Nikku et al, 2005) of cohorts. This trend was consistent between the studies with the exception of Nikku et al's (2005) findings (Figure 5.2), who did not state what treatments were included in their rehabilitation programme. Therefore it was not possible to determine whether this difference in outcome was attributable to the interventions provided.

5.4.8 Lateral Patellar Apprehension

The Fairbank apprehension test (Fairbank, 1936) to assess post-rehabilitation patellar apprehension was reported in four papers (Nikku et al, 1997; Hawkins et al, 1986; Larsen and Lauridsen, 1982; Savarese and Lunghi, 1990). A positive apprehension test was reported in 29% (Nikku et al, 1997) to 53% of cohorts (Larsen and Lauridsen, 1982). Whilst this was a large range, the treatment strategies adopted between these studies were broadly similar, consisting of immobilisation followed by various forms of quadriceps exercises. The exception was Hawkins et al's (1986) study where their cohort was not prescribed exercises. In this study 10 individuals (50%) demonstrated a

positive apprehension test at a mean of 40 months post-injury. Nonetheless, the inter-rater reliability of the apprehension test has been shown to be poor (Smith et al, 2011b; Sallay et al, 1996), raising uncertainty in these findings.

Figure 5.2. Bar chart to illustrate the frequency of recurrent instability (not dislocation) symptoms post-rehabilitation of the 11 studies which evaluated this outcome measurement.



5.4.9 Patellar Mal-Tracking

Post-rehabilitation patellar mal-tracking, defined as the patella's inability to normally remain within the femoral trochlear during knee range of motion, was reported in two papers (Hawkins et al, 1986; Atkin et al, 2000). Hawkins et al (1986) reported that eight people (40%) presented with residual mal-tracking after 3.5 years post-injury. Whilst only 12 people (16%) in Atkin et al's (2000)

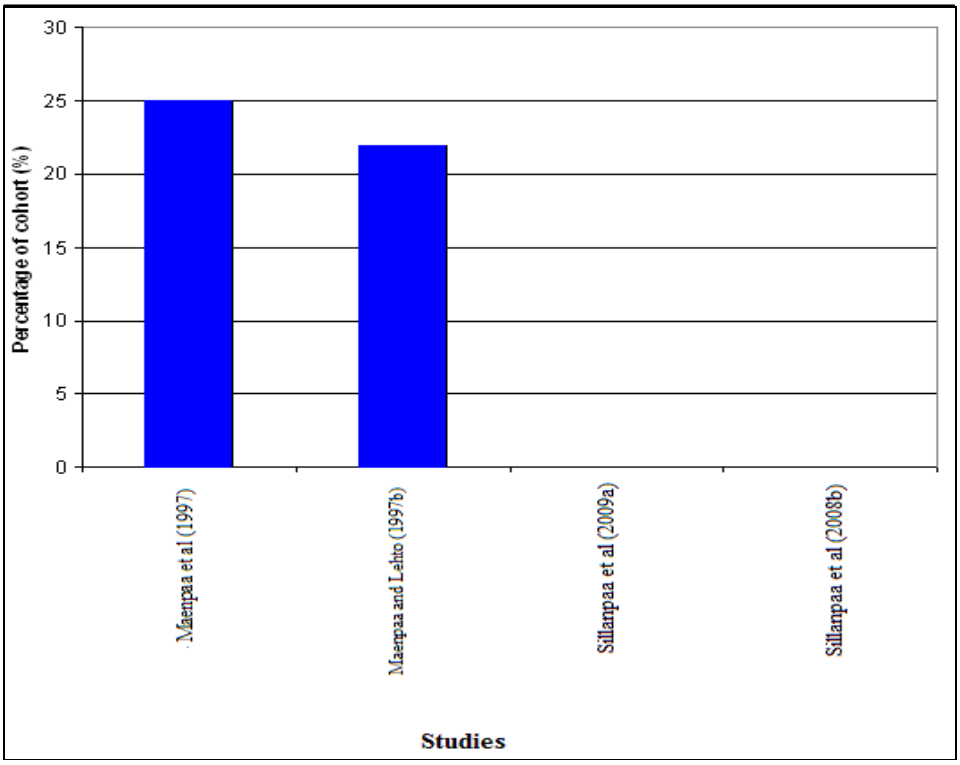
cohort presented with lateral patellar tracking after two years. This difference in mal-tracking may therefore be related to the interventions prescribed since participants in Hawkins et al's (2000) study were immobilised and did not receive exercises, whereas Atkin et al's (2000) cohort was prescribed passive and closed-chain strengthening exercises. Alternatively, this difference in outcome may be attributed to the different follow-up periods (mean= 24 weeks versus 40 months respectively). Finally measurement error may also have impacted on these results as the reliability of mal-tracking has been questioned with reported intra- and inter-rater reliability of 0.28 and 0.53 (weighted Kappa) respectively (Smith et al, 2011b).

5.4.10 Radiological Evidence of Patellofemoral Osteoarthritis

Signs of radiological patellofemoral joint osteoarthritis were reported in four papers (Mäenpää and Lehto, 1997b; Sillanpää et al, 2009a; Sillanpää et al, 2008b; Mäenpää et al, 1997) using with the Kellgren and Lawrence or Alback osteoarthritic scores (Kellgren and Lawrence, 1957; Alback, 1968). There was considerable variation in the incidence of patellofemoral joint osteoarthritis amongst the four papers (Figure 5.4). The mean incidence of patellofemoral osteoarthritis ranged from zero (Sillanpää et al, 2009a; Sillanpää et al, 2008b) to 22% (Mäenpää et al, 1997). Those papers which presented the highest incidence of osteoarthritis had the longest follow-up periods of 11 (Mäenpää et al, 1997) to 13 years (Mäenpää and Lehto, 1997b). Conversely both Sillanpää et al (2008b) and Sillanpää et al (2009a) reported that none of their participants presented with patellofemoral osteoarthritis following rehabilitation. However these cohorts were only followed for a mean of 6.9 and 7.5 years respectively. Furthermore, as the studies reviewed did not comment on the incidence of patellofemoral osteoarthritis before commencing rehabilitation, it was not possible to determine whether the incidence of osteoarthritis in Mäenpää and Lehto (1997b) or Mäenpää et al's (1997) cohorts was already evident or developed following FTPD. Nevertheless, previous literature has suggested that

the assessment of patellofemoral joint osteoarthritis is a reliable assessment in the hands of those following formal training (Günther and Sun, 1999; Günther et al, 1997; Scott et al, 1993). Given that none of the studies provided information pertaining to the degree of radiological training undertaken by their assessors this may have impacted on the reliability of these findings.

Figure 5.3. Bar chart to illustrate the frequency of patellofemoral osteoarthritis at follow-up post-rehabilitation in the four studies which evaluated this outcome measurement.



5.5 Methodological Limitations of the Identified Studies

The literature reviewed in this chapter presents a number of methodological limitations. Firstly, 11 studies did not clearly define their cohorts in respect of diagnoses, duration since injury or past musculoskeletal history. Only three studies reported how their participants were recruited and the process of

identification and recruitment of participants is unclear in 24 papers. This is a weakness since it is important to understand this factor when constructing generalisations around a cohort to the wider population (Kendall et al, 2003). Only four papers justified their sample sizes based on power calculations (Christiansen et al, 2008; Atkin et al, 2000; Palmu et al, 2008; Sillanpää et al, 2009a), thus raising the potential for samples recruited to be insufficiently large to detect a difference between the groups even if one exists (type II statistical error; Bland, 2006).

Nine papers clearly described the treatment interventions prescribed. Whilst general management strategies where clearly acknowledged in these papers, only five gave sufficient information to be able to reproduce their methods (Garth et al, 1996; Helgeson and Smith, 2008; Osterhues, 2004; Racouillat, 2007). Furthermore, whilst all studies reviewed used appropriate outcome measures to evaluate their cohorts, only three detailed the number and/or types of assessors employed (Palmu et al, 2008; Sillanpää et al, 2009a; Sillanpää et al, 2008b). By not providing this information, it is unclear whether assessment error, bias, or the influence of assessor knowledge and experiences were important factors which may have impacted through measurement error (Chow and Liu, 2004). Whilst it may have been logistically difficult to blind individuals to the physical interventions they received, no studies stated that their assessors were blinded to treatment allocation. By not blinding assessors, these results may have been affected by assessor expectation, perceptions and therefore introduced bias (Friedman et al, 1998). Whilst inferential statistics were presented in 19 publications, confidence intervals were only provided in two papers (Nikku et al, 2005; Nikku et al, 1997). Accordingly, the interpretation of the precision of the statistical tests remains unknown (Bland, 2006). Further information on the importance of confidence intervals, randomisation, sample size calculations and blinding will be explored in Chapter 14.

5.6 Summary

The current literature suggests that people following FTPD who are treated with a physiotherapy regime largely return to a good level of function and gain acceptable clinical results. Nonetheless a proportion of individuals report recurrent patellar dislocation and instability complaints, experience residual pain, with some impairment in their activity post-rehabilitation. The evidence-base does however present two major limitations. Firstly studies poorly described baseline measurements. Accordingly it has been difficult to determine the effect of each described physiotherapy treatment over time. Secondly since no specific physiotherapy treatment is compared to another, it is not possible to determine the efficacy of specific physiotherapy treatments.

The literature does highlight that quadriceps exercises were frequently prescribed to this population. However it remains unclear as to whether general-quadriceps strengthening exercises or specific-VMO strengthening exercises are superior for people following FTPD. Given the dearth of evidence assessing the effectiveness of specific physiotherapy interventions and the confusion surrounding both types of quadriceps exercises, answering this question remains important.

Chapter 6. Preferential activation of the vastus medialis oblique

6.1 Introduction

Authors have advocated the prescription of specific-VMO exercises to people following FTPD (Camanho et al, 2009; Garth et al, 1996; Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001). This is based on the understanding that a difference exists between the VMO and vastus lateralis muscle onset timing or activity in this population. It also assumes that the VMO can be preferentially recruited over the vastus lateralis and other quadricep muscles.

This chapter will examine the evidence pertaining to the preferential recruitment of VMO using different lower limb exercises. The chapter will present the literature search results (Section 6.2), then the different forms of lower limb exercises which have been assessed for their ability to preferentially activate the VMO. These include quadriceps contraction exercises in different lower limb positions including hip adduction-abduction (Section 6.3), hip internal-external rotation (Section 6.4), tibial internal-external rotation (Section 6.5), combined tibial/femoral internal-external rotation (Section 6.6), ankle dorsiflexion-plantarflexion (Section 6.7) and foot pronation-supination (Section 6.8)

6.2 Search Results

Twenty studies were identified which have assessed whether different lower limb exercises can preferentially activate the VMO. A summary of the characteristics of these study's is presented in Appendix 4.

6.3 Hip Adduction-Abduction

Eight studies compared the effect of hip adduction or abduction exercises on VMO to vastus lateralis EMG activity. Four studies compared the VMO to vastus lateralis activity of an isometric quadriceps contraction or straight leg raise exercise performed with or without maximum isometric hip adduction contraction (Karst and Jewitt, 1993; Monteiro-Pedro et al, 1999; Laprade et al, 1998; Cerny et al, 1995). All studies reported that there was no statistically significant difference in VMO:vastus lateralis activity for these exercises with healthy individuals ($p>0.05$; Karst and Jewitt, 1993; Monteiro-Pedro et al, 1999) and in people diagnosed with PFPS ($p>0.05$; Laprade et al, 1998; Cerny et al, 1995).

Four studies assessed the effect of a semi-squat quadriceps contraction with or without isometric hip adduction (Hertel et al, 2004; Coqueiro et al, 2005; Earl et al, 2001; Hodges and Richardson, 1993). Hertel et al (2004), Coqueiro et al (2005) and Earl et al (2001) reported no statistically significant difference between VMO and vastus lateralis EMG activity when a semi-squat exercise was performed with compared to without an isometric hip adduction contraction ($p>0.05$). However Hodges and Richardson (1993) concluded that isometric hip adduction with a semi-squat exercise provided statistically significantly greater VMO:vastus lateralis ratios, indicating preferential VMO activity, compared to a semi-squat exercise performed in lower limb neutral ($p<0.01$). This difference was greater in weight-bearing compared to a non-weight bearing semi-squat position ($p<0.05$). In relation to the other three studies, Hodges and Richardson (1993) assessed their EMG analysis of VMO at 60° knee flexion. They justified this by citing Basmajian et al's (1971) recommendation that this position can facilitate VMO activity. Since Karst and Jewitt (1993) and Cerny's (1995) studies did not assess EMG activity in this degree of knee flexion, this may account for why these papers reported different

findings to Hodges and Richardson's (1993) paper. Nonetheless, all the studies identified assessed either asymptomatic individuals or people diagnosed with PFPS. It is therefore not possible to state whether these findings are generalisable to the FTPD population. Secondly, all studies recruited small and potentially underpowered samples which may have permitted type II statistical error (Cleophas et al, 2009).

In summary, the majority of the literature would suggest that the addition of isometric hip adduction does not significantly influence VMO:vastus lateralis ratios compared to performing a quadriceps contraction without hip adduction. However, Hodges and Richardson's (1993) study identifies that semi-squat exercises with isometric hip adduction at 60° knee flexion may preferentially recruit the VMO.

6.4 Hip Internal-External Rotation

Seven studies assessed the effect of hip rotation on VMO activity. Six studies reported no statistically significant difference between VMO:vastus lateralis EMG activity with quadriceps exercises such as isometric, isotonic and semi-squats performed in hip external or internal rotation compared to hip joint neutral ($p>0.05$; Cerny, 1995; Herrington et al, 2006; Karst and Jewett, 1993; Lam and Ng, 2001; Livecchi et al, 2002; Mirzabeigi et al, 1999; Wild et al, 1982). Only Lam and Ng (2001) report preferential activation of the VMO compared to vastus lateralis when a semi-squat exercise was performed with the hip joint in internal rotation. They reported that VMO activity at 40° knee flexion, and the hip in internal rotation was significantly greater than the vastus lateralis ($p<0.05$). This statistically significant difference was not detected at 20° knee flexion ($p>0.05$).

It is unclear why there is a difference in outcomes between Lam and Ng's (2001) findings and the other studies identified. One reason for the discordance

may be due to the severity of their cohort's symptoms. Whilst Cerny et al (1995) and Wild et al (1982) included symptomatic individuals, only Lam and Ng (2001) documented the duration of individual's PFPS, and whether this was aggravated during the test procedures. Pain can influence normal EMG activity (Le Pera et al, 2001; Rutherford et al, 1986). Accordingly, pain may have acted as a confounding variable to account for this difference between the studies.

In summary, the evidence suggests that performing a quadriceps exercise in hip internal or external rotation does not preferentially activate the VMO. However, there was some evidence to indicate that performing a semi-squat exercise in hip internal rotation may preferentially recruit the VMO over the vastus lateralis for those with PFPS (Lam and Ng, 2001).

6.5 Tibial Internal-External Rotation

Three studies assessed tibial rotation on VMO and vastus lateralis EMG activity. Serrão et al (2005) and Laprade et al (1998) both assessed the effects of isometric quadriceps exercises in lower limb neutral compared to tibial internal or external rotation. They reported no statistically significant difference in VMO:vastus lateralis EMG activity between these different quadriceps exercises ($p>0.05$).

Willis et al (2005) reported that the VMO could be preferentially recruited when a quadriceps exercise was performed with the tibia in external rotation. They assessed the effects of VMO EMG activity during cycling performed in external versus neutral tibial rotation. This was evaluated with eight people diagnosed with PFPS and 20 asymptomatic individuals. The mean VMO:vastus lateralis ratios were significantly higher when cycling was performed in tibial external rotation ($p<0.01$) compared to neutral for both the healthy and PFPS cohorts.

In summary, current literature suggests that cycling in tibial external rotation preferentially activates the VMO, but that the VMO cannot be preferentially recruited by quadriceps exercises preformed in tibial internal or external rotation during open kinetic chain isometric quadriceps exercises.

6.6 Combined Tibial/Femoral Internal-External Rotation

One study published twice evaluated the effect of performing a quadriceps exercise in tibial and femoral rotation (Miller et al, 1997b; Miller et al, 1997c). They reported a statistically significantly greater VMO:vastus lateralis EMG activity ratio, indicating preferential VMO activity, in a cohort of asymptomatic participants who performed a semi-squat and step-dip exercises in femoral and tibial internal rotation compared to external rotation ($p<0.01$). This difference was not evident in the PFPS cohort ($p>0.05$). Furthermore this study only included nine participants, thus potentially introducing a type II statistical error (Bland, 2006). Nonetheless this study provides some indication that semi-squat and a step-dip exercise when performed in femoral and tibial internal rotation may preferential recruit the VMO.

6.7 Ankle Dorsiflexion-Plantarflexion

Four studies have assessed the effect of quadriceps exercises performed with the ankle dorsiflexed or plantarflexed on EMG VMO:vastus lateralis activity ratios (Cerny, 1995; Tepperman et al, 1986; Zakaria et al, 1997; Bos and Blosser, 1970). All reported that the VMO was not preferentially recruited in any of these positions.

Wong and Ng (2006) and Callaghan et al (2009) previously questioned whether inconsistency in electrode placement could influence data collection and its interpretation. Both Tepperman et al (1986) and Bos and Blosser's (1970) studies document that the distal vastus medialis was assessed rather than using

the term 'VMO'. Since electrode placement was poorly described in these studies the reliability of data collection may be questioned and accurate replication of these studies is impossible (Kollmitzer et al, 1999).

In summary, no significant evidence suggests that the VMO could be preferentially activated by performing a quadriceps exercise in different ankle joint positions.

6.8 Foot Pronation-Supination

Three studies assessed the effect of different foot positions with quadriceps loading on VMO and vastus lateralis EMG activity. Two studies reported no difference in VMO:vastus lateralis ratio between a quadriceps contraction performed in subtalar supination or pronation (Hung and Gross, 1999; Cerny, 1995). However Gregersen et al (2006) assessed foot position and quadriceps muscle activity during a cycling task with 15 competitive cyclists who had no history of knee injury. They found that cycling with the foot in a pronated position provided a significantly greater VMO:vastus lateralis activity ratio compared to neutral or in supination ($p<0.01$). This paper did not however provide sufficient EMG data for a detailed analysis or clinical interpretation. Furthermore, since this study's cohort consisted of asymptomatic, competitive cyclists, it is of questionable relevance to the FTPD population seen in clinical practice.

To conclude, foot pronation may preferential recruit the VMO during a cycling task, but this was not demonstrated during semi-squat or isometric exercises performed in subtalar supination or pronation.

6.9 Summary

The current evidence-base has assessed this domain in both asymptomatic healthy individuals and people diagnosed with PFPS. However, no studies have investigated whether the VMO can be preferentially activated through lower limb exercises in individuals following FTPD. Whilst there remains a wealth of evidence to the contrary, some evidence exists to suggest that performing semi-squat, step-dip exercises or isometric quadriceps exercises in 40° to 60° knee flexion in tibial and femoral internal rotation or with isometric hip adduction may preferentially recruit the VMO. However the lack of agreement within the literature may be attributable to the considerable methodological variation and recurrent limitations identified above.

This chapter concludes the Literature Review section of this thesis. After examining the existing literature pertaining to FTPD, the following sections will present the methods and findings of the three studies undertaken in this programme to advance our current knowledge of this population.

Section Three

National Survey Study

Chapter 7. National Survey Methodology

7.1 Introduction

The previous chapters have indicated that a number of different methods have been ascribed to assess, treat and evaluate people following FTPD. There appears little consensus on what constitutes the optimal management strategy (Chapter 5). It also remains unclear how musculoskeletal physiotherapists currently assess and treat people following FTPD. The following chapter will describe and justify the methods of a national survey conducted to answer this question. The rationale (Section 7.2), aims and objectives (Section 7.3), design (Section 7.4), population (Section 7.5), sampling strategy (Section 7.6) and sample size of this study (Section 7.7) will be discussed. Following this, the procedures undertaken to construct a questionnaire (Section 7.8), the use of incentives (Section 7.9), the questionnaire delivery (Section 7.10) data analysis (Section 7.11) and ethical considerations (Section 7.12) will be presented.

7.2 Rationale

The literature review revealed that no previous national or international surveys to determine how physiotherapists manage people following FTPD have been published. Addressing this limitation in the published literature would be valuable for two reasons: Firstly the majority of the literature pertaining to FTPD has been written by orthopaedic surgeons (Chapter 5, Section 5.3.4). Whilst a wealth of literature was identified focussing on the specific surgical interventions used, authors have categorised ‘physiotherapy’ or ‘rehabilitation’ as a single intervention neglecting to specify what treatments constituted these interventions. Therefore, whilst exercise, electrotherapy, taping and manual techniques have been cited within the literature, it remains unclear which specific types of exercises or treatments have been prescribed. A national survey to identify which specific interventions are used during the assessment,

treatment and evaluation of UK musculoskeletal clinicians for this population is therefore warranted. Additionally, whilst three case studies have been written by physiotherapists (Helgeson and Smith, 2008; Osterhues, 2004; Racouillat, 2007), none were UK-based. Accordingly no literature has documented UK physiotherapy practice and it remains unknown how musculoskeletal physiotherapists in the UK manage this population and whether it differs to practice abroad.

Secondly the literature review identified a paucity of evidence investigating the clinical effectiveness of physiotherapy treatment for people following FTPD. By identifying the most frequently used current practice, future research prioritises may be better informed, and thus enhance the clinical applicability of future research.

7.3 Aims and Objectives

Key objectives in this study were:

- How musculoskeletal physiotherapists in the NHS assess people following FTPD?

- What interventions are used by musculoskeletal physiotherapists in the NHS to treat people following FTPD?

- What outcome measurements and evaluation tools are used by musculoskeletal physiotherapists in the NHS to evaluate people following a FTPD?

7.4 Study Design

A descriptive survey design was adopted. This was most appropriate as this design can facilitate the collection of a large quantity of descriptive data on people's activities, behaviours or experiences, thus answering the research question (Portney and Watkins, 2009; Miller and Crabtree, 1999; Buckingham and Saunders, 2004). This study's exploratory design also facilitated the development of theories and hypotheses: a key objective given that this research question has not been previously answered.

A cross-sectional strategy was adopted as the study aimed to collect data at one time point. The study was not designed to assess whether behaviour changed over time which would have been more suited to a longitudinal design (Dooley, 2001). Furthermore the study did not aim to assess whether the seniority of the respondent was important. This would have favoured a hierarchical study design (Aldridge and Levine, 2001).

7.5 Population

Senior musculoskeletal physiotherapists who practiced in acute NHS hospitals in 2009 were the target population. By sampling this group of senior clinicians it was anticipated that physiotherapists who had experience of managing people following FTPD on multiple occasions would respond. This was considered better than gathering data from lesser experienced clinicians, since expertise has been suggested to affect the validity of questionnaire responses (Aldridge and Levine, 2001). Finally by assessing a specific group of clinicians, greater generalisations could be constructed to this specific group of respondents.

Physiotherapists who work in community settings or private practice were not surveyed for two reasons. Firstly, anecdotally in the East of England, the majority of people following FTPD receive physiotherapy through acute NHS

hospital departments rather than primary care or private sector services. Since the aim of this survey was to capture the activities of clinicians most experienced with this population, acute hospital physiotherapists were considered more appropriate. Secondly, all acute NHS hospitals were identified in January 2009 using the websites www.nhs.uk, www.show.scot.nhs.uk, www.healthandcareni.co.uk and www.wales.nhs.uk. At the time of devising the study, the NHS websites clearly defined these as hospital trusts. The identification of all community physiotherapists, who may have worked in a variety of settings such as community hospitals, general practices or the domiciliary sector was less well defined. Accordingly sampling error may have occurred if community physiotherapists were included in the sampling frame. Similarly, a number of private hospitals could be identified through the internet. However some degree of uncertainty in the sampling would have occurred if the sampling frame had included all private physiotherapists since not all clinicians subscribe to the UK private physiotherapist registers such as the Chartered Society of Physiotherapist's Association of Chartered Physiotherapists working in Independent Healthcare and Charities. Therefore to minimise such error only acute hospital NHS physiotherapy departments were surveyed.

7.6 Sampling Strategy

Physiotherapy departments were eligible if their hospital provided an accident and emergency service and/or a department of trauma and orthopaedics, determined by the researcher from their hospital's website. This criterion was appropriate as a preliminary survey of physiotherapy referrals to five East of England hospitals identified that the majority of referrals to their physiotherapy departments were made through these two sources during a three month audit (Appendix 5). It was assumed that hospitals which did not have either of these departments would have less experience of managing individuals following

FTPD and therefore would be less representative of 'typical' management of this population for this survey.

7.7 Sample Size

In descriptive studies such as this, the recruitment of a sufficient sample to allow findings to be generalisible to a wider population is essential (Bowling, 2005). The required sample size figure can be estimated based on previously reported outcomes or though the estimation of variance in a sample with relatively similar characteristics using the standard error (Barnett, 1999). However, such calculations require previous results to inform these values. Since a similar survey had not previously been undertaken, it was not possible to estimate the required sample size.

Although sampling in survey methods is considered important in respect to a survey's validity and reliability (Sapsford, 1999), no studies have assessed the effect of adopting different sampling strategies on response rate or validity in health service research. This study therefore adopted a convenience sampling strategy by including all potentially eligible respondents. This constituted 306 possible sites. Whilst directly answering this research question, by surveying such a large number of sites, there was less potential for the results to be influenced by extreme responses which may have occurred if a small number of physiotherapists had been sampled.

7.8 Construction of the Questionnaire

Data was collected using a self-administered questionnaire (Appendix 6). This was considered advantageous over other data collection methods such as interviews for a number of reasons. For example, although face-to-face interview surveys allow an interviewer to explain complex questions if required, these can be expensive and geographically limited requiring

researchers to meet with every respondent. The presence of an interviewer can also introduce bias to their interaction with the interviewee and impact on reliability (Bloch, 2007; Dooley, 2001). To address geographical limitations, telephone interviews have been advocated, curtailing the need for a researcher to travel, whilst costing approximately half as much as face-to-face interviewing (Groves and Kahn, 1979; Dooley, 2001). However this can make asking sensitive questions more difficult and also requires prior access to all potential respondent's telephone numbers. This can introduce potential selection bias when attempting to generalise the findings to a wider population (Bloch, 2007).

Postal questionnaires have been advocated as an appropriate means of collecting geographically dispersed information. Such a design was adopted in this national survey since this approach was more cost-effective. Self-administered postal surveys also negate the need for a researcher in each site to facilitate data collection thereby minimising interviewer bias and increasing respondent autonomy and anonymity particularly when answering sensitive questions (Bloch, 2007; Bowling, 2009; Edwards and Talbot, 1999). Lastly, postal questionnaires can provide respondents with greater time for data gathering and to check records or documents before answering compared to interviews, thus accurate results may be generated rather than guessing some data if time constraints are made (Bloch, 2007).

Postal questionnaire surveys do present some limitations. Although recommendations can be made on who completes them, the researcher can never be sure whether the person they intended to complete the survey actually satisfied the sampling strategy (Bloch, 2007). Response rates for postal questionnaires are commonly lower than interview responses, where 40% to 60% have been considered excellent (Oppenheim, 1992). It is therefore unclear as to what affect non-respondents may have on overall findings (Portney and Watkins, 2009).

7.8.1 Question Order

Previous literature has suggested that question order may not necessarily be a major source of response error according to six health-related studies which have assessed this topic (Dunn et al, 2003; McColl et al, 2003; Barry et al, 1996; Kaufmann et al, 1997; Bolman et al, 2007; Bischof et al, 2005). Five reported that question order did not influence the responses obtained in RCTs assessing different questionnaires (Dunn et al, 2003; McColl et al, 2003; Barry et al, 1996; Kaufmann et al, 1997; Bolman et al, 2007). One reported that question order significantly affected the responses obtained ($p<0.001$; Bischof et al, 2005). In this study, Bischof et al (2005) randomised over 10,000 people to receive two different questionnaires assessing alcohol use with different question orders. Although they reported a difference, these authors acknowledged that their groups differed at baseline with respect to the proportions of females and smokers between the study groups. This was considered a major confounding variable by the authors (Bischof et al, 2005).

The questionnaire was developed with 14 questions. This covered topics including: grade of responding physiotherapist, frequency of FTPD referrals, assessment, treatment, onward referral of people and where the population are discharged to following their treatment. The questions were presented in an order to reflect a typical patient-pathway, from assessment, treatment to discharge. This was appropriate in order to facilitate the respondent's understanding of the questionnaire's flow and thereby attempting to reduce undue confusion to risk response error (Oppenheim, 1992).

7.8.2 Questionnaire Length

Six studies have investigated the effect of questionnaire length in health-related surveys. Five studies have reported no statistically significant difference in response rates between the use of shorter or longer questionnaires ($p>0.05$;

Koloski et al, 2001; Jepson et al, 2005; Dirmaier et al, 2007; Jenkinson et al, 2003; Mond et al, 2004). One study reported a contrary finding. Kuskowska-Wolk et al (1992) randomised 6783 women following mammogram to receive one of eight different questionnaires of varying lengths. They reported response rates were 20% lower for longer compared to shorter questionnaires (Odds Ratio (OR) = 1.20; 95% CI: 1.06, 1.37). However, the questionnaire contents differed between the shorter and longer questionnaires posing different questions on different domains. Since the topic under investigation can affect response rate (Bloch, 2007; Hing et al, 2011), it was therefore not possible to state whether the length or topic of the questionnaires used accounted for Kuskowska-Wolk et al's (1992) results. Thus, based on the available literature, it appeared highly appropriate not to limit the questionnaire length but to ask all questions required to address the research question.

7.8.3 Questionnaire Responses

The questionnaire provided partial closed-ended responses. The list of potential responses provided in the questionnaire was identified by two means. Firstly, the literature review examining the assessment (Chapter 4), treatment and outcome measures used (Chapter 5) for people following FTPD was reviewed to identify how physiotherapists may 'theoretically' manage this population . Secondly, the questionnaire was piloted with ten senior physiotherapists who were asked to identify any additional response options not previously stated. This piloting will be further discussed in Section 7.8.6.

The list of possible activities physiotherapists may use was augmented with space for respondents to include additional activities not initially included. This was important since such a survey had not been previously undertaken, and so it was therefore considered prudent to collect all unexpected or unpredictable responses as part of this exploratory research (Bowling, 2009).

The partial closed-ended responses were categorised numerically as to the frequency with which techniques or procedures were undertaken for people following FTPD. Potential responses were '100%', '99-75%', '74-50%', '49-25%', '24-1%', '0%' and a 'don't use' response. These responses were used given the common usage of Likert scale responses in survey studies, hence it was anticipated that response rate may be enhanced and completion error minimised (Petersen, 2000). The use of the percentage response format was adopted to reduce differences in respondent's interpretation of the response options. Streiner and Norman (2008) reported that variation between respondent's interpretations of "very often", "often" or "sometimes" can result in measurement error. By using exact percentages, this error related to response format interpretation is minimised since there is universal understanding of the meaning assigned to different percentage values (Streiner and Norman, 2008).

The use of partial closed-ended responses has been examined in one trial of healthcare professionals. Griffith et al (1999) randomised 1007 Canadian doctors to receive either an open- or closed-ended questionnaire to assess various clinical issues. The authors reported a significant association, with greater missing responses to open-ended response questionnaires (OR: 2.51 (95% CI: 1.94, 3.26). However this study only evaluated demographic characteristics. Therefore it is not possible to generalise these findings to questionnaires which require further, more detailed, or less predictable responses, as in the case of this national survey.

7.8.4 Questionnaire Appearance

All questionnaires were printed single-sided on white A4 paper. This was justified since whilst paper colour and format are hypothesised as being important variables, white A4 paper has been shown not to demonstrate a significant difference on response rate when compared to coloured paper questionnaires printed on different sized paper. The questionnaires were not

printed on thick paper since of the three studies which have evaluated the effect of paper quality and size on response rate, none have demonstrated a statistically significant difference (Clark et al, 2001; Beebe et al, 2007; Mallen et al, 2008).

Taylor et al's (2006) paper was the only study identified which has assessed the effect of envelope colour on response rate in health care surveys. They reported no overall affect of envelope colour on response rate in their survey of 2,524 patients across five general practices (OR=0.90; 95% CI: 0.76, 1.06; Taylor et al, 2006). They did however report that green rather than black ink questionnaires provided a significantly greater response rate of 65.7% to 61.4% respectively (OR=1.20; 95% CI: 1.02, 1.41). However, on further appraisal of this paper, there was significant heterogeneity between the general practices involved in this study, limiting the confidence placed on these findings due to this potential confounding factor. Thus questionnaires in this study were posted in plain white envelopes and printed in black ink.

Although the printing costs incurred would have been lower if the questionnaire was printed double-sided all were single-sided in this study. This was justified through the only study which has assessed this variable in healthcare research. Brehaut et al's (2006) paper, a survey of 399 members of the Canadian Association of Emergency Physicians, demonstrated that those questionnaires printed on a single-sided sheet had a seven percent higher response rate when compared to double-sided (OR=1.41; 95% CI: 0.90, 2.20).

7.8.5 Covering Letter

Whilst no studies have assessed the importance of covering letters on response rate or survey validity it would be unethical to withhold information pertaining to the justification and background of a study. Potential respondents should understand why and how information collected will be used before consenting

to complete a questionnaire (World Medical Association, 2000). Accordingly a covering letter was deemed essential (Appendix 8).

The use of deadlines has been hypothesised to encourage people to complete and return questionnaires speedily to enhance response rate (Oppenheim, 1992). This assumption is supported in the literature. The use of a deadline has been shown to significantly improve response rate in Roberts et al's (1978) study (p=0.02). Furthermore, a deadline ensured that repeat mailing could be organised within a timescale to better facilitate study progression. Thus, in this study, the covering letter stipulated that the questionnaire should be completed and returned within three weeks of receipt.

Each questionnaire's covering letter was not signed by hand but a photocopied signature was used instead. A single study has assessed this in health service research. McKenzie-McHarg et al's (2005) randomised trial of 3,799 Members and Fellows of the Royal College of Obstetricians and Gynaecologists reported no significant difference in respect of response rate (Risk Ratio (RR)=1.01; 95% CI: 0.98, 1.04) or time taken to respond (p=0.39) for respondents who received a covering letter with a computer-printed compared to a hand-written signature.

7.8.6 Pilot Phase

The questionnaire and the covering letters were piloted in May 2009 by 10 senior physiotherapists from an out-patient physiotherapy department at a large teaching hospital in the East of England. This group were chosen as their characteristics reflected the target sample's. Each participant was asked to complete the pilot questionnaire and a feedback form (Appendix 9). Using the feedback it was possible to determine whether all potentially eligible responses were provided, and if not, to identify any important responses omitted. These could then be incorporate into the final version of the questionnaire. The pilot

provided an opportunity for respondents to state whether they felt any of the questions were ambiguous or incorrectly formatted or if they were being biased with leading questions. The participants were also asked to review the covering letter supplied with the questionnaire. This further reduced the possibility of the researcher's views from inadvertently influencing the questionnaire findings through its design, whilst also examining face validity (Portney and Watkins, 2009). Each participant was asked to assess whether they understood the aims and objectives of the study, who should complete the questionnaire and to whom it should be returned.

The results of this pilot study were analysed and are presented in Appendix 10. They indicated that no substantial amendments were required to the questionnaire's structure or the covering letters. This suggested that it was fit for purpose to answer the research question, thereby possessing face validity. A small numbers of additional responses, not initially included in the questionnaire, were incorporated during the construction of the final version (Appendix 6).

The first question posed in the questionnaire determined the grade of responding physiotherapist. In 2004, the NHS's Agenda for Change grading system (Department of Health, 2005) was adopted by NHS hospitals where Band 5 physiotherapists were newly qualified, Band 6 physiotherapists were more senior physiotherapists, Band 7 physiotherapists were more experienced physiotherapists who have a specialised interest in a clinical area, whilst Band 8a physiotherapists were categorised as further experienced specialist physiotherapist who may or may not be working out of their traditional scope of practice. Consensus was sought and achieved in the pilot study to determine whether these categories were appropriately interpreted.

7.9 Incentives

Incentives were not used in this survey. Although a number of studies have reported that cash or lottery ticket incentives can optimise response rate (Parkes et al, 2000; Dirmaier et al, 2007; Jones et al, 2000; Kenyon et al, 2005; Kalantar and Talley, 1999; Asch et al, 1998; Robertson et al, 2005), only one study has assessed the use of incentives in a survey of physiotherapists (Jamtvedt et al, 2008). They reported no significant difference in response rate between those who received a chocolate bar compared to those who did not with 2054 Norwegian physiotherapists (Actual Relative Risk: 0.4; 95% CI: -3.44, 2.6; Jamtvedt et al, 2008). Whether monetary incentives would have demonstrated the same effect is unknown. However, given Jamtvedt et al's (2008) findings, there is limited evidence to support the added cost incurred with the use of an incentive to optimise response rate.

7.10. Questionnaire Delivery

The questionnaire was delivered through the UK postal system. A postal questionnaire was justified over electronic or telephone delivery systems for two key reasons. Firstly, although a number of studies have evaluated the effects of different modes of questionnaire administration, only three health-related studies have assessed this variable. These have suggested that response rate does not significantly differ between postal and electronic surveys (Addington-Hall et al, 1998; Akl et al, 2005; Beebe et al, 2007). Secondly, telephone or electronic surveys can only be conducted when telephone numbers or email addresses are available. Since neither could be accessed for this cohort, a postal questionnaire approach was the only feasible strategy.

All eligible hospital's postal addresses were identified from their respective websites. The Superintendent or Senior Physiotherapist of each identified out-patient physiotherapy department was sent a copy of the questionnaire, a

covering letter and a stamped addressed envelope. The letter was addressed to the most senior member of staff as it was perceived that they could act as a 'gate-keeper'. This was essential as the covering letter asked that the questionnaire should be completed by a senior member of the physiotherapy team who had an interest in knees or the most experienced senior staff member. Hence the letter receiver could delegate the questionnaire to the most appropriate physiotherapist.

7.10.1 Repeat Mailing

Three weeks after posting the first questionnaires non-respondents were identified. This was done by decoding a coded number written on each questionnaire to identify which sites had or had not responded. Three weeks was deemed a suitable period of time to allow the questionnaires to be delivered to each department, for the 'gate-keepers' to direct them to a suitable physiotherapist, and for the physiotherapist to complete and return the questionnaire.

All identified non-respondents were sent a reminder letter (Appendix 11). A further three weeks after sending the reminder letter, all further non-respondents were identified using the decoding form and were sent a second copy of the questionnaire with a stamped addressed envelope. The use of a multiple mailing strategy was considered essential. Three studies have assessed the effect of mailing strategies with non-respondents in the health-related evidence-base. All reported that this strategy significantly increased response rate (Wensing et al, 1999; Asch, 1996; Roberts et al, 1994). The use of an initial reminder letter was justified since Asch (1996) and Roberts et al (1994) both reported no significant difference in response rate in the form of reminder used, either a simple postcard, follow-up letter or a second copy of the questionnaire. They also acknowledged that a reminder letter is cheaper than re-sending the full questionnaire. However, for the second mailing, a full questionnaire was

posted in the recognition that the original questionnaire may have been mis-laid.

The third mailing was the final mailing. No further approaches were made to non-respondents as it was felt that may produce undue stress on non-respondents. Furthermore, it was assumed that if respondents were going to respond, they were most likely to have done so by that time.

7.11 Data Analysis

All completed questionnaires were analysed and responses collated into a data extraction form.

The primary research question was to determine what assessment tools, treatment modalities and outcome measures were used, and to what frequency, by senior musculoskeletal physiotherapists in NHS acute hospitals when managing people following FTPD.

Secondary questions included knowing of:

- The grade of the responding physiotherapists.
- The treatment settings.
- The frequency with which individuals following FTPD were referred to these departments.
- The proportion FTPD formed the respondent's typical caseload.
- The duration of physiotherapy rehabilitation.
- Which other professions were consulted during the management of this population.
- Where these people were discharged to once treatment had completed.

In order to address the primary and secondary questions, descriptive statistics and frequency distributions were used to collectively assess all completed questionnaires. This data is presented as frequency distributions, mean values and standard deviations as appropriate. Inferential statistical tests were not appropriate as it was not the objective of the study to compare the results of different respondents in respect to clinical grade or hospital location. All analyses were performed on SPSS version 16.0 for Windows (IBM, New York, USA).

7.12 Ethical Considerations

Ethical approval

Before commencing this study, ethical approval was sought through the Norfolk Research Ethics Committee (Reference Number: 09/H0310/84) and the East Norfolk and Waveney Research Governance Committee (Reference Number: 2009ORTH10/190-11-09) (Appendix 12). This was necessary at the time of conducting the study as this study required the participation of human subjects, employed in the NHS.

Data handling and storage

All data sheets were kept in a locked cupboard at the researcher's place of work. Once data has been processed and the findings disseminated, all original data sheets will be destroyed in a hospital confidential waste system.

Confidentiality and anonymity

All data were managed and handled by the researcher confidentially. Respondent's personal information was not recorded to protect anonymity. Although a coded number was used to identify non-respondents, it was not

possible to identify the exact individual who responded, thus ensuring individual anonymity. The use of the coded number to identify non-respondents was stressed in the covering letter to alley potential concerns regarding the attribution of responses to a specific hospital. Anonymity and confidentiality of questionnaire data does not affect validity (Gerbert et al, 1998; Campbell and Waters, 1990; Leohnard et al, 1997; Malvin and Moskowitz, 1983) and issues of privacy and confidentiality have been legislated for in the Data Protection Act (1998). This states that data should be adequate, relevant and not excessive in relation to the purposes of the research, and that data should only be obtained to address the researcher's aims and not processed in a manner incompatible with those objectives.

Consent

A consent form was not necessary in this study. The covering letter stated that consent would be implied if the participant completed and returned their questionnaire. This satisfied the ethical considerations outlined by the approving local research ethics committee (Appendix 12) and the Declaration of Helsinki (World Medical Association, 2000).

Coercion

The covering letter stated that institutions which declined to participate would not be identified in the final write-up, and that this would not jeopardise the representation of their hospital. Although literature suggests that incentives may enhance response rate, no financial or gift incentives were used in this survey as limited resources were available and there is limited evidence for incentives in physiotherapy surveys.

Informing potential participants

The study's aims and objectives and methods of analysis and dissemination were clearly explained to all potential respondents in the accompanying covering letter. Thus the respondents and their 'gate keepers' were fully informed about the study.

7.13 Summary

In this chapter, the rationale and methods for this exploratory study have been described. Methodological approaches and strategies adopted to answer the research questions posed, plus the ethical and data analysis issues have been discussed. The next chapter will present the findings of this study, before considering the clinical and research implications in the Discussion section.

Chapter 8. National Survey Results

8.1 Introduction

The previous chapter outlined the rationale and methods of a survey to determine how physiotherapists assess, treat and evaluate people following FTPD. This chapter will present the survey findings.

The chapter has been subdivided to present data relating to response rate (Section 8.2), respondent characteristics (Section 8.3), followed by the assessment (Section 8.4), treatment (Section 8.5), treatment settings (Section 8.6) and outcome measurements (Section 8.7) used by respondents. Finally the results pertaining to the typical discharge destinations for these people following physiotherapy treatment (Section 8.8) and treatment durations will be presented (Section 8.9).

The raw data for Tables 8.1 to 8.4 is presented in Appendix 13.

8.2 Response Rate

The study procedure is summarised in Figure 8.1. Of the 306 questionnaires sent, 180 were returned (59% response rate). One hundred and two departments responded to the first questionnaire, 38 following the second and 40 physiotherapy departments responded following the third mailing. The regional response rates are presented in Figure 8.2. Geographically response varied with the South East, the East of England and Scotland responding very well whilst less than 50% of physiotherapy departments from the South West of England and London responded.

Figure 8.1. Study flow diagram to illustrate the methodological pathways undertaken as part of this national survey.

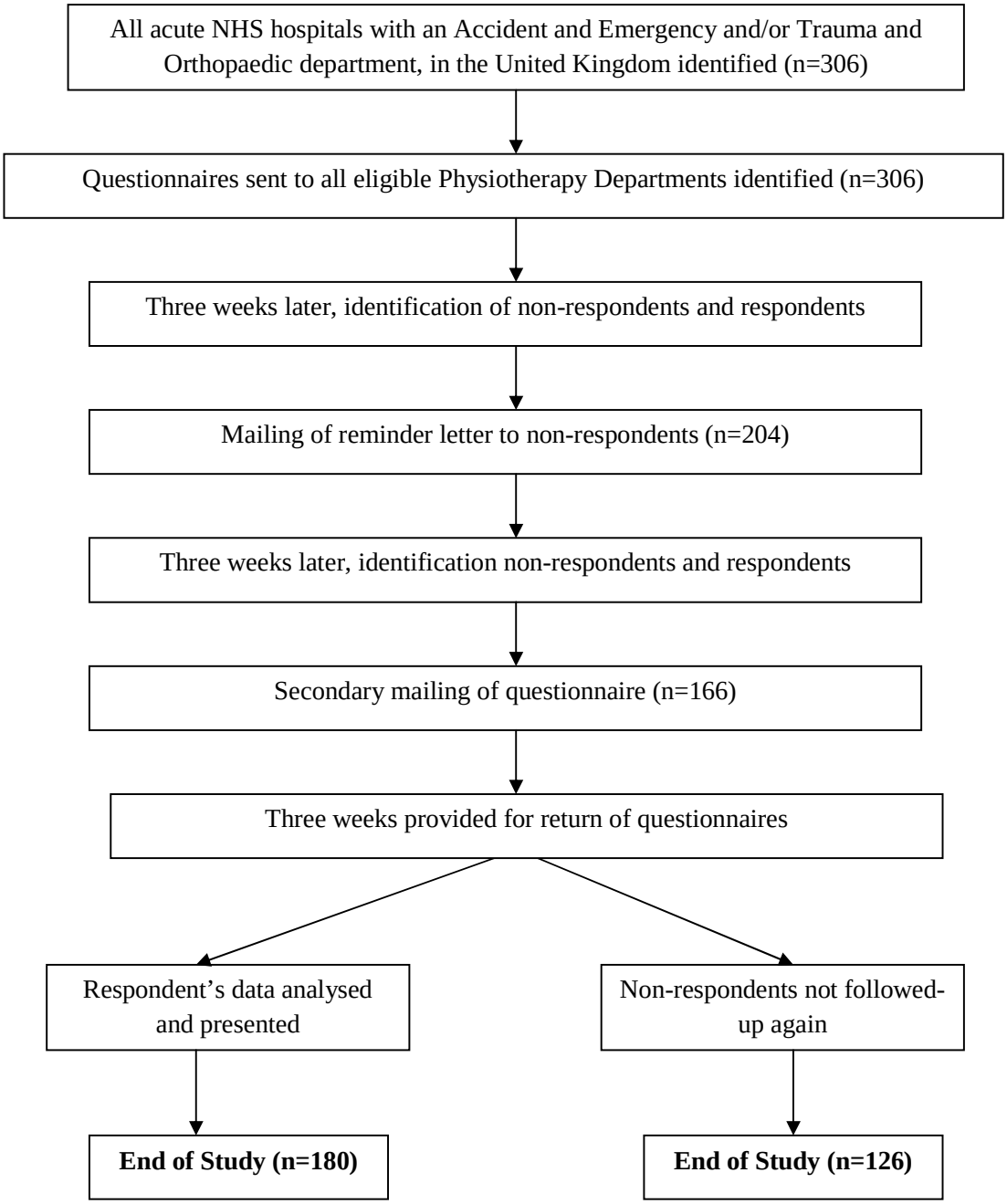
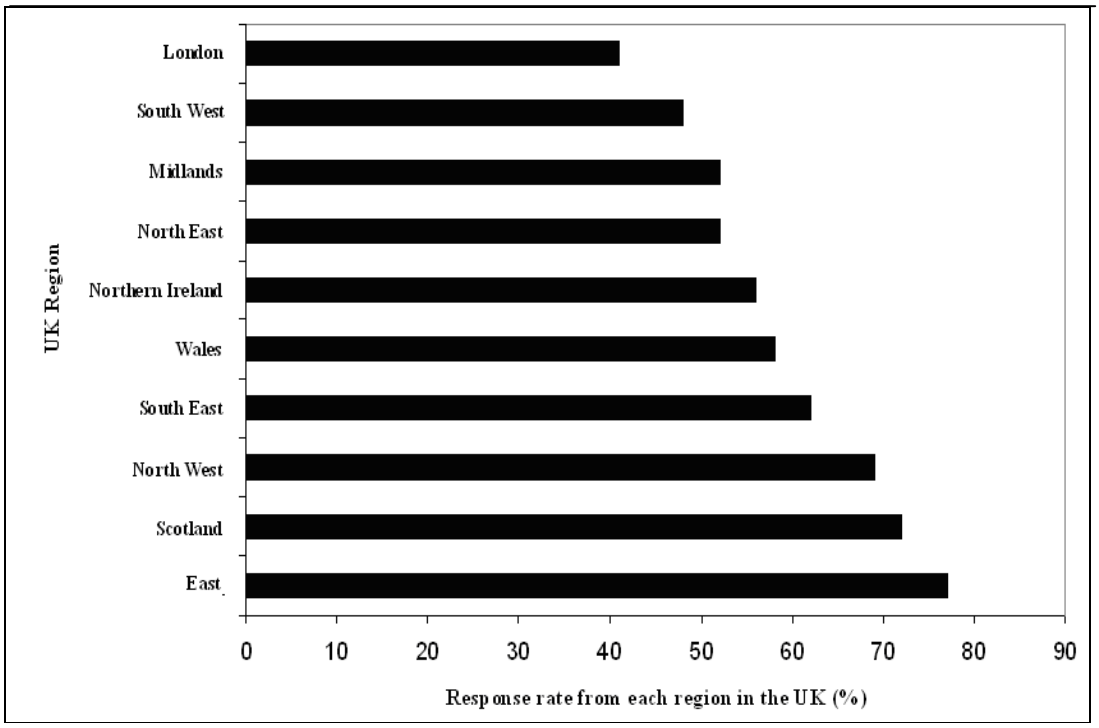
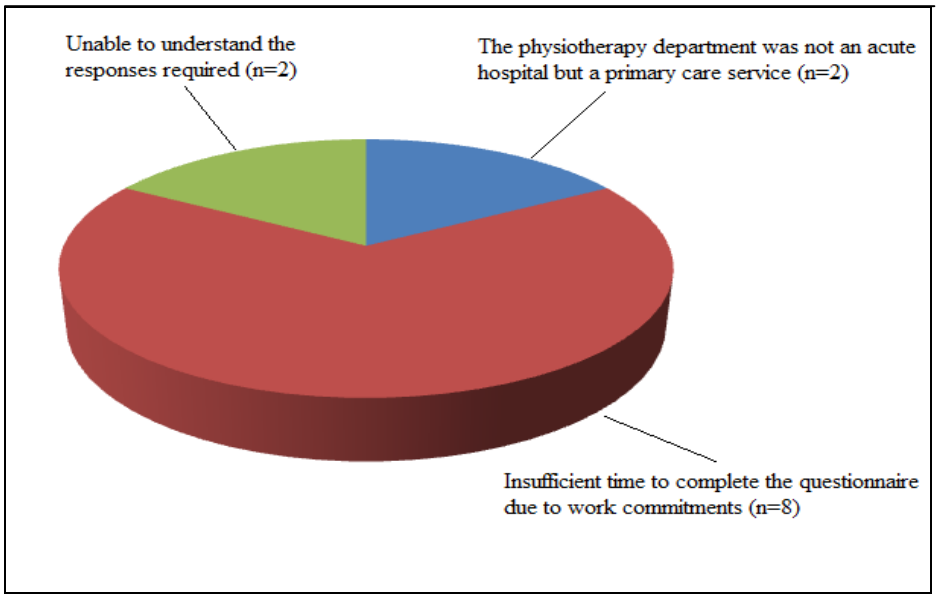


Figure 8.2. Histogram to illustrate the regional response rates from this national survey.



Of the 180 respondents, 160 reported that they had treated people following a FTPD. Eight physiotherapists reported that they had not managed this population and therefore did not feel able to complete the questionnaire. None completion is fully described in Figure 8.3.

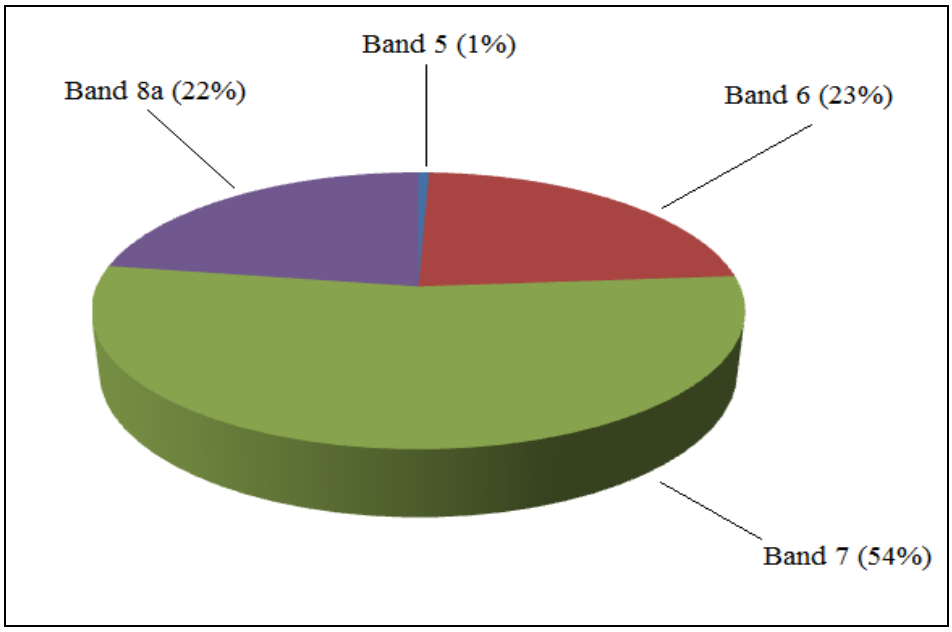
Figure 8.3. Pie-chart depicting the reasons for not completing the questionnaire.



8.3 Respondent Characteristics

Respondents most commonly worked as Band 7 physiotherapists. The distribution of grade is presented in Figure 8.4. The survey indicated that FTPD was not a commonly seen pathology for physiotherapists in acute NHS hospitals in the UK. Respondents reported that a median of two people (Inter-Quartile Range (IQR) 1-3) were treated per month in each department. This constituted a median of two percent (IQR 1-5) of respondent's typical caseloads.

Figure 8.4. Pie-chart to illustrate the specific grade of the responding physiotherapists, and the frequency to which each grade responded.



8.4 Assessment Methods

The most frequently cited assessment method used for people following FTPD was quadriceps muscle strength. This was reported by 86% of respondents for 75% or more of their caseloads. Assessments such as the observation of lateral or medial patellar glide (84%), knee effusion (83%), patellar tracking (79%), and a convincing report of a patellar dislocation by referral (78%) or by the individual (76%) were reported as most frequently undertaken for over 75% of FTPD caseloads (Table 8.1).

The use of patellofemoral-specific assessment methods was less widely seen. Sixty-eighty percent and 47% of respondents reported using the apprehension test and patellar compression test respectively for at least 75% of their caseloads. However 81% and 48% of respondents reported that they either never used or were not aware of the Bassett's sign or J-sign test.

8.5 Treatment Strategies

Table 8.2 illustrates the frequency of treatments which respondents used for people following FTPD. The most frequently cited treatment was reassurance which was used by all respondents for at least 75% of their FTPD caseloads. This was closely followed by exercise prescription. The most commonly prescribed exercises were active knee motion (96% of respondents for 75% or more of their typical caseloads), proprioceptive (95%), general quadriceps (90%) and specific-VMO strengthening/recruitment exercises (81%) (Table 8.2).

Respondents reported using quadriceps and specific-VMO strengthening/recruitment exercises for the majority of people following FTPD. There was however a wide variation in the specific types of exercises prescribed (Table 8.3). The most commonly used quadriceps/VMO exercise prescribed was the semi-squat performed in lower limb neutral which was used by 78% of respondents for 75% or more of their patients following FTPD. Exercises such as isometric knee extension (73%), static bike and cycling exercises (69%), straight leg raises (68%) and isotonic knee extension exercises (57%) performed in lower limb neutral, were also prescribed for 75% or more of respondent's typical FTPD caseload.

Table 8.1. Table to document the frequency of assessment methods used to diagnose people following FTPD.

Assessment method		**Frequency (%) to which respondents used assessment methods for % of their patients**						
		100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of test**
Convincing report of a patellar dislocation by patient		51	25	8	3	4	9	0
Convincing report of a patellar dislocation by referral		44	33	13	6	1	2	0
Observation of:	Gait pattern	68	12	7	8	3	9	0
	Genu valgum	52	13	8	11	6	11	0
	Pronation of the foot /pes planus	53	15	9	10	3	10	0
	Patellar malposition (baja, alta, squinting; tilt)	51	24	13	4	3	5	0
	Patellar tracking	66	18	7	3	4	8	0
	VMO atrophy/hypertrophy	66	18	6	6	2	29	0
Assessment of:	Patellofemoral crepitations	43	14	9	11	7	16	0
	Effusion	63	19	6	3	4	4	0
	Femoral anteversion	34	13	18	12	8	16	0
	Tibial torsion	33	14	20	11	11	12	0
	Multi-joint ligamentus laxity	39	26	18	7	6	4	0
	Quadriceps Strength	67	19	7	4	2	1	0
	Glutei strength	45	18	14	6	5	13	0
	Hamstring Strength	46	19	14	8	8	1	0
Special tests:	Q-angle	20	18	14	13	11	24	0
	Apprehension test	47	21	12	6	4	10	1
	Bassett's Sign	3	3	6	5	2	9	73
	J-sign	16	9	10	6	12	12	36
	Patellar compression test	23	24	18	6	8	16	6
	Lateral or medial patellar glide	63	23	6	4	3	3	0
Other…	X-ray	1	0	0	0	1	0	0

Assessment method		Frequency (%) to which respondents used assessment methods for % of their patients						
		100%	99-75%	74-50%	49-25%	24-1%	0%	Not aware of test
Other…	Length of ITB	3	3	0	0	0	0	0
	Lat retinaculum tightness	1	0	0	0	0	0	0
	Sag sign	0	1	0	0	0	0	0
	Medial retinaculum tightness	0	0	1	0	0	0	0
	Lateral patellar swelling	0	1	0	0	0	0	0
	Range of motion	3	0	0	0	0	0	0
	Proprioception	3	1	0	0	0	0	0
	Core stability	1	0	0	0	0	0	0
	Single leg squat	2	0	1	0	0	0	0
	Knee ligament test	1	0	0	0	0	0	0
	Retropatellar palpation	1	0	0	0	0	0	0
	Clark test	1	0	0	0	0	0	0
	Muscle length (Quad/Ham/Calf)	4	0	0	0	0	0	0
	Lunge	0	0	1	0	0	0	0
	Squat	1	0	0	0	0	0	0
	VMO firing-timing	1	0	0	0	0	0	0
	Step down test	1	0	0	0	0	0	0
	Gastronmeius strength	1	0	0	0	0	0	0
	Hop test	0	1	0	0	0	0	0
	Genu recurvatum assessment	1	0	0	0	0	0	0
	Neuro pattern movement	1	0	0	0	0	0	0

ITB – Iliotibial Band; Ham – Hamstring; Quad – Quadriceps; VMO – Vastus Medialis Obliquus

Table 8.2. Table to document the frequency of different treatment strategies used to manage people following FTPD.

Treatment		**Frequency (%) to which respondents used treatment methods for % of their patients**						
		100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of treatment**
Exercises (Range of motion)	Active knee exercises	73	21	3	1	1	1	0
Exercises (strengthening/ recruitment)	General quadriceps	74	16	2	3	1	4	0
	Specific VMO	64	17	6	4	3	6	0
	Hamstring	29	27	17	9	9	9	0
	Glutei muscle	30	29	13	9	3	4	0
	Transversus abdominus	5	16	23	13	14	30	0
Exercises (stretches)	Quadriceps	25	19	21	14	9	10	0
	Hamstrings	28	24	18	16	4	13	0
	Calf muscles	26	22	19	11	8	11	0
	ITB/tensor fascia lata	21	27	17	13	8	12	0
Exercises (others)	Proprioception lower limb exercises	76	19	3	1	1	1	0
Manual therapy	Patellar accessory mobilisations	8	19	20	16	19	14	0
Advice	Rest and/or behaviour/sporting modification	64	19	5	3	4	2	0
	Reassurance	91	9	0	0	0	0	0
	Elevation	25	19	19	11	14	13	0
Taping	VMO stimulating taping techniques	4	16	24	16	14	16	0
	VL inhibiting taping techniques	2	3	6	14	26	43	6
	ITB inhibiting taping techniques	0	3	9	9	24	47	8
Appliances	Knee braces	4	6	12	17	27	33	1
	Footwear adaptation/ over-the-counter orthotics	3	8	17	25	28	19	0
Electrotherapy	Ultrasound	1	3	4	6	28	59	0
	Electronic stimulation	0	3	6	11	18	63	0
Biofeedback	Electronic biofeedback techniques	0	3	4	6	23	61	2

Treatment		Frequency (%) to which respondents used treatment methods for % of their patients						
		100%	99-75%	74-50%	49-25%	24-1%	0%	Not aware of treatment
Miscellaneous	Postural correction	16	21	20	17	11	14	1
	Acupuncture	0	0	4	11	23	62	1
Others	Cognitive Behavioural Therapy	1	4	4	14	22	60	1
	Sport rehabilitation	1	0	0	0	0	0	0
	Gait re-education with crutches	0	0	1	0	0	0	0
	Hydrotherapy	0	0	0	1	1	0	0
	Movement pattern re-education	2	0	0	0	0	0	0
	Patella self-mobilisation	0	1	0	0	0	0	0
	Unloading tape	0	0	0	1	0	0	0
	Exercises for lower limb	1	0	0	0	0	0	0
	Functional strength	1	0	0	0	0	0	0

ITB – Iliotibial Band; VL – Vastus Lateralis; VMO – Vastus Medialis Obliquus

Table 8.3. Table to demonstrate the frequency of quadriceps/VMO exercise prescription used in the treatment of patients following FTPD.

Exercise		**Frequency (%) to which respondents used treatment methods for % of their patients**						
		100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of Exercise**
Semi-squat with	Lower Limb Neutral	52	26	9	3	1	9	0
	Hip Adduction	9	9	10	3	11	58	1
	Hip Abduction	4	9	19	6	9	51	2
	Hip Internal Rotation	3	4	9	6	21	54	3
	Hip External Rotation	10	11	13	6	9	50	2
	Tibial Internal Rotation	0	0	4	5	9	77	4
	Tibial External Rotation	3	5	9	4	13	62	3
	Femoral and Tibial Internal Rotation	1	0	6	4	7	78	5
	Femoral and Tibial External Rotation	1	8	6	8	7	65	6
	Foot Supination	4	6	8	6	10	60	6
	Foot Pronation	1	3	3	3	9	77	6
	Ankle Dorsiflexion	3	3	4	5	6	74	6
	Ankle Plantarflexion	1	5	3	4	6	74	8
Isometric knee extension with…	Lower Limb Neutral	51	23	6	4	1	16	1
	Hip Adduction	5	8	8	6	3	67	4
	Hip Abduction	3	5	7	4	6	72	4
	Hip Internal Rotation	1	4	5	4	4	77	4
	Hip External Rotation	11	15	12	5	7	50	0
	Tibial Internal Rotation	1	3	4	8	13	68	4
	Tibial External Rotation	4	5	4	4	10	69	4
	Foot Supination	1	2	2	3	5	82	6
	Foot Pronation	0	1	3	3	6	79	8

Exercise		Frequency (%) to which respondents used treatment methods for % of their patients						
		100%	99-75%	74-50%	49-25%	24-1%	0%	Not aware of Exc
Isometric knee extension with…	Ankle Dorsiflexion	10	13	7	4	4	60	3
	Ankle Plantarflexion	1	1	3	1	8	81	6
Straight leg raise with…	Lower Limb Neutral	45	23	9	5	3	16	1
	Hip Adduction	2	6	6	4	7	72	3
	Hip Abduction	4	4	4	4	6	74	3
	Hip Internal Rotation	1	5	6	4	9	73	3
	Hip External Rotation	16	24	12	6	9	34	0
	Ankle Dorsiflexion	16	21	7	4	6	46	1
	Ankle Plantarflexion	1	4	2	1	7	84	1
Isotonic knee extension with…	Lower Limb Neutral	41	16	9	1	3	29	1
	Hip Adduction	2	6	3	3	5	79	3
	Hip Abduction	2	4	3	4	6	79	3
	Hip Internal Rotation	1	3	3	3	7	81	3
	Hip External Rotation	8	11	8	3	8	60	3
	Tibial Internal Rotation	0	4	3	4	4	82	2
	Tibial External Rotation	2	7	6	4	7	72	3
	Ankle Dorsiflexion	9	8	9	3	6	63	2
	Ankle Plantarflexion	1	1	1	3	5	88	3
Static Bike/Cycling with…	Lower Limb Neutral	47	23	16	3	1	11	0
	Tibial Internal Rotation	0	3	1	1	6	84	4
	Tibial External Rotation	0	3	3	4	4	84	3
	Foot Supination	0	2	2	2	5	87	3
	Foot Pronation	0	1	1	1	5	89	4
Step-Up Step-Down exercises with…	Femoral and Tibial Internal Rotation	5	5	6	1	7	72	4
	Femoral and Tibial External Rotation	10	18	9	1	6	54	3
	Foot Supination	6	7	5	4	3	74	1
	Foot Pronation	1	1	2	2	3	87	4

Fewer physiotherapists reported prescribing exercises not performed in lower limb neutral. For example, isometric knee extension exercises with hip adduction, hip internal rotation, foot supination or foot pronation were never used for over 75% of respondent's caseloads. The most frequently used variation was a semi-squat exercise performed in hip external rotation, used by 53% physiotherapists for over 50% of their FTPD caseloads.

Instead of lower limb neutral, there was an overall trend for the prescription of exercises performed in external rather than internal rotation. For example, respondents more frequently prescribed semi-squat, isometric or isotonic knee extension exercises in femoral or tibial external rotation, compared to internal rotation for 75% or more of their typical FTPD caseload (Table 8.3).

Conventional concentric and eccentric (isotonic) knee extension exercises were less commonly prescribed compared to isometric or functional exercises such as squats, step exercises and cycling. Fifty-seven percent of respondents reported using isotonic exercises in lower limb neutral for 75% or more of their caseloads compared to 78% for semi-squat, 73% with isometric and 69% for static bike exercises (Table 8.3).

Over 65% of physiotherapists reported using quadriceps, hamstring, calf or iliotibial band/tensor fascia lata stretches for the majority of their patients (Table 8.2). Electrotherapy modalities such as ultrasound, electronic stimulation and biofeedback systems, as well as taping and manual therapies were used infrequently by respondents in comparison to exercise prescription (Table 8.2). Ultrasound was reported as never used by 59% of respondents, whilst 63% and 61% reported that they never use electronic stimulation or biofeedback systems respectively for those following FTPD.

8.6 Treatment Setting

Physiotherapists reported treating their FTPD cohorts either one-on-one (51%) or in a combination of one-on-one and a group settings (48%). One percent of physiotherapists reported that their patients were exclusively managed in a group setting.

8.7 Outcome Measures

The most commonly used outcome measure was patient's self-reported satisfaction adopted by 90% of respondents (Table 8.4). They frequently reported not being familiar with a number of outcome measurements. For example the Hughston visual analogue scale (VAS) knee score and the Lower Extremity Functional Score were used by only 14% and eight percent of physiotherapists respectively for over 75% of their patients (Table 8.4). Similarly the Measure Yourself Outcome Profile (MYMOP) and the Lysholm Knee Score were used by only five and four percent of physiotherapists respectively for over 75% of their patients following FTPD (Table 8.4).

8.8 Onward Referrals

Thirty-three percent of physiotherapists reported involving biomechanics departments in the majority of their FTPD caseload's care. Thirty-one percent reported involving an orthopaedic surgeon. Eight percent of physiotherapists reported requesting additional radiological imaging for over 50% of their caseloads.

Table 8.4. Table to document the frequency of different outcome measurements used to evaluate treatment outcomes following FTPD.

Outcome measure	**Frequency (%) to which respondents used outcome measures for % of their patients**						
	100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of tool**
Subjective Patient Satisfaction	66	16	5	1	1	10	0
Cincinnati	0	1	4	1	4	62	30
Fulkerson Patellofemoral Rating Scale	0	0	1	1	2	54	45
Hughston VAS knee score	10	4	1	0	1	48	39
IKDC	3	1	1	0	3	57	37
Short-Form 12 or 36	1	1	3	1	4	57	36
Lysholm	1	3	5	2	3	50	40
Kujula	0	1	2	1	1	48	50
Tegner	1	3	1	1	2	47	49
Musculoskeletal Function Assessment Injury and Arthritis Survey	1	1	1	1	3	54	42
MYMOP	2	3	1	0	0	0	0
KOOS	1	1	1	0	1	0	0
PFPS	1	0	1	1	0	0	0
LEFS	7	1	2	1	1	0	0
VAS Pain	1	1	0	0	0	0	0
Objective functional and clinical measures	3	1	0	0	0	0	0
In house knee questionnaire	0	1	0	0	0	0	0
Achievement of agreed goals	1	0	0	0	0	0	0
Oxford/MRC muscle strength	1	0	0	0	0	0	0

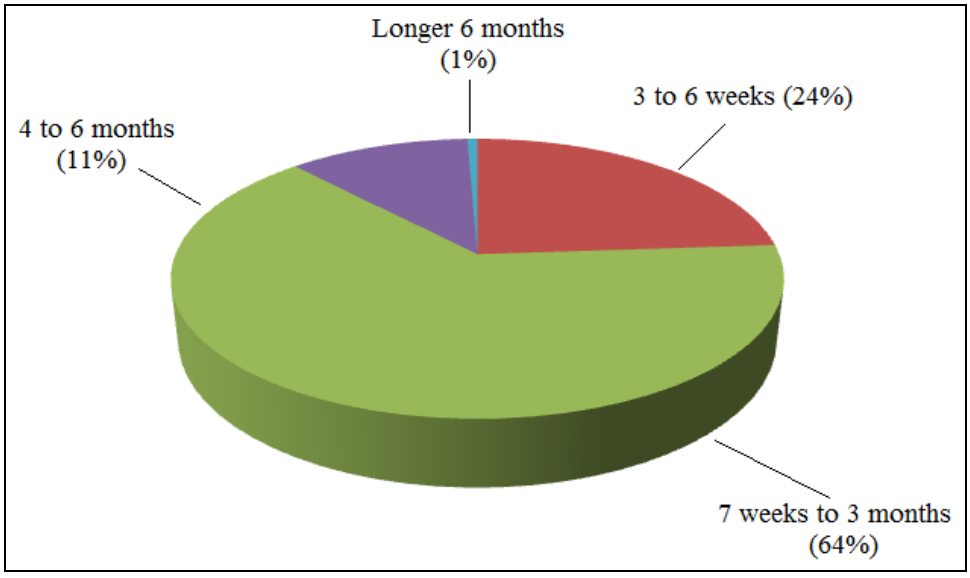
IKDC - International Knee Documentation Committee; KOOS – Knee Injury and Osteoarthritis Outcome Score; LEFS – Lower Extremity Functional Score; MRC – Medical Research Council; MYMOP – Measure Yourself Medical Outcome Profile; PFPS – Patellofemoral Pain Score; VAS – Visual Analogue Scale

Eighty-nine percent of physiotherapists reported typically discharging the majority of their caseloads without further referral on completion of their course of physiotherapy without further referral. If not, people were either discharged to another senior physiotherapist, general practitioner, orthopaedic surgeon or to a biomechanics department for on-going treatment.

8.9 Treatment Duration

Treatment duration was most commonly reported as between seven weeks to three months after commencing physiotherapy (Figure 8.5).

Figure 8.5. Pie-chart to demonstrate the total duration of rehabilitation patients typically receive from physiotherapists following FTPD.



8.10 Summary

The findings of this survey suggest that people following FTPD constitute a small proportion of a typical musculoskeletal physiotherapist's caseload working in an acute NHS hospital. Quadriceps strength, effusion and patellar tracking and glide are the most commonly used assessment methods. The predominant treatment strategies employed are reassurance and exercises directed to improve proprioception, knee range of motion, quadriceps and VMO strength/recruitment. Patient self-reported satisfaction was the most frequently used outcome measure.

The implications of these findings and how these relate to the previous evidence-base will be discussed further in the following Discussion chapter.

Chapter 9. National Survey Discussion

9.1 Introduction

The findings of the national survey (Chapter 8) indicated that FTPD constitutes two percent of musculoskeletal physiotherapist's caseloads when working in an acute NHS hospital. Whilst quadriceps strength, patellar tracking and glide and effusion were most commonly assessed, the predominant treatment strategies for people following FTPD were re-assurance and exercises directed at improving proprioception, knee range of motion, quadriceps and VMO strength or recruitment. Patient satisfaction was the most frequently cited outcome measure.

This chapter will explain the findings reported in Chapter 8. It will discuss possible explanations for these findings (Section 9.2), clinical implications of the results (Section 9.3), will make recommendations on future studies to further develop this area (Section 9.4) and will finally identify possible limitations to this study (Section 9.5).

9.2 Explanation for the Findings

The literature review demonstrated that the current evidence-base for the assessment of people following FTPD is limited in size and methodological quality (Chapter 4). Only the sensitivity and specificity of the apprehension test, Bassett's sign, clinical tibial tubercle to trochlear groove distance and Q-angle have been assessed in people following lateral patellar dislocation (Sallay et al, 1996; Ando et al, 1993; Shakespeare and Fick, 2005; Nonweiler and DeLee, 1994). The reliability of physical examination tests used in the FTPD population has previously only been estimated with orthopaedic surgeons and not with physiotherapists (Smith et al, 2011b). The low awareness and clinical application of specialist patellofemoral tests was demonstrated with 81% and

48% of respondents reporting either never using or being unaware of the Bassett's sign or J-sign tests. This low awareness may be related to physiotherapist's limited knowledge of such tests based on a paucity of research. Alternatively this may be attributed to limited educational and clinical exposure. As the survey identified, people following FTPD typically constituted two percent of respondent's caseloads. Given this, clinicians may be less inclined to undertake further study or enquiry into this pathology compared to the more frequently exhibited patellar disorders such as PFPS or patellar tendinopathy (Callaghan and Selfe, 2007).

The survey indicated that re-assurance was the most frequently cited treatment, used by all respondents in at least 75% of their caseloads. This finding supports previous generic and specialist texts on the management of soft-tissue injuries (Brukner and Khan, 2010; Norris, 2000). Such texts recommended that educating people regarding their musculoskeletal disorder and predicted recovery is important to increase understanding of their prescribed treatment programme, motivation and compliance (Brukner and Khan, 2010). Previous authors have suggested that advice on rest, ice, elevation and compression techniques are essential during the management of acute injuries (Norris, 2000; Brukner and Khan, 2010). Others have stressed the importance of education on the pathophysiological mechanisms involved to increase individual's awareness of their musculoskeletal complaint (May, 2010). It remains unclear what information should be provided to people following FTPD under the term "reassurance". Whilst it may be assumed that these generic advice strategies are provided, it was unclear whether advice on activity avoidance, possible rehabilitation goals and treatment time-frames to return to occupational or sporting pursuits were provided. Furthermore it was not clear whether the interpretation of 'reassurance' varied between respondents.

Exercises are considered the mainstay treatment for people following patellar dislocation (Mears and Cosgarea, 2001; Beasley and Vidal, 2004; Solomon et

al, 2001; Aichroth, 1983; Howell, 2002). Consequently questions probing the specific types of exercises prescribed by respondents were made. The survey indicated that both general quadriceps and specific-VMO exercises were frequently prescribed to this population (Table 8.2). A variety of different exercises have been purported to preferentially recruit the VMO (Hodges and Richardson, 1993; Miller et al, 1997a; Miller et al, 1997b; Ng and Lam, 2001; Willis et al, 2005; Gregersen et al, 2006). These have included semi-squats with hip adduction, isometric quadriceps and tibial-femoral internal rotation, isometric quadriceps in tibial-femoral internal rotation and leg dips in tibial-femoral internal rotation (Hodges and Richardson, 1993; Willis et al, 2005; Gregersen et al, 2006). However, the evidence-base supporting the notion that the VMO can be preferentially activated is limited in both size and methodological quality (Chapter 6, Section 6.9). Furthermore no studies have assessed this with a FTPD cohort.

The survey sought to determine the frequency of general quadriceps and specific-VMO exercise prescription. It did not distinguish between these two types of exercises. This was justified because there remains some confusion regarding the definition of 'specific-VMO' exercises (Chapter 6, Section 6.9). However exercises performed out of lower-limb neutral have been considered exercises which use the VMO compared to the quadriceps in general (Zakaria et al, 1997). Therefore there appeared a trend towards prescribing quadriceps exercises in external rather than internal lower limb orientations. This was in contrast to the literature where there was no supporting evidence to validate these interventions (Chapter 6, Section 6.4, Section 6.6). This may be a consequence of a misinterpretation of literature, for example the frequently cited paper by Syke and Wong's (2003) study. These authors reported an increased VMO activity in exercises with lower limb external rotation (Syke and Wong, 2003). However they did not assess vastus lateralis activity to determine 'preferential activation'. Studies which have demonstrated increased EMG activity for the VMO but did not compare this to vastus lateralis activity,

do not demonstrate whether the exercises preferentially activated the VMO. This confusion may also be attributed to previous recommendations by McConnell and Australian musculoskeletal physiotherapists who over the past 20 years have advocated external rotation exercises to preferentially recruit the VMO (McConnell, 1997; McConnell, 2002; Cowan et al, 2003; Cowan et al, 2002; Cowan et al, 2001). Such recommendations have not been based on EMG research conducted with FTPD cohorts, but on healthy asymptomatic cohorts or those people with PFPS (Cowan et al, 2003; Cowan et al, 2002; Cowan et al, 2001).

A number of treatment strategies were reported as rarely utilised by physiotherapists to treat people following FTPD. These included electrotherapy modalities, acupuncture and taping techniques. This may be attributed to the specialist post-registration skills required to undertake some of these treatments, particular acupuncture and specialist taping techniques. Acupuncture is more widely used in the UK by physiotherapists to treat individuals with chronic or poorly controlled pain (Hurley and Bearne, 2008). Such symptoms are not frequently associated with FTPD. Similarly the evidence-base surrounding the use of taping and acupuncture is limited for this population. Taping has been reported as part of a physiotherapy treatment programme in two single-case reports (Osterhues, 2004; Racouillat, 2007). Acupuncture has not been reported within the patellar dislocation literature (Chapter 5). Accordingly there may be little incentive for physiotherapists to adopt these treatments in their routine management for people following FTPD.

The survey identified that proprioceptive exercises were widely prescribed. Ninety-five percent of respondents prescribed these exercises to at least 75% of their FTPD caseloads. Although not assessed in FTPD, Jerosch and Prymka (1996a) reported a significant deterioration in proprioceptive capability following recurrent patellar dislocation ($p<0.05$). However this was only assessed in a cohort of nine individuals. The frequent use of proprioceptive

exercises may reflect the wide-spread use of these techniques for people following other knee injuries such as anterior cruciate ligament rupture (Pezzullo and Fadale, 2010). It remains unclear as to which specific exercises are taught in clinical practice as this was not explored in this survey.

Gluteal strength and core stability exercises were identified as commonly used treatments. Previous literature has associated poor gluteal control and core stability muscle recruitment and control in those with PFPS (Powers, 2010; Reiman et al, 2009; Dierks et al, 2008; Cowan et al, 2009). Cowan et al (2009) hypothesised how hip and trunk control may related to altered knee biomechanics. They suggest that motor neurone inhibition may occur at the hip due to changes in neuromotor control found in the quadriceps vasti muscles or due to proximal factors such as gluteal control as demonstrated in 10 participants diagnosed with PFPS compared to 27 asymptomatic controls (Cowan et al, 2009). However, Powers and colleagues have suggested that lateral patellar subluxation can be a result of the femur internally rotating underneath the patella during weight-bearing activities (Souza and Powers, 2009; Powers et al, 2003; Powers, 2010). They suggest that this can occur through insufficient gluteal control resulting in overt internal femoral rotation (Souza and Powers, 2009; Powers et al, 2003). Whilst generalising the findings of PFPS to FTPD cohorts may be attractive, given the excessive lateral translation associated with patellar dislocation, these assumptions may not necessarily be founded. This therefore remains hypothetical until further study is conducted on the gluteal and core stability control of FTPD cohorts.

Physiotherapists have been encouraged to evaluate clinical outcomes using validated and reliable outcome measures (Mayo, 1994; Jette et al, 2009). The survey indicated that the most commonly used outcome measure reported was patient's self-reported satisfaction with their outcome. This was reported by 82% of respondents in at least 75% of their FTPD caseloads. Whilst other outcome measures were used by some physiotherapists, the results from this

study indicate that nearly 75% of respondents reported either not using or being unaware of any other outcome measure to evaluate this population. The reliability and validity of a number of outcome measures used by physiotherapists including the Lower Extremity Functional Score, the MYMOP and the Knee Injury and Osteoarthritis Outcome Score have not been determined. In contrast, the less frequently used Lysholm Knee Score, Kujala Patellofemoral Disorder Score, modified IKDC form, Fulkerson Knee Instability Scale, Tegner Level of Activity score, SF-12 and the MFA score have demonstrated reliability and validity in this population (Paxton et al, 2003).

Paxton et al (2003) recommended that three key domains should be assessed to establish clinical outcome following patellar dislocation. These included the use of an activity-based questionnaire, a quality-of-life tool, and a knee-specific measurement (Paxton et al, 2003). Given this recommendation, the results of this survey suggest current physiotherapists are not meeting these suggested recommendations for outcome measures for this population. Nonetheless it may be suggested that this difference may reflect a limited interest by clinicians to engage with the literature on this topic. It may also reflect the possibility that clinical outcome measures are infrequently used in practice unless research is undertaken. This negligible use of evaluation tools may reflect normal musculoskeletal physiotherapy practice (Abrams et al, 2006). Other barriers to the implementation of evidence-base practice to inform outcome measure selection may exist, such as limited availability of relevant evidence, limited knowledge in respect to appraising the evidence for methodological quality, and time available to extract information relevant to their practice. Clinical caseloads, ethical and business issues are cited as sources of conflict when attempting to implement healthcare service changes (Kumar et al, 2010; Schreiber et al, 2009; Menon et al, 2009), as reflected in previous national surveys of physiotherapy care (Abrams et al, 2006; Lennon, 2003; Chesson et al, 1996).

9.3 Clinical Implications

The survey indicated that musculoskeletal physiotherapists most commonly adopt generic lower limb assessment and treatment strategies rather than specific patellofemoral techniques for people following FTPD. This may be due to the relative rarity of this condition or due to the scarcity of literature supporting such techniques (Chapter 4, Section 4.6; Chapter 5, Section 5.6).

The findings indicate that a proportion of clinicians prescribe specific-VMO exercises. However, there is currently a limited, poor quality evidence-base to determine that the VMO can be preferentially recruited with specific exercises (Chapter 6). Accordingly there appears a 'mis-match' between the evidence and clinical practice. It is therefore recommended that further study be undertaken to evaluate the effectiveness of specific-VMO exercises in this population. Furthermore clarity regarding the role and type of exercises prescribed should be widely disseminated to inform practice.

The only consistently adopted outcome measure for this population was patient satisfaction. This was used by 90% of respondents. Given Paxton et al's (2003) recommendations that patient-reported domains should be assessed for this population, further promotion of the use and value of activity-related, quality of life, and knee-specific clinical outcome measures is required. Through this physiotherapists may be encouraged to assess their treatments based on reliable and valid methods in this population which re-enforces the importance of using outcome measurements (Roberts et al, 2003; Abrams et al, 2006).

Dissemination of these results will increase the awareness of the limited consensus regarding physiotherapist's assessment, treatment and evaluation of this population in the UK. This may increase the recognition of this frequently

neglected pathology, thus encouraging development of the evidence in this area.

9.4 Recommendations for Future Study

This study aimed to identify research priorities. Given the paucity of literature on this topic, the findings of this survey have highlighted a number of areas for further research.

9.4.1 General quadriceps versus specific-VMO exercises

The survey identified that UK physiotherapists prescribe general quadriceps and specific-VMO exercises to their patients following FTPD. However it is unclear which exercise regime is the most effective for this population (Chapter 5; Section 5.3.1). This equipoise supports the conduct of a RCT to assess the effectiveness of general quadriceps versus specific-VMO exercises.

9.4.2 Proprioceptive and Gluteal Muscle Exercises

The survey identified that physiotherapists commonly use other exercises in addition to quadriceps programmes such as proprioceptive and glutei regimes during the rehabilitation of people following FTPD. However it remains unclear what these exercise regimes consist of, why physiotherapists use these exercises, and what they physiologically achieve. Further study is indicated to answer these questions in relation to proprioceptive stability and gluteal control and strength in a FTPD population.

9.4.3 The Role of Reassurance

Although the most frequently cited treatment, it was unclear exactly what ‘reassurance’ and ‘advice’ was provided to people by physiotherapists following FTPD. Accordingly further study to identify what information is

imparted to this population is warranted. This may investigate whether there is a difference in physiotherapist's recommendations for the time required until individuals can return to work or sporting activities, or whether advice imparted on avoidance of particular activities is beneficial. Further exploratory research is necessary to provide physiotherapists with a consensus as to what information should be provided to ensure optimal rehabilitation.

9.4.4 Physical Examination Methods

Respondents indicated that patellofemoral-specific tests such as the J-sign or Bassett's test were rarely used. These two tests were identified from the literature review as two of the four tests whose reliability and validity have been previously examined. Given that other tests were reported as being used but whose reliability or validity remains unknown, further study is required to examine the sensitivity and specificity of such clinical tests for those following FTPD. Since there was a dearth of literature assessing this domain, only once the evidence-base has been improved can clinicians have greater confidence and awareness of such tests.

9.5 Limitations of the Study

Whilst efforts were made during the study design to minimise bias, on reflection, this was evident to some degree in this study. Firstly, little restriction was enforced on those who completed the survey. Questionnaires were sent to gate-keepers in each eligible department who were instructed to pass it on to a senior physiotherapist with a clinical interest in knee rehabilitation or the most experienced physiotherapist. This strategy was adopted to obtain the views of the most 'expert' member of each department who may have treated the most people with this relatively uncommon pathology. However, by not controlling who completed the questionnaire, a potential limiting factor to every postal questionnaire (Oppenheim, 1992), some heterogeneity in the grade of

participating physiotherapist was permitted. This may have accounted for a potential variation in the experiences of clinicians who responded.

Question 13 asked respondents to indicate their present physiotherapy position (Appendix 4). The response options were based on the NHS's Agenda for Change banding (Department of Health, 2005). As Chapter 7 described, this was justified as the most commonly used banding system for grading physiotherapy positions in the UK. The question was required since, although requested to, the survey may not have necessarily been completed by the most senior physiotherapist within the department, or a physiotherapist with the most experience of managing people following FTPD. It was therefore not possible to assume what position the respondent held. The respondent's position was an important variable since it provided information on the generalisability of the results, to be able to attribute the findings to a specific group of physiotherapists. Nonetheless, the physiotherapist's grade may not directly relate to their clinical experience. Similarly, it would not be inconceivable for physiotherapists to work above or below their awarded grade. Nonetheless, the question was important as it indicated that the questionnaire was completed by senior physiotherapists (i.e. those in positions of Band 6 or above (Department of Health, 2005). This survey was not intended to determine whether differences occurred in clinical practices between those in a higher compared to lower physiotherapy banding. In order to answer this, further, more specific demographic questions related to job title, role and work-place setting may have been required. Similarly, a more purposive sampling strategy, recruiting sufficient numbers of different physiotherapists would have been warranted. Whilst not the objective of this particular study, the effect of physiotherapist experience and post-graduate training may be an interesting avenue for further study.

The survey's response rate was 59% which may be regarded as respectable for a postal survey (Oppenheim, 1992). However it remains unclear whether the

remaining 41% had different experiences to those who responded. Whilst strategies were adopted to minimise non-response, the issue of non-response should be considered when interpreting the results of this study.

Based on the results from Figure 8.2, this survey may be particularly generalisable to physiotherapists in Scotland or the East of the England given their high response rates. However, greater caution may be adopted when generalising the findings to physiotherapists working in NHS acute hospitals in London or the South West of England.

Questionnaire length was not considered a significant factor to respondent validity (Chapter 7, Section 7.8.2). There is however a small body of literature to suggest that respondent fatigue may occur during the completion of excessively complicated or long questionnaires (Oppenheim, 1992). In order to assess this, the study's pilot sample was specifically asked whether they felt the length of the questionnaire was justified, and whether this affected their ability to complete it. Since no problems were raised from this group when asked, this was not considered important. Nonetheless this may have been a factor for why eight centres did not complete the questionnaire due to insufficient time (Chapter 8, Figure 8.3).

Two physiotherapy departments did not complete the questionnaire because they could not understand the response options (Chapter 8, Figure 8.3). The survey responses were presented as percentages rather than the more conventionally used Likert-scale terms (Steiner and Norman, 2008). However there may be differences in perceptions between Likert-scale response options, particularly in the definition of 'often' and 'very often' (Steiner and Norman, 2008). Accordingly, percentage values were used where respondents were able to attribute the percentage to which their FTPD caseloads are given a specific assessment methods, treatment modalities or outcome measurement. This facilitated a more accurate statement on frequency of use, rather than assuming

that each respondent had the same perception of the Likert scale's response terminology. Whilst they may be unfamiliar to physiotherapists and this may have been a problem for two non-respondents, the benefits justified its inclusion in the final questionnaire.

9.6 Summary

Survey findings appeared to mirror the evidence in respect of the widespread use of exercise-based treatments in the management of people following FTPD. There remain differences in relation to which strengthening/recruitment exercises should be used to preferentially recruit the VMO in this population. Similarly, although literature is available to support the use of knee-specific evaluation tools, these were rarely used in clinical practice. These differences may be attributed to the infrequent presentation of such people in NHS caseloads. Further study has therefore been outlined to construct a more rigorous evidence-base to inform the optimal management of this population.

Section Four

Activity Survey Study

Chapter 10. Activity Survey Methodology

10.1 Introduction

Patellar instability is regarded as the primary complaint for people following a patellar dislocation (Donell, 2006). It is therefore important to understand what activities are associated with this key symptom to better inform clinical decision-making and enhance understanding of this injury. However, it is currently unclear what activities cause people to experience patellar instability symptoms (Chapter 3, Section 3.3).

This chapter will present the rationale for the study (Section 10.2) and its objectives (Section 10.3). It will describe how each part of the study, i.e. the development, piloting of the questionnaire, the assessment of the questionnaire's reliability and the principal data collection was delivered (Sections 10.4 to 10.10). The chapter will also present how the data was analysed (Section 10.11) and will highlight the ethical issues which were considered during the study's design (Section 10.12).

10.2 Rationale

Previous epidemiological studies have acknowledged that patellar subluxation and dislocation most frequently occurs during physically demanding activities (Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a). No studies have demonstrated which specific activities are associated with people's instability symptoms. By understanding this, clinicians will be better informed as to which activities should be limited in order to avoid aggravating symptoms. Alternatively, this understanding could indicate which activities physiotherapists should specifically target during rehabilitation to treat potentially symptomatic tasks. This survey could be used to better inform physiotherapists on the advice and information they should provide to people

following a patellar dislocation. This is particularly important given that reassurance and advice were reported as the most commonly adopted treatments used by UK acute hospital NHS physiotherapists for people following FTPD (Chapter 8, Section 8.5).

10.3 Study Objective

The aim of this study was to answer to following research question: - during which activities and with what frequency do people with patellar instability perceive their patella to be unstable?

10.4 Study Design

A survey design was appropriate to review large numbers of people and answer this research question. This would not have been possible using face-to-face interview or focus group techniques within the study time-frame (Edwards and Talbot, 1999). A descriptive, cross-sectional survey design was considered the optimal method to collect the descriptive data required for the survey. This design permits the identification of data on activities and discovers the demographic features of this population (Dooley, 2001; Buckingham and Saunders, 2004).

10.5 Population

The target population was individuals with patellar instability. These were recruited from two sources within a teaching hospital in the East of England: the physiotherapy and orthopaedic departments. These were appropriate as both departments received referrals from people who had experienced FTPD and recurrent patellar dislocations (Appendix 5; Appendix 14). Secondly, the hospital was locally situated, allowing the researcher to be personally involved in recruitment.

10.5.1 Eligibility Criteria

This study's selection criteria were predefined as:

- **People aged 11 years and over**; as previous literature suggested that people can present with patellar instability from the age of 11 years onwards (Woo and Busch, 2001).

- **An ability to read and write English**; since this study used a paper questionnaire requiring comprehension of English for completion.

- **Provide informed written consent**; as it was ethically essential for people to be given a sufficient account of the study, which they understood, before deciding whether or not to participate. They should be able to reach a rational, autonomous decision on whether to participate or not, and should not be placed under pressure, influenced or coerced. Accordingly, this complied with both the Declaration of Helsinki and local ethical approval requirements.

- **A diagnosis of patellar instability on initial examination performed by a physiotherapist or orthopaedic surgeon**; this was satisfied if the person: reported two or more episodes where their patella either dislocated, or they reported a feeling that their patella was going to dislocate; and, presented with one or more of the following signs and symptoms of patellar instability:-

a) Apprehension when a lateral-directed force was applied to the patella
b) Tenderness along the medial retinaculum

c) Abnormal patellar tracking or position e.g. lateralised, tilted, excursion such as J-sign, where the patella shifts laterally in terminal knee extension as it disengages from the femoral intertrochlear groove.

Flexibility in points (1) to (3) was permitted as people with a more acute dislocation may present differently to people with symptoms of chronic patellar instability (Woo and Busch, 1998; Mulford et al, 2007). The reliability and validity of all physical examination tests used for this population has been shown to be questionable (Salley et al, 1996; Ando et al, 1993; Shakespeare and Fick, 2005; Smith et al, 2008; Smith et al, 2011b). However, these criteria have been widely adopted in previous trials to identify this population (Atkin et al, 2000; Mäenpää et al, 2000; Mäenpää et al, 1997). The literature indicated that the criterion of a history of multiple episodes of patellar dislocation can differentiate patellar instability from PFPS (Chapter 4, Section 4.4). Radiological investigations were not included as part of the study eligibility. Plain radiographs have shown a varying degree of reliability and validity between their measurements (Smith et al, 2011a). Whilst computer tomography and MRI have demonstrated greater reliability (Toms et al, 2009; Smith et al, 2011a), these were not routinely conducted for all people with patellar instability in the participating hospital. Thus this was not considered an applicable eligibility criterion for this study.

Based on these criteria, this population was appropriate as it included only those people who had experienced symptoms of patellar instability. Consequently the study excluded those with other patellofemoral pathologies such as PFPS. Although this population can report mild symptoms of instability, their overriding symptom is pain (Donell, 2006). Accordingly, such people were excluded as the survey principally assessed instability. By recruiting individuals who had experienced recurrent episodes of dislocation or instability, it was anticipated that this cohort would present with a longer history of instability symptoms and therefore greater exposure of these

symptoms during everyday activities than people following FTPD. This would therefore provide 'richer' data on which to answer the research question (Barnett, 1999).

People referred to the participating hospital for active treatment were recruited. This was most appropriate since when recruited, these people were experiencing current symptoms of patellar instability. Accordingly, individuals would be asked to recall recent experiences when completing the questionnaire. Such a strategy is supported by previous sociological and healthcare studies indicating that retrieval of more recent or memorable experiences can improve the validity of an individual's responses (Brédart et al, 2002; Saal et al, 2005; Keller et al, 1997; Litwin and McGuigan, 1999; Chapter 7, Section 7.5).

10.6 Sampling Strategy

People were identified by their treating clinician during a standard out-patient orthopaedic or physiotherapy appointment at the participating hospital. The sampling strategy is presented as a flow-chart in Appendix 15.

The objective of this study was to obtain a representative view of what activities typically cause instability symptoms in this population. Given this, a quota sampling method was a suitable sampling strategy to ensure the recruitment of a representative sample of males and females from different age groups (Oppenheim, 1992; Miles and Huberman, 1994). The specific quotas are presented in Appendix 15. The quota sampling method ensured that more females than males were recruited to reflect the gender distribution for this population (Fithian et al, 2004a; Rünow, 1983; Garth et al, 1996). Patellar dislocation has frequently been reported in individuals from the age of eleven years upwards (Atkin et al, 2000; Fithian et al, 2004a). Anecdotally, people aged 11 years have reported that they typically participate in different everyday activities to those aged forty years or more for example. To address this

variation, the quota recruitment process of people from different age groups was conducted to ensure an adequate representation of this population. The potential range of responses arising from a limited range of characteristics would have been reduced if a convenience sampling approach had been adopted (Oppenheim, 1992). However this sampling strategy is only generalisable to those seeking treatment for patellar instability at an acute hospital. It is thus not possible to make assumptions on people who do not seek treatment or are managed in primary or private care services.

This sampling strategy may also be considered random self-selecting; random as it remained unintentional to who completed and returned the questionnaire, and self-selecting as people volunteered to participate (Bowling, 2009). This strategy reduced the potential for selection bias from using a recruiting researcher (Polgar and Thomas, 2000).

Whilst not included in the quota sampling strategy, the existence of a family history of patellar instability and hypermobility were also recorded. Hypermobility was assessed using the Contompasis Hypermobility Score (McNerney and Johnston, 1979; Appendix 16). The literature remains unclear whether family history or joint hypermobility are prognostic indicators for patellar instability (Carter and Sweetnam, 1958; Fulkerson and Shea, 1990; Atkin et al, 2000; Arnoldi, 1991; Fithian et al, 2004a). Therefore there was insufficient evidence to justify the stratification of these characteristics, but sufficient speculation to record the frequency of their presentation with the study cohort.

Individuals were asked to only volunteer once and to inform their physiotherapist or surgeon of any previous involvement in this survey if approached a second time. This was done to prevent multiple responses from the same individual.

10.7 Sample Size

A sample size calculation can be undertaken in surveys when the aim is to compare different cohorts, or when there is a pre-defined or known variance value in the outcome of interest which can be described using the standard error of a population (Barnett, 1999). It is not possible to calculate a sample size for a descriptive survey study, particularly when the topic under investigation is novel and has not been previously researched, as here. Hence a pragmatic approach was taken, recruiting 90 people. This was a suitable sample size to be recruited within a one year period, thus practical for the PhD timetable (Appendix 17).

10.8 Questionnaire

The evidence of superiority of researcher-administered over participant-administered questionnaires is limited (Addington-Hall et al, 1998). The strengths of self-administered questionnaires have been presented in Chapter 7 (Section 7.8). Thus a formal self-administered questionnaire was developed as it could be completed solely by the participant, limiting potential researcher bias and reducing research costs.

The questionnaire included a variety of activities identified as having the potential to be associated with patellar instability symptoms. These items were identified through two methods.

- **Anecdotal**; people had previously cited a number of activities which they felt caused patellar instability. In addition, five previous patients with recurrent patellar dislocation were specifically asked during their physiotherapy sessions about which activities caused their instability symptoms.

- **Literature review**; presented a number of different biomechanical positions which may predispose individuals to experience a patellar dislocation (Aglietti et al, 2001; Scudero and McCann, 2005; Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a; Hughston, 1989). Using these principles, it was hypothesised that if such activities could cause patellar dislocation, these may also cause patellar instability symptoms.

Both methods identified twisting and turning motions, particularly during sporting activities most associated with instability symptoms. Given this, activities of daily living and recreational sporting pursuits which incorporated such motions were listed in the final questionnaire. These approaches ensured that the questionnaire exhibited face validity, providing rigor to the tool prior to piloting (Polgar and Thomas, 2000).

The questions were groups according to activity. Activities including sedate and lower-energy tasks such as walking in a straight line, crossing legs and looking over a shoulder whilst standing were listed early in the questionnaire. Higher-energy activities such as negotiating stairs and stepping onto a high step formed the middle section. Questions related to sporting activities such as running, hopping and jumping formed the final section of the questionnaire. This structure was anticipated to minimise measurement error when completing the questionnaire. However, there is little evidence to suggest that question order may significantly affect the responses obtained from questionnaires in health-service survey studies (Dunn et al, 2003; McColl et al, 2003; Barry et al, 1996; Kaufmann et al, 1997; Bolman et al, 2007; Chapter 7, Section 7.8.1).

Since people aged 11 years upwards were approached, two versions of the questionnaire were constructed. This was important as some activities such as pushing a shopping trolley were considered less appropriate for a child, but

highly applicable to adults. Therefore those aged over 16 years completed a 19-question version whilst those under 16 years completed an 18-item questionnaire with the removal of the 'pushing a shopping trolley' activity. The questionnaire was also purposely limited in size to minimise the inconvenience and confusion caused to younger as well as older people, whilst not detracting from the questionnaire's validity.

Once a list of questions had been devised, consideration was given to the methods of response. Likert scores ('Always', 'Often', 'Sometimes', 'Rarely', 'Never') were adopted as this was considered the most appropriate approach to assess frequency of behaviour or activity (Oppenheim, 1992). This method can also be converted to a score to quantify the order of importance of each activity. It was anticipated this was important to aid the construction of an outcome measurement from these findings. Furthermore, since the Likert system has been widely adopted in social and commercial studies as well as health, the familiarity this response system provides was considered useful to ease questionnaire completion and minimise measurement error (Bowling, 2009). This system was also appropriate for collecting data from those aged 11 years and upwards (Bowling, 2009), thus making it suitable for this cohort. The closed-ended response format was supported by the literature (Griffith et al, 1999; Chapter 7, Section 7.8.3) as this has demonstrated superiority when answering demographic questions, rather than questions assessing individual's detailed experiences and in-depth attitudes which was not the aim of this study (Griffith et al, 1999).

The respondent was provided with the opportunity to add a response if the pre-defined responses were not applicable to them; this was the 'Others' response. This allowed respondents to identify any other activities which they associated with instability symptoms, but which had not been explored in the questionnaire. This was important given that this topic had not been previously

examined and it was therefore not clear whether the list of activities was exhaustive.

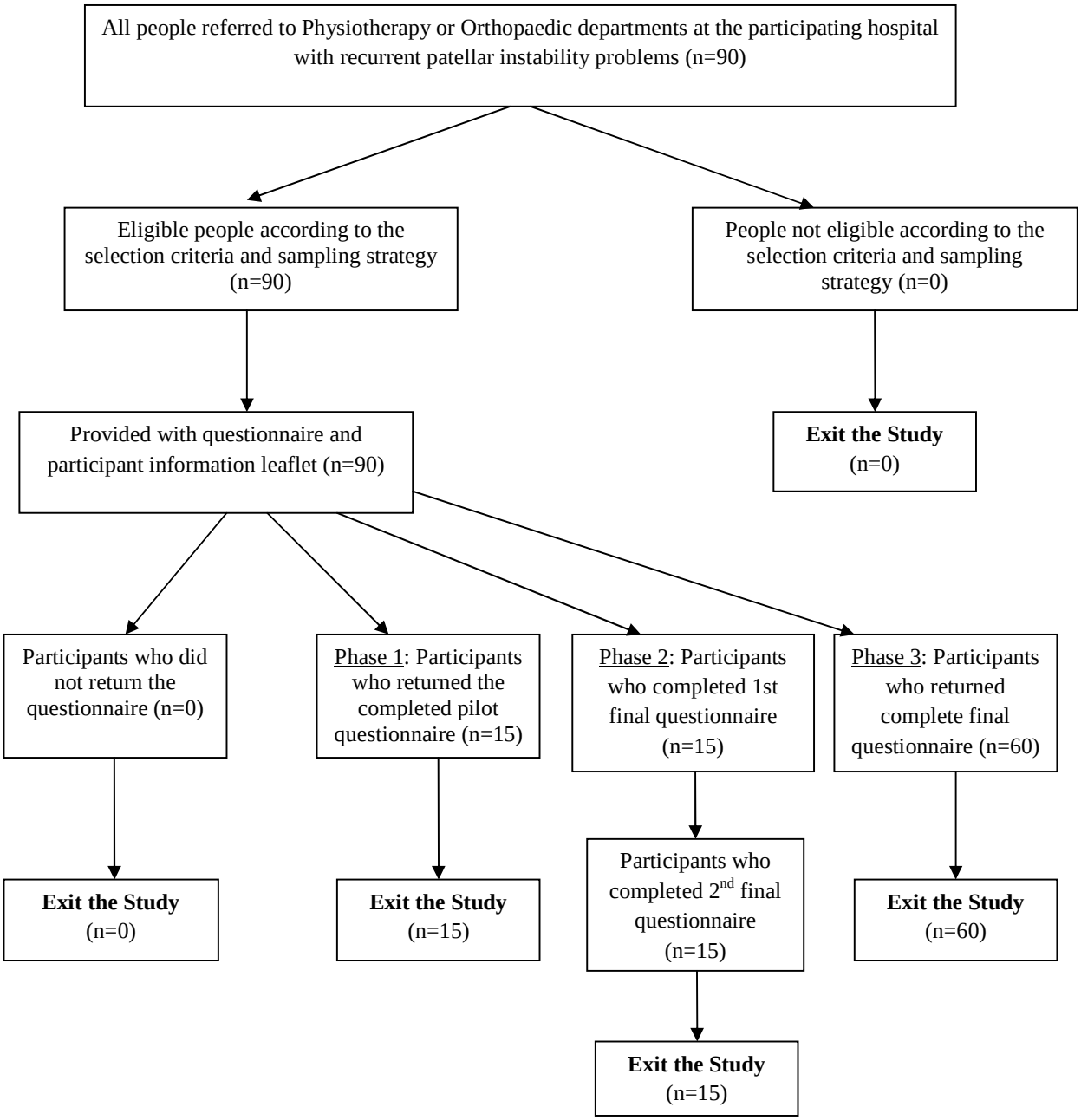
Finally, an additional response of 'don't do' was included as although instability is considered a predominant symptom for this population (Donell, 2006), individuals may also experience pain and general lower limb weakness which may prevent participation in certain activities. It was expected that all people would undertake some of the activities such as walking in a straight line, and looking over their shoulder, however some sporting activities may not have been performed. The 'don't do' response would therefore capture this to prevent people from failing to respond to all the questions. There was the potential for people to use this response because of instability symptoms. To prevent this, the cohort was encouraged to only use this response if any other symptom apart from instability prevented them from undertaking such tasks. This was stated in the covering letter.

The evidence has not demonstrated the superiority of different coloured papers or presentational features so the questionnaire was printed in black ink on white paper (Clark et al, 2001; Beebe et al, 2007; Mallen et al, 2008; Chapter 7, Section 7.8.4). The questionnaires were printed in landscape so that all activities were presented single-sided over two pages. This was to ease completion and reduce measurement error (Bowling, 2005; Oppenheim, 1992).

10.9 Procedure

A flow-chart of the study procedure is presented as Figure 10.1. This demonstrated that the study was divided into three parts; the piloting of the questionnaire, the assessment of its reliability and the principal questionnaire's data collection.

Figure 10.1. Flow-chart to illustrate the pathways taken during this survey



10.9.1 Recruitment

All physiotherapists at the out-patient physiotherapy department and orthopaedic surgeons involved in the two consultant orthopaedic surgeon's out-patient clinics at the participating hospital were informed about the study. The sample was known to be referred to these departments, thus making these the best sources from which to recruit from. All potential participants fulfilling the selection criteria were given a copy of the study's covering letter (Appendix 18; Appendix 19; Appendix 20), a participant information leaflet (Appendix 21; Appendix 22; Appendix 23; Appendix 24), a questionnaire (Appendix 25; Appendix 26) and a stamped addressed envelope.

Before the physiotherapist or surgeon provided a participant with this pack, the demographic details printed on the questionnaire's front sheet were completed to record each participant's characteristics such as age, gender, family history of patellar instability and Contompasis score (McNerney and Johnston, 1979). This information was obtained through the physiotherapist's or surgeon's standard musculoskeletal examination. Each participant was then asked to read through the participant information leaflet (Appendix 21 to Appendix 24) and covering letter (Appendix 18 to Appendix 20) at home. Once they were clear about the aims and procedures of the study, if they wished to participate, they were asked to complete the questionnaire and to post it to the researcher using the stamped addressed envelope provided. A stamped addressed envelope was included since it has been shown to increase the likelihood of questionnaires being returned (Edwards et al, 2002). This was done to limit the inconvenience and cost incurred by potential respondents.

The researcher liaised with the clinicians recruiting participants to inform them of which types of people were required in accordance with Appendix 16's

quota sampling strategy as the trial progressed. Through this, the researcher was able to ensure that only those individuals who needed to be recruited based on the quota sampling strategy were approached.

Eligibility and recruitment were ascertained by the participating surgeon or physiotherapist. They identified all individuals who were eligible following the physical examination identified in the eligibility criteria. This contact also provided clinicians with the opportunity to describe the aims and objectives of the study to potential participants. This provided a further opportunity for the participants to be given information and to ask questions before consenting to participate. Thus further clarification could be gained through the clinicians to potentially reduce completion error (Dooley, 2001).

10.9.2 Questionnaire Delivery and Completion

The questionnaire was provided to the participant by the researcher, participating surgeon or physiotherapist in the clinic-setting. Whilst other methods of survey delivery such as postal or web-based methods may have been used, this method of face-to-face provision was justified to increase interest in the survey through imparting greater information about the study and minimising completion error (Dooley, 2001, Chapter 7, Section 7.8). Furthermore the e-mail addresses of potentially eligible participants were not routinely collected by the participating hospital. This therefore reduced the feasibility of conducting an electronic survey.

Questionnaires were expected to be completed by participants at home after consulting the participant information leaflet and covering letters and then returned through the post using the stamped addressed envelope provided. In practice, the majority of participants completed their questionnaire whilst in the clinic (99%). This was permitted only after the participant had been offered opportunity to take the questionnaire home and ensured informed consent.

10.9.3 Questionnaire Deadline

The covering letters specified a three-week deadline for questionnaire returns (Appendix 18 to Appendix 20). This was used to prompt participants into returning their questionnaire whilst allowing adequate time to complete the form. A three-week period was stipulated to facilitate younger participants time to decide whether they wanted to complete the questionnaire and consult their parents/guardians and family.

Deadlines, such as the three-week period used in this study, may increase response rates (Oppenheim, 1992). This has also been supported by the empirical evidence-base (Roberts et al, 1978; Chapter 7, Section 7.8.5). Repeat mailing was not completed for this study since, to maintain anonymity throughout, there was no means of identifying non-responders. Furthermore, since the majority of participants completed the questionnaires in the clinic, there was no need for such a reminder strategy.

10.10 Data Collection Phases

After constructing both the questionnaire and supportive information, these were then distributed. The initial two phases of data collection were aimed at piloting the questionnaire and to assess the validity of this tool (Phase 1, Section 10.10.1) and the intra-rater reliability (Phase 2, Section 10.10.2). The final phase surveyed a larger cohort to answer the research question (Phase 3, Section 10.10.3). The structure of the questionnaire did not change during each phase. Data from each phase of the study was therefore collated and analysed together to obtain the responses from 90 people in total. Each phase will be discussed below.

10.10.1 Phase 1: Questionnaire Validation Process

After constructing the questionnaire, its validity was assessed with 15 people (17% of the total cohort). The aim of this was: to assess the feasibility of the study; assess its methods; to evaluate the ease of completion of the questionnaire and the inclusion of all pertinent activities; and to assess for ambiguous questions or instructions before embarking on the principal study.

The quota sampling strategy was adopted (Appendix 16). The number sampled for this phase was sufficient to provide an insight into the results of each quota in the sampling strategy without over-recruiting participants. In relation to the questionnaire's construct, it was decided before commencement that if a specific activity was identified by three or more participants (20%), this would be incorporated into the final questionnaire. As a result, only those activities shown to be important to a proportion of the sample were included. This was important because activities specific to a participant and not representative of a larger cohort, would not be included and so unnecessarily increasing the size and complexity of the questionnaire. Increasing the burden of the questionnaire may have led to greater measurement error and impacted on study reliability (Aldridge and Levine, 2001). This also provided a degree of face validity to ensure that the questionnaire 'appeared' to measure what the research question asked. Additionally, content validity was enhanced, where all the important domains of the research question were answered (Polgar and Thomas, 2000; Aldridge and Levine, 2001; Buckingham and Saunders, 2004).

Potential bias through the questionnaire's design was also minimised by incorporating a pilot phase. During this respondent's were able to amend the questionnaire's format and content if required (Polgar and Thomas, 2000; Bowling, 2009). Participants were also asked to formally review the questionnaire using the pilot feedback form (Appendix 27). Each was asked to

comment on the ease of completion, whether any questions were ambiguous, and to appraise the appropriateness of the activities presented. This was justified to: limit the researcher's views and biases from influencing the findings; assess face validity; and to make the final questionnaire easier to complete (Oppenheim, 1992). This was particularly important for participants aged under 16 years to ensure that they understood both the participant information leaflet and questionnaire's instructions before the larger principal study was undertaken.

Through this process, a variety of different activities were identified by the cohort in addition to those originally stated. These are listed in Table 10.1. As this illustrates, no one specific activity was identified by three or more participants. All pre-defined activities were acknowledged as associated to their symptoms of patellar instability by more than three participants. These activities were therefore included in the final questionnaire. Given this, the questionnaire was not amended.

Table 10.2 summarises the responses from the Pilot Feedback Form which demonstrated the acceptability of the construction and format of the original questionnaire. Following this, the original questionnaire was not amended, re-structured or re-piloted.

Table 10.1. Table to list the additional activities and the frequency to which these were cited by the pilot sample.

Additional activity	Number of responses
Swimming	2
Getting up from sitting on the floor	2
Sitting down on the floor	1
Wearing tight clothes	1
Flexion and extension knee motions	1
Turning quickly	1
Lunging	1
Sudden movements	1

Table 10.2. Table to present the responses from the Pilot Feedback Form.

Question	Response Opinions	Frequency (%) of pilot cohort's responded
Was the questionnaire easy to complete?	Yes	15 (100)
	No	0
If no, how could it be made clear?	No responses	15 (100)
Approximately how long did it take you to complete the questionnaire?		Mean 4.9 min (Range 2-10 min)
Could this questionnaire have been shorter?	Yes	0
	No	15 (100)
Was the questionnaire easy to understand?	Yes	15 (100)
	No	0
If no, which questions were unclear?	No responses	15 (100)
If you are under 14 years old, did your parents find the questions easy to understand?	Yes	15 (100)
	No	0
Were the activities described relevant to you and your knee problem?	Yes	14 (93)
	No	0
	Not completed	1 (7)
If no, what activities were these and why?	No responses	15 (100)
Are there any activities/tasks you felt should have been on this list which were not?	None	5 (32)
	Swimming	2 (13)
	Getting up from sitting on the floor	2 (13)
	Sitting down on the floor	1 (7)
	Wearing tight clothes	1 (7)
	Flexion and extension knee motions	1 (7)
	Turning quickly	1 (7)
	Lunging	1 (7)
	Sudden movements	1 (7)
What could have been done to make this project easier for you?	No response	10 (65)
	Nothing	5 (35)
Was the patient information leaflet clear and understandable?	Yes	9 (57)
	No	0
	Not completed	6 (43)

Min - minutes

10.10.2 Phase 2: Intra-Rater Reliability Assessment

Following the previous validation procedure, the questionnaire was administered to a further 15 individuals (17% of the total cohort) to assess its intra-rater reliability. This assessed the extent to which repeated measures by

one participant yielded consistent results during a period when change would not be expected (Bland, 2006). This was to provide an insight into the reliability of this instrument without detracting from the principal study's aims. The quota sampling strategy presented in Appendix 16 was used. Each participant was provided with two copies of the questionnaire. They were asked to complete the two questionnaires with an interval of one week between each. This was specified as it was predicted that a participant's functional status would not substantially change between the assessments, whilst the respondent was unlikely to recall their initial responses (Oppenheim, 1992).

Once the two questionnaires had been returned separately, a numerical code printed on each questionnaire was used to compare the two questionnaire's results.

The intra-rater reliability for each activity on the questionnaire was presented as a weighted Kappa value (Table 10.3). Overall intra-rater reliability was Kappa=0.75 (95% CI: 0.69, 0.80) indicating substantial agreement beyond chance alone. A number of activities including 'walking in a straight line on an even surface', 'walking on slippery, wet or icy surfaces' and 'descending stairs' presented with weighted Kappa values of greater than 0.90, indicating almost perfect agreement (Table 10.3). In contrast, activities such as 'crossing legs whilst sitting' and 'turning a heavy trolley around a supermarket aisle' presented with poorer agreement between the first and second questionnaires completed by individuals (Kappa=0.32, 95% CI: -0.34, 0.77; Kappa=0.15, 95% CI: -0.64, 0.71). However since only those people over the age of 15 years were questioned on this latter activity, this low weighted-Kappa value was attributed to only 10 people. Similarly, whilst a number of questions presented with a high agreement score with the Kappa analysis, wide confidence intervals were evident which could be attributed to this small cohort (Table 10.3). Nonetheless, given the overall substantial intra-rater agreement, neither the structure nor content of the questionnaire were amended.

10.10.3 Phase 3: Final Data Collection Procedure

Following the pilot and reliability phases of this study, a further 60 individuals were surveyed using the same methods for the final data collection phase. Once these 60 questionnaires were completed and returned, their data were analysed with the 30 from the previous two study phases. This provided a combined sample of 90 people.

Table 10.3 Table to present the results of the intra-rater reliability assessment.

Activity	Intra-Rater Reliability		
	Weighted Kappa	95% CI	Interpretation (Agreement)
Walking in a straight line on even surfaces	0.58	-0.41,0.84	Moderate
Walking in a straight line on uneven surfaces	0.91	0.73,0.97	Almost perfect
Walking on slippery, wet or icy surfaces	0.93	0.80,0.98	Almost perfect
Turning a heavy trolley round a supermarket aisle	0.15	-0.64,0.71	Slight
Kneeling	0.77	0.32,0.92	Substantial
Squatting	0.54	-0.37,0.85	Moderate
Crossing my legs when sitting	0.32	-0.34,0.77	Fair
Getting in and out of a car	0.80	0.40,0.93	Substantial
Turning to look over my shoulder	0.47	-0.59,0.82	Moderate
Climbing stairs	0.83	0.51,0.94	Almost perfect
Going down stairs	0.92	0.76,0.97	Almost perfect
Stepping onto or over a high step	0.68	0.05,0.89	Substantial
Running in a straight line on even surfaces	0.68	0.33,0.93	Substantial
Running in a straight line on uneven surfaces	0.78	0.43,0.94	Substantial
Running sideways	0.81	0.34,0.93	Almost perfect
Changing direction when running, such as cutting or slalom	0.78	0.42,0.93	Substantial
Jumping	0.81	0.46,0.94	Almost perfect
Hopping	0.82	0.14,0.90	Almost perfect
Twisting or changing direction during Sports or PE activities	0.71	0.01,0.89	Substantial

95% CI – 95 percent confidence intervals

10.11 Data Analysis

All 90 questionnaires were reviewed by the researcher and data was manually extracted from each questionnaire to compile a final results table. Due to the potential for data extraction error, this was repeated by the researcher a second time to verify the original findings. An optical marking reader could have been used as an alternative to this manual assessment. Whilst this may have reduced the time involved in data extraction and potential for inaccuracy, this was not adopted due to the costs involved.

The analysis aimed to assess which activities were associated with symptoms of patellar instability. A secondary analysis aimed to determine which activities were most or least often associated with instability symptoms by using the ranked Likert scale results. This was performed by converting the results into numerical scores as presented below.

Always	**Often**	**Some of the time**	**Rarely**	**Never**
4	**3**	**2**	**1**	**0**

Descriptive statistics were used to collectively assess all completed questionnaires. The frequency of each Likert response was calculated for each question and described as a percentage. This data was converted to a score using the converted Likert scale and presented as mean and standard deviation values. It was therefore possible to rank each activity to determine which was the most and the least aggravating when associated with patellar instability.

A further analysis was undertaken to assess the effects of age, gender, family history of patellar instability and hypermobility on perceived patellar instability. Using the converted Likert response score, the effects of these characteristics were compared descriptively (mean and standard deviation values), and with non-parametric inferential statistics (Mann-Whitney U Test and Kruskal-Wallis test) as the data were not normally distributed. The relationship between this score and the responses was made using a Spearman's Rank Correlation Coefficient. Age was analysed by sub-grouping respondents to three groups: 11 to 15, 16 to 24 and 25 years and over. These were considered appropriate as Fithian et al (2004a) categorised these age groups as possessing different incidences of patellar dislocation therefore potentially being important confounding variables. The difference between those individuals who presented without joint hypermobility (more than or equal to 26 points) compared to those with significant joint hypermobility (more than or equal to 59 points) was assessed using the Mann-Whitney U test. These cut-off parameters were selected as these are considered the clinical meaningful values for benign joint hypermobility (McCormack et al, 2004). Statistical significance was considered when a probability (p) value was less than 0.05.

As stated, to assess the intra-rater reliability, the first and second questionnaire results were compared by assessing the weighted Kappa statistic. This test was adopted to determine whether there was agreement between the first and second assessments of the questionnaire for each participant, and whether this agreement was due to chance or not. This was appropriate as the data collected in the questionnaire was ordinal data. Weighted Kappa values were interpreted using Landis and Koch's (1977) recommendation (Table 10.4).

Table 10.4. Table to present Landis and Koch's (1977) interpretation of Kappa analysis values.

Weighted-Kappa Value	Interpretation
0 to 0.2	Slight agreement
>0.2 to 0.4	Fair agreement
>0.4 to 0.6	Moderate agreement
>0.6 to 0.8	Substantial agreement
>0.8	Almost perfect agreement

> - More than

All analyses were performed by the researcher on SPSS version 18.0 on Windows (IBM, New York, USA).

10.12 Ethical Considerations

Whilst devising this study, a number of ethical issues arose. These were considered and addressed during the construction of this study's research protocol, and are discussed below:

Ethical Approval

Since this study required the participation of human subjects recruited from NHS hospital services, ethical approval was sought through the Cambridgeshire 3 Research Ethics Committee (Reference Number: 08/H0306/80) and the East Norfolk and Waveney Research Governance Committee (Reference Number: 2008PHYS02S (106-08-08) (Appendix 28). People were only approached once these organisations had approved the study.

Data Handling and Storage

All questionnaires and subsequent data were managed by the researcher. Since the questionnaire's reliability was assessed, the first 15 questionnaires after the pilot study included a numerical code. This allowed the researcher to match the two questionnaires each individual completed. Through this, participants were not identifiable, but their results could be compared between the two questionnaires. Participant's personal information was not recorded to protect anonymity. All data sheets were kept in a locked cupboard at the researcher's place of employment. Once all data has been processed and findings disseminated, all original data sheets will be destroyed in the participating hospital's confidential waste system.

Confidentiality and Anonymity

All data were confidential with no participant being identifiable. Participants were made aware of this confidentiality and their anonymity through the participant information leaflet (Appendix 21 to Appendix 24) and covering letters (Appendix 18 to Appendix 20). Whilst maintaining anonymity and confidentiality has not been shown to impact on response rate (Gerbert et al, 1998; Campbell and Waters, 1990; Leohnard et al, 1997; Malvin and Moskowitz, 1983), the ethical considerations, as discussed in Chapter 7 (Section 7.12), recommend that these issues be respected for all potential participants.

Consent

A consent form was not necessary since consent was implied through the participant completing and returning their questionnaire. This was stated in the covering letters (Appendix 18 to Appendix 20). This therefore satisfied the ethical considerations outlined in the Declaration of Helsinki (World Medical Association, 2000), and those stipulated by the approving local research ethics committee.

Coercion

To prevent coercion, participants were informed within the participant information leaflet that declining to participate would not affect their current or future treatment (Appendix 21 to 24). Although a body of the literature has suggested that incentives can enhance response rate (Parkes et al, 2000; Dirmaier et al, 2007; Jones et al, 2000; Kenyon et al, 2005; Kalantar and Talley, 1999; Robertson et al, 2005; Chapter 7, Section 7.9), no financial or gift incentives were used due to limited resources available to undertake the study. Accordingly it was assumed that potential participants were not coerced into participating in the study through the provision of incentives.

Informing Potential Participants

Specific participant information leaflets were designed for people aged 11 to 14 years (Appendix 21), 14 to 16 years (Appendix 22) and for those 16 years and over (Appendix 23). A participant information leaflet was devised for the parents/guardians of participants under the age of 16 years (Appendix 24). This ensured that all participants were fully informed about the study when they considered whether to participate or not. Similarly, separate covering letters were designed for participants aged under 16 years (Appendix 18), for their parents/guardians (Appendix 19), and for those aged 16 years and over (Appendix 20) to introduce the project in order to maximise 'informed' consent.

10.13 Summary

This chapter has outlined the rationale and methods of the second study undertaken as part of this thesis. It has discussed the methodological approaches and strategies used in order to answer the research question. The

ethical and data analysis issues considered when designing this study have also been discussed. The following chapters will present the findings and discussion points raised following data collection.

Chapter 11. Activity Survey Results

11.1 Introduction

The previous chapter outlined the methods used during this activity survey of 90 people who had experienced recurrent patellar dislocations. This documented how the questionnaire was constructed and tested to answer the research question.

This chapter will present the results on response rate (Section 11.2), the demographic characteristics of the respondents (Section 11.3), the overall study results (Section 11.4) and the relationship between specific population characteristics (age, gender, presentation of joint hypermobility syndrome, family history of patellar instability) to the responses obtained (Section 11.5).

11.2 Response Rate

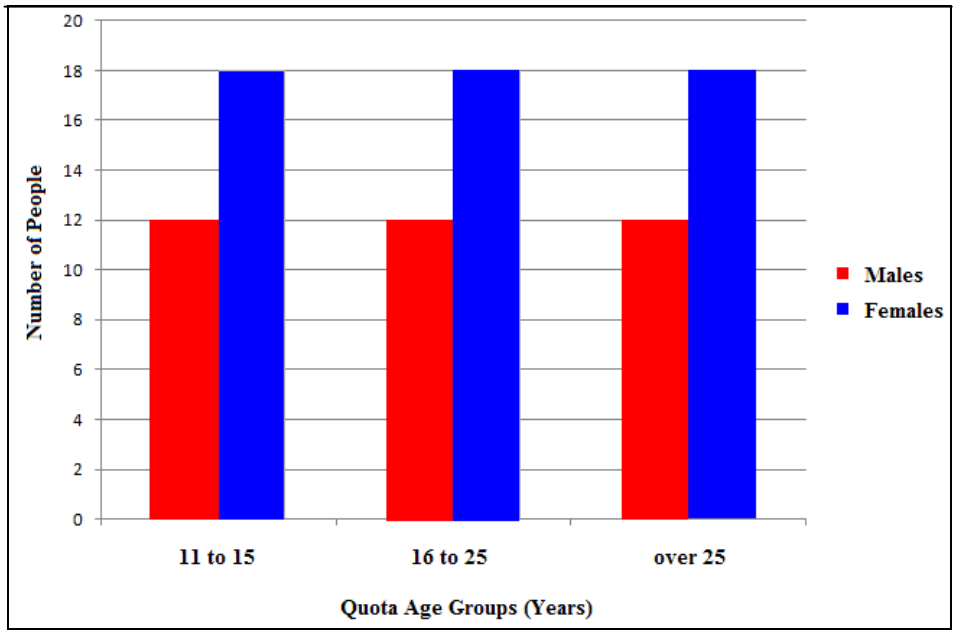
All 90 people approached to participate in the survey completed and returned the questionnaire, thus achieving a 100% response rate. All questions on each questionnaire were answered.

11.3 Cohort Demographics

As per the quota sampling strategy, of the 90 participants, 36 were male (40%), 54 female (60%). The divisions between males and females between the different age groups are presented in Figure 11.1. Twenty-seven respondents (30%) had a family history of patellar instability. Mean Contompasis (hypermobility) score was 31.9 (Standard deviation (SD) = 13.6) from a maximum 72. Thirty respondents (33%) presented with a Contompasis score of 26 or less, indicating non-clinically meaningful signs of hypermobility syndrome (McCormack et al, 2004). Sixteen patients (18%) presented with a Contompasis score of 59 or more, indicating that they presented with

significant signs of joint hypermobility syndrome (Grahame and Hakim, 2008; McCormack et al, 2004).

Figure 11.1. Bar chart to illustrate the age and gender quota sampling distribution.



11.4 Results

The raw data for this survey is presented in Table 11.1. These frequency results were converted to a score, as planned in the Method's Data Analysis section (Chapter 10, Section 10.11). These results are presented in Table 11.2.

The results indicated that the activity most commonly associated with patellar instability was twisting or changing direction during sports. This was reported as always or often associated with patellar instability by 66% of the cohort. Other activities which were also reported as frequently (always or often) associated with patellar instability included running on uneven surfaces (56%)

and walking on slippery or icy surfaces (46%) (Table 11.1). Sporting activities such as running sideways, hopping, jumping and running on even surfaces were associated with instability symptoms. These were reported as always or often associated with symptoms of patellar instability by 51%, 46%, 41% and 39% of respondents respectively. Activities of daily living such as descending stairs, squatting, kneeling, and ascending stairs were also reported as associated with instability symptoms always or often in 34%, 37%, 35% and 31% percent of respondents respectively.

There was considerable variation amongst the cohort in respect to whether turning a heavy trolley round a supermarket aisle was associated with their instability symptoms. Sixteen percent reported that this always or often caused instability, 20% as sometimes, whilst 26% reported that patellar instability rarely or never occurred during this task.

Activities which were less frequently (either rarely or never) associated with symptoms of patellar instability included walking in a straight line on even surfaces (58%), getting in or out of a car (60%), turning to look over a shoulder (68%) and crossing legs when sitting (57%).

The study identified 21 other activities which were not initially listed in the original questionnaire (Table 11.3). These included activities involving sporting, multi-directional activities, and tasks performed on uneven ground, including trampling, dancing, skiing, swimming, karate and lunging exercises. No one particular activity was consistently identified. Moving into and out of bed and moving from sitting to standing were the most frequently additional reported activities. Bed transfers were cited by four people (4%) who reported that they associated these activities to patellar instability. The motion of sitting

Table 11.1. Table presenting the overall results of the 90 respondents surveyed in this study.

Question Number	Activity	Likert Response (Frequency)					Do not do activity
		Always	Often	Sometimes	Rarely	Never	
1	Walking in a straight line on even surfaces	5	6	27	25	27	0
2	Walking in a straight line on uneven surfaces	9	21	30	14	16	0
3	Walking on slippery, wet or icy surfaces	16	25	25	11	13	0
4	Turning a heavy trolley round a supermarket aisle*	7	7	18	11	12	5
5	Kneeling	19	16	17	18	13	7
6	Squatting	17	20	14	24	12	3
7	Crossing my legs when sitting	7	10	17	26	25	5
8	Getting in and out of a car	4	3	28	22	32	1
9	Turning to look over my shoulder	4	6	19	23	38	0
10	Climbing stairs	11	17	22	20	20	0
11	Going down stairs	14	17	29	16	14	0
12	Stepping onto or over a high step	9	11	29	22	16	3
13	Running in a straight line on even surfaces	22	13	20	14	11	10
14	Running in a straight line on uneven surfaces	23	26	16	8	5	12
15	Running sideways	25	21	10	9	7	18
16	Changing direction when running, such as cutting or slalom	27	23	14	7	4	15
17	Jumping	19	18	18	18	8	9
18	Hopping	23	18	14	12	11	12
19	Twisting or changing direction during Sports or PE activities	30	26	15	4	2	13

* Not assessed by the 30 respondents aged under 16 years

Table 11.2. Table presenting the ranked activities related to the frequency of perceived patellar instability reported by 90 individuals with a history of recurrent patellar dislocation.

Activity	Likert Response (Scored Conversion)					Mean (SD)	Rank
	Always	Often	Sometimes	Rarely	Never		
Twisting or changing direction during Sports or PE activities	120	78	30	4	0	46.4 (51.6)	1
Changing direction when running, such as cutting or slalom	108	69	28	7	0	42.4 (45.5)	2
Running in a straight line on uneven surfaces	92	78	32	8	0	42.0 (41.3)	3
Walking on slippery, wet or icy surfaces	64	75	50	11	0	40.0 (32.9)	4
Running sideways	100	63	20	9	0	38.4 (42.1)	5
Hopping	92	54	28	12	0	37.2 (36.7)	6
Jumping	76	54	36	18	0	36.8 (29.8)	7
Running in a straight line on even surfaces	88	39	40	14	0	36.2 (33.6)	8
Going down stairs	56	51	58	16	0	36.2 (26.5)	8
Squatting	68	60	28	24	0	36.0 (27.9)	10
Kneeling	76	48	34	18	0	35.2 (29.0)	11
Walking in a straight line on uneven surfaces	36	63	60	14	0	34.6 (27.7)	12
Climbing stairs	44	51	44	20	0	31.8 (21.3)	13
Stepping onto or over a high step	36	33	58	22	0	29.8 (21.2)	14
Crossing my legs when sitting	28	30	34	26	0	23.6 (13.5)	15
Walking in a straight line on even surfaces	20	18	54	25	0	23.4 (19.5)	16
Getting in and out of a car	16	9	56	22	0	20.6 (21.4)	17
Turning a heavy trolley round a supermarket aisle*	28	21	36	11	0	19.2 (14.1)	18
Turning to look over my shoulder	16	18	38	23	0	19.0 (13.7)	19

* Not assessed by the 30 respondents aged under 16 years; SD – Standard deviation

to standing was associated with patellar instability for one person every time this activity was performed, whilst three people 'often' experienced patellar instability during this activity.

Table 11.3. Table to present the additional activities identified by respondents which were not included in the survey's original questionnaire tool.

Activity	Likert Response (Frequency)				
	Always	**Often**	**Sometimes**	**Rarely**	**Never**
Wearing tight clothes	1	0	0	0	0
Swimming	0	2	1	0	0
Lifting leg off footstool	1	0	0	0	0
In/out of bed	0	4	0	0	0
Sit to stand	1	3	0	0	0
Armchair exercises	0	1	0	0	0
Crawling	0	1	0	0	0
Gardening	0	1	0	0	0
In/out of bath	0	1	0	0	0
Dancing	1	1	0	0	0
Trampolining	1	0	0	0	0
Catching a ball	0	1	0	0	0
Skiing	0	1	0	0	0
Lunging	1	0	0	0	0
Turning quickly	1	0	0	0	0
Walking in high heels	1	1	0	0	0
Karate	1	0	0	0	0
Sitting in the cinema	1	0	0	0	0
Carrying a heavy weight	1	0	0	0	0
Driving	0	1	0	0	0
Rope climbing	1	0	0	0	0

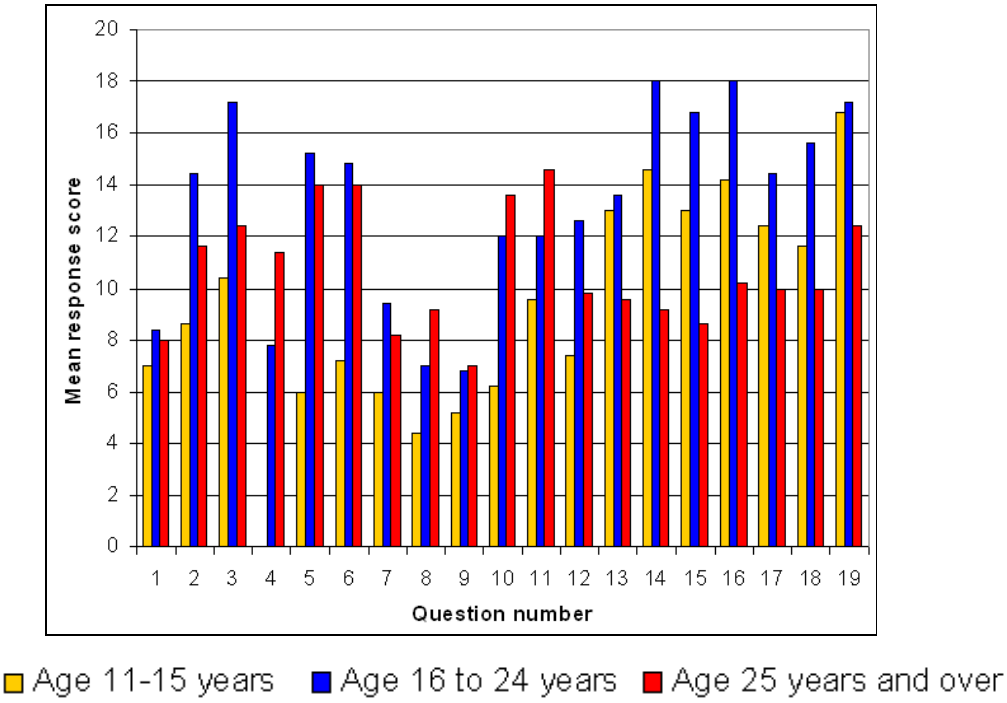
11.5 Effect of Population Characteristics on Response

Further analyses were performed to identify whether respondent's demographic factors were important variables to perceived patellar instability.

11.5.1 Age

There was a difference between the responses provided by different age groups within this cohort (p=0.01; Figure 11.2).

Figure 11.2. Bar-chart to demonstrate the difference in score between respondent age groups and frequency of instability symptoms.

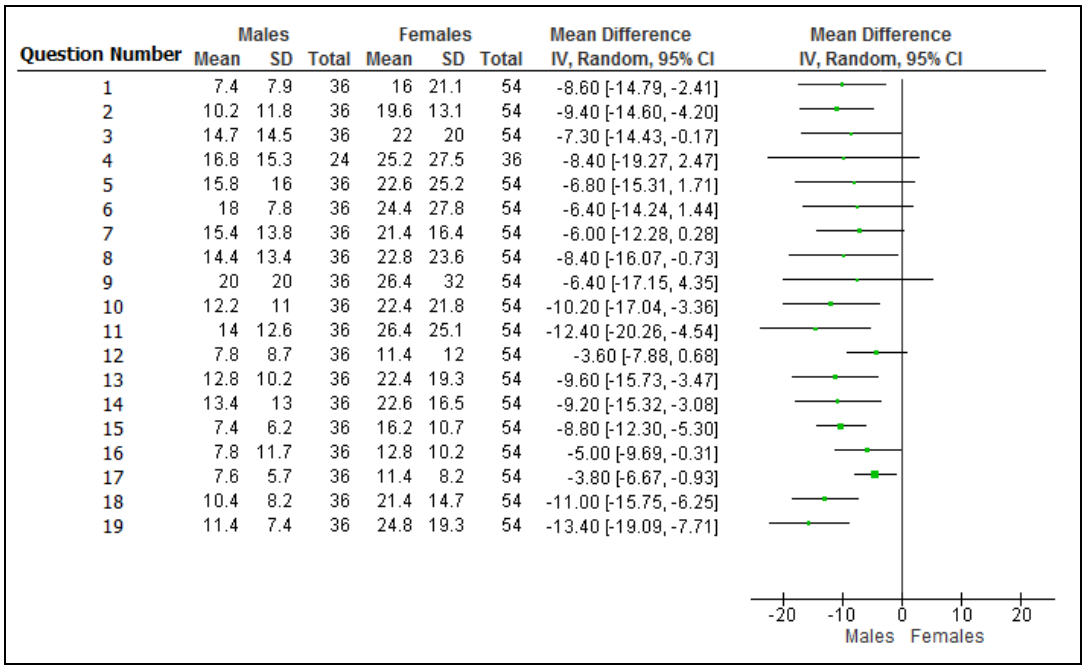


Those respondents between the ages of 16 to 24 years more frequently experienced patellar instability symptoms compared to those between 11 and 15 years, or those who were 25 years and over. After converting the Likert scale responses to numerical values (Chapter 10, Section 10.11), the mean instability score was 9.1 (SD: 3.7) for the 11 to 15 year olds, 13.2 (SD: 3.8) for 16 to 24 year olds and 10.7 (SD: 2.3) for the 25 years and older groups. This reached statistical significance between the 11 to 15 years compared to the 16 to 24 year olds ($p<0.01$). Statistical significant was also reached with a difference between

the 16 to 24 year olds compared to the over 25 year olds (p=0.01). However there was no statistical significant difference between the 11 to 15 years olds compared to the 25 years and over group (p=0.29).

The 11 to 15 year olds reported a greater frequency of patellar instability during less physically demanding activities (Questions 1 to 10) compared to those aged 25 years or over (p<0.01; Figure 11.2). This older age group reported less frequent instability during more sporting and physically demanding tasks (Question 13 onwards; mean: 3.7; SD: 1.2) compared to the youngest age group (mean: 5.0; SD: 1.7; p=0.05; Figure 11.2).

Figure 11.3. Forest-plot to demonstrate the difference in score between respondent gender and their reported instability for each question.

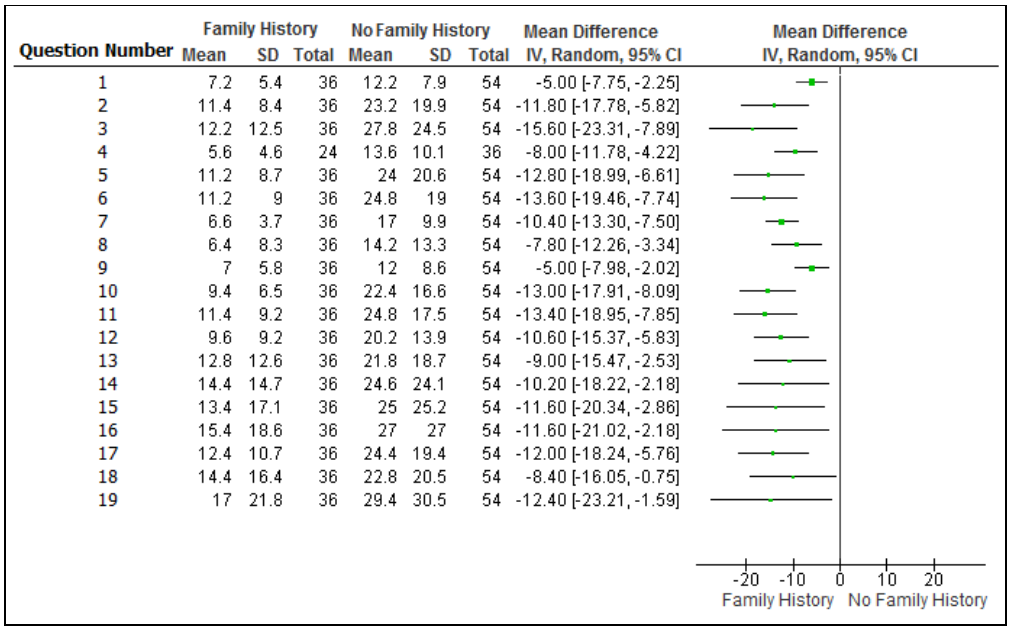


Question Number	Males Mean	SD	Total	Females Mean	SD	Total	Mean Difference IV, Random, 95% CI
1	7.4	7.9	36	16	21.1	54	-8.60 [-14.79, -2.41]
2	10.2	11.8	36	19.6	13.1	54	-9.40 [-14.60, -4.20]
3	14.7	14.5	36	22	20	54	-7.30 [-14.43, -0.17]
4	16.8	15.3	24	25.2	27.5	36	-8.40 [-19.27, 2.47]
5	15.8	16	36	22.6	25.2	54	-6.80 [-15.31, 1.71]
6	18	7.8	36	24.4	27.8	54	-6.40 [-14.24, 1.44]
7	15.4	13.8	36	21.4	16.4	54	-6.00 [-12.28, 0.28]
8	14.4	13.4	36	22.8	23.6	54	-8.40 [-16.07, -0.73]
9	20	20	36	26.4	32	54	-6.40 [-17.15, 4.35]
10	12.2	11	36	22.4	21.8	54	-10.20 [-17.04, -3.36]
11	14	12.6	36	26.4	25.1	54	-12.40 [-20.26, -4.54]
12	7.8	8.7	36	11.4	12	54	-3.60 [-7.88, 0.68]
13	12.8	10.2	36	22.4	19.3	54	-9.60 [-15.73, -3.47]
14	13.4	13	36	22.6	16.5	54	-9.20 [-15.32, -3.08]
15	7.4	6.2	36	16.2	10.7	54	-8.80 [-12.30, -5.30]
16	7.8	11.7	36	12.8	10.2	54	-5.00 [-9.69, -0.31]
17	7.6	5.7	36	11.4	8.2	54	-3.80 [-6.67, -0.93]
18	10.4	8.2	36	21.4	14.7	54	-11.00 [-15.75, -6.25]
19	11.4	7.4	36	24.8	19.3	54	-13.40 [-19.09, -7.71]

11.5.2 Gender

Overall females reported a greater frequency of patellar instability symptoms compared to males (Figure 11.3). Using the converted Likert scale responses, females reported a greater score (mean: 20.6; SD: 4.8) compared to males (mean: 12.5; SD: 3.8). This reached statistical significance ($p<0.01$). This finding was most notable for questions pertaining to negotiating stairs and steps (mean: 21.4 versus 10.4), as well as turning a shopping trolley around a supermarket aisle (mean: 11.4 versus 7.5).

Figure 11.4. Forest-plot to demonstrate the difference in score between those who had a family history of patellar instability to those who did not, in relation to frequency of instability symptoms.

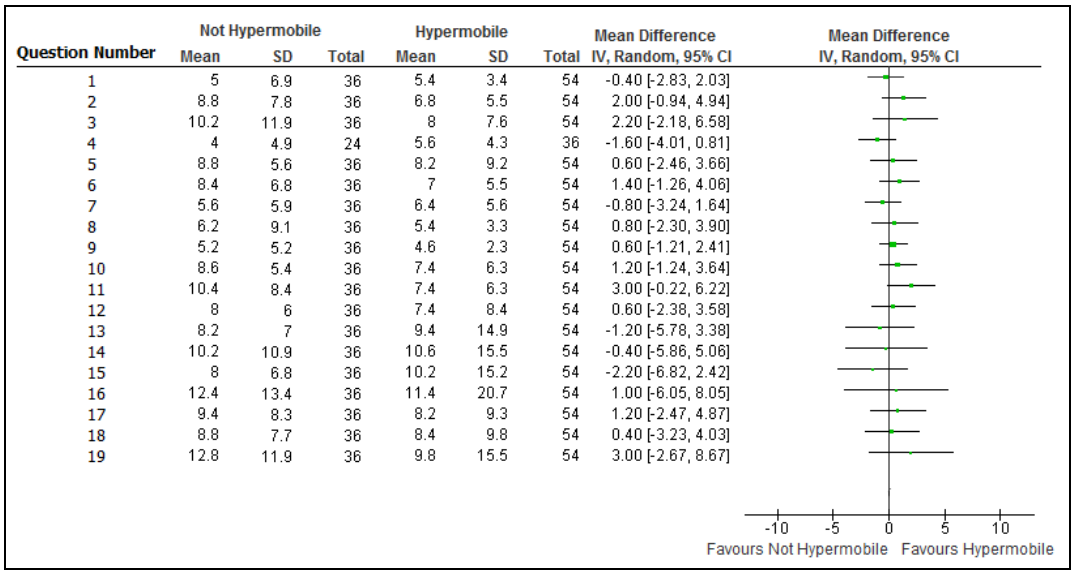


11.5.3 Family History

There was a statistically significant difference between the frequency of patellar instability symptoms in respondents who had a family history of patellar

instability compared to those with no family history ($p<0.01$). Respondents with no family history of patellar instability reported a substantially greater frequency of instability symptoms (mean: 21.6; SD: 5.3) compared to those with a family history (mean: 11.0; SD: 3.3; Figure 11.4).

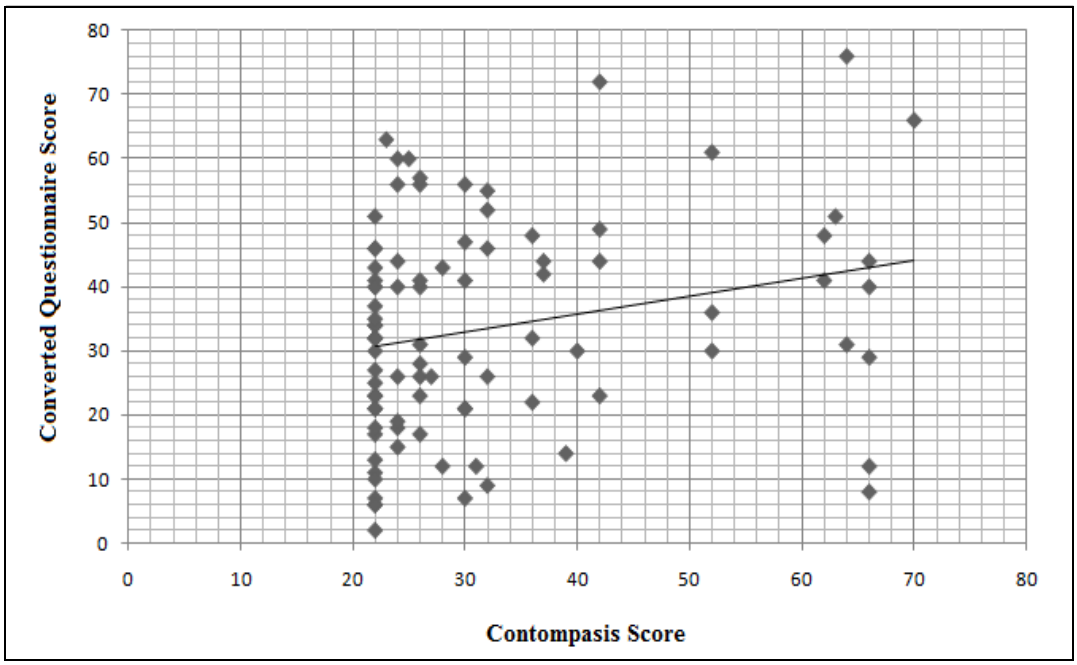
Figure 11.5. Forest-plot to demonstrate the difference in score between those who were hypermobile to those who did not, in relation to frequency of instability symptoms.



11.5.4 Hypermobility

There was no obvious trend in the frequency of patellar instability symptoms between the activities assessed for those respondents who presented with no signs of hypermobility compared to those with joint hypermobility (Figure 11.5). The mean converted Likert score was 7.8 (SD: 1.9) for those with clinically significant signs of joint hypermobility compared to those without (8.4; SD: 2.3). This did not reach statistical significance ($p=0.33$). When assessed as a correlation of questionnaire score to Contomposis score, the relationship also did not reach statistical significance ($p=0.06$; Figure 11.6).

Figure 11.6. Scatter graph to demonstrate the correlation between Contompasis score for join hypermobility and questionnaire response regarding perceived instability symptoms.



11.6 Summary

The results of this study suggest that sporting and multi-directional twisting activities are associated with greater perceived patellar instability symptoms compared to lower energy, uni-planar activities. There appears little difference in symptoms of patellar instability for individuals who are hypermobile compared to those who are not. However, there was a statistically significant difference in perceived patellar instability symptoms between different age groups, genders, and for those with no family history of patellar instability compared to those with a family history.

The next chapter will explore the meaning of these results, to interpret them in relation to previous literature and clinical practice.

Chapter 12. Activity Survey Discussion

12.1 Introduction

The previous chapter reported that sporting and multi-directional activities were associated with patellar instability. The study indicated the perception of patellar instability symptoms was greater in females than males, and younger compared to older adults. Those with a family history of patellar instability reported a reduced frequency of instability symptoms compared to those without a family history. There was however no statistical difference in the activities associated with symptoms of patellar instability for those who presented with signs of hypermobility compared to those who did not.

This chapter will consider how these results relate to the literature (Section 12.2), the clinical implications of the findings (Section 12.3), the limitations to the study design and procedure (Section 12.4), and finally it will discuss future research needs identified following this study (Section 12.5).

12.2 Explanations for the Findings against the Literature

Previous literature has supported the finding that symptoms of patellar instability are associated with multi-directional activities (Diederichs et al, 2010; Fithian et al, 2004a; Atkin et al, 2000). The most frequently cited cause of patellar instability in the literature was femoral internal rotation, with the knee in valgus, the foot fixed, whilst the quadriceps contracts in near terminal extension (Hinton and Sharma, 2003; Bassi and Kumar, 2003). Although not investigated under laboratory conditions, previous textbooks and review papers have suggested that torsional tasks such as these can increase the potential for patellar lateralisation through a greater quadriceps force vector during close-kinetic chain rotational motions (Aglietti et al, 2001; Scuderi and McCann, 2005). Conversely activities such as walking in a straight line or turning in bed

are less frequently associated with patellar instability (Hsiao et al, 2010). These findings support this study where such uni-directional open-chain activities were less frequently associated with patellar instability. Nonetheless these less energetic activities were reported as associated with symptoms of patellar instability for some individuals. This may be attributed to differences in the anatomy or morphology of the patellofemoral joint such as rupture of the MPFL or trochlear dysplasia in this cohort. In such individuals minimal force vector stresses may have been sufficient to cause instability symptoms (Kan et al, 2009; Lee et al, 2003; Mizuno et al, 2001). However, since such anatomical information was not collected in this study, this remains hypothetical.

Age was reported as an important factor related to patellar instability. Younger people reported a greater frequency of patellar instability symptoms compared to older individuals. This difference in perceived instability has not been previously reported. Epidemiological studies such as Fithian et al (2004a) and Atkin et al's (2000) have reported that patellar dislocation can occur in young and middle aged individuals. However a proportion of respondents aged 25 years and older reported that they did not participate in sporting activities such as running on uneven surfaces (33%), running sideways (40%) and multi-directional sports (33%). In contrast all 11 to 15 year olds reported that they ran on uneven surfaces and participated in multi-directional sports. The lower frequency of instability symptoms may therefore be attributed to the reduced participation in such 'at risk' activities in this older age group. Whilst it is acknowledged that increasing age may be associated with reduced participation in sporting activities (Armstrong et al, 2000; Australian Bureau of Statistics, 2003; Dale and Ford, 2002; United Stated Department of Health and Human Services, 2002; Coberley et al, 2011), it is unclear whether this reduced participation was a consequence of patellar instability, or whether this was an independent life-style choice.

The under 16 year olds in this study reported participating in a greater level of sporting pursuits compared to the over 16 age group. Their greater frequency of instability symptoms may be a consequence of participating in more physically-demanding tasks such as running, jumping and changing direction during sporting pursuits. One study, a randomised controlled trial assessing operative versus non-operative management following FTPD, specifically commented on the effect of age on function. In this trial, Palmu et al (2008) reported that whilst 71% of under 16 year olds in the non-operative treatment arm reported recurrent patellar dislocation events, the functional outcomes and satisfaction scores were high with 'good' to 'excellent' functional results reported by 75% of the non-operatively managed group. Accordingly the variety of sporting activities performed by this younger age group may not necessarily be related to the severity of their patellar instability, but to their attitudes to sport. Alternatively literature has suggested that school children may be encouraged to participate in sporting activities either by their family, friends or school (Bradley et al, 2011; Ward et al, 2010; Pabayo et al, 2011). Whilst such encouragement may also exist for adults, the external motivators to participate in exercises may be less (Toscos et al, 2011; Lloyd and Little, 2010). This may have accounted for a difference in the degree of activity and related symptoms reported between the age groups.

A further possible explanation for this finding may be related to osseous development. Trochlear dysplasia can increase in severity during puberty through the development of the distal femur's morphology (Tardieu and Dupont, 2001). Children between 14 to 16 years may present with a gradual increase in symptoms until the dysplasia has fully developed (Tardieu and Dupont, 2001). However this has recently been questioned by Balcarek and colleagues (2011a) who report that the magnitude of trochlear dysplasia was similar across children, adolescents and adults in a cohort of 22 knees assessed using MRI. However Balcarek et al (2011a) did not assess whether there was a correlation between the reported magnitude of trochlear dysplasia and

symptoms of patellar instability. Given this conflicting evidence, longitudinal studies to investigate the development of trochlear dysplasia in relation to patellar instability are required. Until such evidence is provided it will not be possible to determine the relationship between morphological features of the patellofemoral joint and individual's perceived symptoms and functional capabilities.

Females reported a greater frequency of patellar instability compared to males in all the activities assessed. Previous epidemiological studies have supported this finding (Atkins et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a; Hsioa et al, 2010). This difference in gender may be attributed to a difference in the frequency that certain tasks were performed. For instance, the frequency of patellar instability symptoms when turning a shopping trolley around a supermarket differed between males and females. Previous studies have reported that females do supermarket shopping more frequently than males (Kelly, 1991; Thompson, 1996; Woodruffe-Burton et al, 2006). As females more frequently undertake the household's supermarket shopping, this may provide greater experience to this specific activity. As previously acknowledged, recall has demonstrated a significant affect on the responses provided through self-administered questionnaires (Brédart et al, 2002; Saal et al, 2005; Keller et al, 1997; Litwin and McGuigan, 1999). Therefore a difference in recall may account for the apparent difference between males and females in this survey.

Previous studies have reported differences between genders in quadriceps muscle activity seen on EMG for dynamic tasks such as changing direction during running (Beaulieu et al, 2009) and football (Landry et al, 2007). From a biomechanical perspective, the greater force vector which exists in the female pelvis may also account for why females reported a greater frequency of patellar instability during such twisting motions (Johnson et al, 1998; Livingston and Mandigo, 1997). Furthermore, previous studies have suggested

that females more frequently report greater musculoskeletal symptoms and pain than males in this same age group (Debi et al, 2009; Antonopoulou et al, 2007; Picavet and Schouten, 2003; Leroux et al, 2005; Fillingim et al, 2000). Antonopoulou et al (2007) and Fillingim et al (2000) suggested that this difference may be attributed in part to factors such as different psychosocial aspects and behaviours (Fillingim et al, 2000). However whether this can be generalised to individuals with symptoms of patellar instability is unknown, particularly given the anatomical differences between males and females in relation to the patellofemoral joint's force vector and quadriceps angle (Johnson et al, 1998; Livingston and Mandigo, 1997).

Individuals with a family history of patellar instability less frequently reported patellar instability symptoms compared to those with no family history ($p<0.01$). They also participated more often in sporting and higher-level activities compared to those without a family history of this disorder. This difference in participation could therefore not explain the difference in responses. However, there are two potential explanations. One may be related to a learnt effect in individual's perceptions and behaviours. Previous studies of other musculoskeletal disorders have suggested that individuals adapt their functional activities to minimise the risk of adverse symptoms (Schanberg et al, 2001; Besier et al, 2010). Therefore individuals with a family history of patellar instability may have learnt 'fear-avoidance' strategies through family members to limit potential symptoms. For example, children at an early age may be discouraged to change direction vigorously and to be more cautious during certain activities if their parents were aware of a family history of patellar instability. Although not previously assessed in a patellar instability cohort, this finding was reflective of Wilson et al's (2011) cohort study. The authors reported that parental practices and protection led to reduced activity and fear-avoidance in their cohort of 42 adolescents who reported chronic pain. However, no studies have assessed the biomechanical differences between

individuals with patellar instability who have, or do not have a family history of patellar instability.

A second explanation for why individuals with a family history of patellar instability less frequently reported symptoms of patellar instability may relate to parental anxieties. Families with a history of patellar instability may have less anxiety regarding instability symptoms. Previous studies have demonstrated that parent's attitudes towards a medical condition can influence parenting approaches in relation to melanoma and sun protection (Nelson and Lucozant-Peterman, 2001; Robinson et al, 2000), juvenile arthritis (Kashirkar-Zuck et al, 2008) and fibromyalgia (Vandvik and Forseth, 1994). However no qualitative studies have been performed exploring the relationship between patellar instability within the family, and whether siblings with symptoms of patellar instability are treated differently. Further qualitative investigations to determine whether family history influences an individual's perceptions of their patellar disability would provide insight into this.

Joint hypermobility has been shown to be associated with patellar instability (Nomura et al, 2006; Stanitski, 1995). Previous authors have acknowledged that activities which are less frequently associated with joint instability in non-hypermobile people are sufficient to cause instability symptoms in those individuals with joint hypermobility syndrome (Grahame and Hakim, 2008; Hakim and Grahame, 2003; Simpson, 2006). The MPFL and vastus medialis have been cited as important medial restraints to lateral patellar translation (Sevanongse et al, 2003; Amis et al, 2003). An increase in the elasticity of these tissues may facilitate greater functional instability. However this survey reports results which are contrary to these laboratory findings. There appears to be no statistically significant difference in patellar instability for those individuals who were hypermobile, compared to those who showed no signs of benign joint hypermobility ($p=0.33$). Whilst the 90 people sampled may provide an acceptable representation of this population, only 16 presented with clinically

meaningful benign joint hypermobility (Contomposis score 65 and above; McCormack et al, 2004). Accordingly the statistical analysis may be underpowered to demonstrate a difference even if one actually existed (Bland, 2006). Finally the Contomposis score, as with the Beighton score, assesses global joint hypermobility (Grahame and Hakim, 2008). Individuals may present with features of joint hypermobility localised to one joint, such as genu recurvatum or excessive patellar mobility (Nomura et al, 2006), but would not be acknowledged as being hypermobile if no other features were recorded (Grahame and Hakim, 2008). This has been recognised as an important factor by Nomura et al (2006) who compared the affect of assessing generalised joint laxity using the Carter and Wilkinson's criteria (Carter and Wilkinson, 1964) with the evaluation of manual lateral patellar hypermobility. Using a cohort of 82 people who had experienced recurrent patellar dislocation, they reported that manual patellar hypermobility was more significantly correlated than generalised joint laxity as a predisposing factor to patellar dislocation ($p<0.01$; Nomura et al, 2006). This may be another reason for the conflicting findings from this survey compared to the previous evidence.

12.3 Clinical Implications

The findings of this study can be translated into clinical practice in a number of ways. Firstly the results indicate what activities people report as symptomatic. The use of patient-centred goals is widely supported within the physiotherapy literature (Kidd et al, 2011; Grill et al, 2010; Leach et al, 2010; Rosewilliam et al, 2011) thus these results may inform the construction of patient-centred goals. Alternatively physiotherapists may choose to target activities as part of a functional exercise programme given the reported association of specific activities to instability symptoms. For example treatments may be paced to progress an individual from tasks such as walking in a straight line, to higher-level goals such as sporting pursuits and twisting activities. Targeted functional activities have been shown to be of benefit in the rehabilitation of other

musculoskeletal conditions such as osteoarthritis of the knee (Dias et al, 2003), low back pain (Engbert and Weber, 2011) and shoulder dysfunction (Jørgensen et al, 2010). Accordingly, the hierarchy of activities identified from this survey may be used both to direct and to evaluate treatments.

The results provided a list of ranked activities associated with symptoms of patellar instability. Using this list, the Norwich Patellar Instability (NPI) score, the first formal, patient-reported outcome measure to assess perceived patellar instability was developed. This will be discussed in the next chapter (Chapter 13).

12.4 Limitations of the Study

Study bias is acknowledged as a major limitation of empirical research (Portney and Watkins, 2009; Buckingham and Saunders, 2004). Previous literature on survey design has acknowledged that sources of bias may include: the study design, the respondent's attitudes towards the topic under investigation as well as the researcher's impact from the questionnaire design, sampling strategy and approach towards potential study participants (Oppenheim, 1992; McColl et al, 2001; Rattray and Jones, 2007; Hing et al, 2011). Efforts were made to limit these, for example, the questionnaire posed 19 activities. These were selected after consideration of a number of different sources including: 1) a systematic review of the literature, 2) anecdotal experiences of previous patients and 3) the results of the pilot study (Chapter 10, Section 10.8). Respondents were also asked to augment this list with any additional activities they considered related to patellar instability. Secondly, it was clearly specified in the protocol that all potentially eligible people should be consecutively approached by the physiotherapists, orthopaedic surgeons or the researcher. However to limit selection bias, no safe-guards such as a screening log, were provided to audit this process. Although there was no evidence of selection bias, this may have occurred to the detriment of the study findings.

Participants were advised to complete the questionnaires at home. However in practice all but one individual completed this within their hospital visit. This may have been advantageous as it increased compliance since any confusion regarding questionnaire responses were answered by the researcher at the time of completion, reducing measurement error. However completing the questionnaire at home may have allowed greater consideration of the questions, whilst minimising the potential for researcher bias from influencing the respondent's answers. This is supported by the literature which has suggested that questionnaires should be completed in a quiet room, with minimal distractions in-order to obtain valid responses (Hing et al, 2011; Buckingham and Saunders, 2004). This may have impacted on the study's results, despite attempts to control this in the protocol.

All survey respondents had been referred to an acute hospital due to their symptoms of patellar instability which is typical for this population (Atkin et al, 2000; Fithian et al, 2004a). The survey results can therefore be generalised to this population. However it remains unclear whether these findings reflect the experiences of individuals who do not seek treatment or are treated in primary care settings. Whether there is a difference in the activities undertaken or the perceptions of these populations remains unknown, potentially an area for further study.

12.5 Recommendations for Future Study

The study's stratified sampling strategy ensured representation of different important population characteristics such as age and gender. However the sample was not stratified for joint hypermobility. As a result, only 16 people (18%) were recruited with clinically meaningful benign joint hypermobility syndrome. Consequently the assessment of hypermobility may have been subject to type II statistical error (Bland, 2006). The objective of this study was

to determine what activities are associated with patellar instability and to what frequency they occur. It did not aim to assess the effect of hypermobility on patellar instability, and accordingly, hypermobility score was not stratified for in the sampling strategy. Although this could have been undertaken, it has been suggested that by stratifying a number of different characteristics, the complexity of recruitment is increased (Altman, 2009). Since age and gender were initially identified as key prognostic factors and hypermobility was not, these important variables were stratified for. Further study would be required based on a larger cohort of people who present with varying severities of benign joint hypermobility to determine whether this clinical entity influences symptoms of patellar instability.

Twenty-one additional activities not initially pre-defined in the questionnaire were identified by respondents (Chapter 11, Section 11.2). These included a variety of high- and lower-energy multi-directional and uni-planar activities. The most frequently cited activity was getting in and out of bed. However this was only reported by four people out of a cohort of 90. Recall has been demonstrated to be a significant factor on questionnaire validity (Aldridge and Levine, 2001; Brédart et al, 2002; Saal et al, 2005). Given this, respondents may have had difficulty in recalling specific activities not prompted by the questionnaire. This could have accounted for such few responses to these additional tasks.

Previous trials have indicated that up to 70% of people following FTPD experience recurrent instability symptoms (Nikku et al, 2005; Savarese and Lunghi, 1990; Sillanpää et al, 2008b; Sillanpää et al, 2009a; Sillanpää et al, 2009b). Given this high proportion, the study cohort consisted of individuals who had experienced recurrent patellar instability episodes, rather than those who had experienced a FTPD. This was an important sampling decision since the survey intended to gain the attitudes and experiences of those individuals who had experienced instability symptoms over a period of time having

undertaken a number of different functional activities. This was based on literature which suggests that people with greater experience of the activity will provide more typical experiences (Barnett, 1999; Mason, 2005). Whilst this provided 'richer' data with respect to the functional attributions of instability (Mason, 2005), it remains unclear whether these results reflected people following a FTPD. Further study to compare these results to the FTPD population may therefore be indicated to develop our knowledge of this clinically important, but different population.

A variety of different factors may be associated with the severity of patellar instability. These include morphological features such as trochlear dysplasia and patellar shape (i.e. Wiberg type three; Wiberg, 1941; Bollier and Fulkerson, 2011; Panni et al, 2011), traumatic injuries such as MPFL or medial retinaculum rupture (Balcarek et al, 2010), as well as heredity or developmental features such as patella alta (Balcarek et al, 2011a; Nomura et al, 2006). This study did not collect this data. It was therefore not possible to determine whether the severity of injury was related to perceived patellar instability. Further anthropological studies to assess whether severity of patellar instability symptoms relates to the patellofemoral joint anatomy or whether other psychological or behavioural factors are important, would be a useful avenue for further study. This is particularly interesting given that individuals with severe, bilateral trochlear dysplasia have frequently reported a "good" knee whilst demonstrating near-identical morphological features to the more symptomatic contralateral knee (Simon Donell, personal communication, 2011).

12.6 Summary

This chapter has outlined how the findings of this survey relate to the literature. It has emphasised that patellar instability is associated with higher-energy, multi-directional activities compared to lower-energy uni-planar tasks. The

results have also suggested that differences in age, gender and family history may be important variables for instability symptoms. However the presence of benign joint hypermobility syndrome did not influence instability. However, this should be interpreted with great caution due to the small sample size. The chapter has also presented recommendations for further study to determine whether these results reflect that of people following FTPD, or whether anatomical or morphological features which may predispose individuals to patellar dislocation, relate to the severity of their patellar instability symptoms.

The following chapter will describe how the findings of this study were used to construct an outcome measure in order to assess people's patellar instability; the NPI score.

Chapter 13. Construction of the Norwich Patellar Instability Score

13.1 Introduction

A variety of outcome measures, often generic for a variety of disorders of the knee, have been used to evaluate the clinical and functional outcomes of individuals following patellar dislocation (Smith et al, 2008; Chapter 8). However no outcome measure has been constructed to specifically assess perceived patellar instability (Smith et al, 2008; Chapter 4). This chapter will discuss the construction of such an outcome measure based on the results of the activity survey (Chapter 11).

This chapter will present the rationale behind the development of this outcome measure (Section 13.2), the methodological approaches used (Section 13.3), and the results of this process (Section 13.4). It will also consider areas for further research to assess the validity and reliability of this new tool (Section 13.5).

13.2 Rationale

Knee-specific measurement tools have been used to evaluate outcomes following FTPD. These have included the Fulkerson Patellofemoral Score (Fulkerson and Shea, 1990), the International Knee Documentation form (Hefti et al, 1993), the Lysholm Knee Score (Lysholm and Gillquist, 1982) and the Kujala Patellofemoral Disorder Score (Kujala et al, 1993). However the national survey study indicated that these were only occasionally used in physiotherapy practice, being adopted by less than 15% of respondents for the majority of their FTPD caseloads (Chapter 8). Furthermore these measures were designed to evaluate other knee disorders such as PFPS, osteoarthritis and

anterior cruciate ligament rupture (Paxton et al, 2003). The literature review identified that no outcome measures have been constructed to specifically evaluate perceived patellar instability (Chapter 4) which is considered the predominant symptom and functional limitation for individuals following first-time and recurrent patellar dislocation (Donell, 2006). Accordingly, the inability to assess this domain was considered a major weakness. An objective of the activity survey was therefore to develop items for construction of a new outcome measure specifically for this group.

13.3 Methods

The process used was divided into two phases:

13.3.1 Phase 1: Initial Item Generation

The results of the activity survey were used to devise a list of activities associated with patellar instability (Chapter 11). These were a variety of different activities of daily living and sporting tasks. Participants were asked to describe how often each activity caused patellar instability, recorded using a Likert scale of ‘always’, ‘often’, ‘sometimes’, ‘rarely’ or ‘never’ responses. This data identified which activities were associated with symptoms of patellar instability, and how frequent they were experienced. This formed the basis of the outcome measure’s items.

The use of study data to construct an outcome measurement has been previously recommended (Dawson et al, 1996a; Dawson et al, 1996b). A well-known example of this practice within the orthopaedic literature is the Oxford Hip and Knee Scores (Dawson et al, 1996a; Dawson et al, 1996b; Dawson et al, 1998; Dawson et al, 1999). These instruments have been used extensively to assess outcomes following orthopaedic surgery (Rothwell et al, 2010; Baker et al, 2007). These measures were designed using patient-reported data on

osteoarthritic symptoms (Dawson et al, 1996a; Dawson et al, 1996b; Dawson et al, 1998; Dawson et al, 1999). A similar design process was adopted to enhance content validity by being directly based on a cohort's experiences rather than anecdotal or theoretical assumptions (Portney and Watkin, 2000; Polgar and Thomas, 2000; Steiner and Norman, 2008).

13.3.2 Phase 2: Construction of the Outcome Measurement

13.3.2.1 Question Order

The activity survey's Likert scale scoring system was converted to a numerical value as detailed in Chapter 10 (Section 10.11). Through this the mean value for each activity was calculated. Activities were ranked by the mean value and grouped into six strata at five-point intervals e.g. 35-40, 40-45 etc. This resulted in lower-energy, more sedentary activities itemised first, whilst higher-energy sporting-related activities were presented later. Eight studies have assessed the effect of question order in health outcome questionnaires, however this remains inconclusive. Six studies reported that question order had no significant effect over the responses obtained (Johnson and Murphy, 2007; Bolman et al, 2007; Barry et al, 1996; McColl et al, 2003; Dunn et al, 2003; Lee and Grant, 2009). Two studies have reported that the order of questions posed had a statistically significant effect (Bowling and Windsor, 2008; Rimal and Real, 2005). However, Bowling and Windsor's (2008) questionnaire was not a self-administered but interviewer-administered questionnaire. Whether the mode of administration accounted for these differences is unclear. Secondly Rimal and Real's (2005) response format was a linear interval scale rather than a Likert scale. Whether the response format was an important variable to influence responses was not discussed by the authors.

The terminology used to describe each task was directly extracted from the activity survey questionnaire (Chapter 10). No re-wording or re-defining of the

activities was permitted to maintain content validity. Rephrasing of the outcome's items was therefore avoided to prevent designer bias from reducing the direct translation of the activity survey's results to this outcome measure (Schechter and Herrmann, 1997).

13.3.2.2 Response options

A five-point Likert scale response format was adopted for the new outcome measure to record the frequency of instability symptoms for each activity posed. Responses ranged from 'always' to 'never'. This was justified since Oppenheim (1992) recommends that Likert response formats permit the assessment of frequency of behaviour or activities which is required for this outcome measure. Furthermore due to its common usage in health, social and commercial studies, the familiarity of this response format was considered useful to facilitate ease of completion and to minimise measurement error (Bowling, 2009).

Ten studies have compared the use of Likert scale to other response formats in health measurement outcomes. All have reported no statistically significant difference in response provided between Likert and numerical rating scales such as the visual analogue method (Van Laerhoven et al, 2004; Guyatt et al, 1987; Bolognese et al, 2003; Davey et al, 2007; Johansson et al, 2007; Jaeschke et al, 1990; Brunier and Graydon, 1996; Nagata et al, 1996; Hollen et al, 2005; Gallasch and Alexandre, 2007). However the Likert scale response format has been shown to be superior regarding ease of administration and interpretation by child (Van Laerhoven et al, 2004) and adult populations (Guyatt et al, 1987). Given that patellar instability presents in childhood as well as adult populations (Fithian et al, 2004a; Atkin et al, 2000), the Likert format was adopted.

The order of response format (always to never) was maintained throughout. Some authors have suggested that randomly reversing the order of responses to

change categories from high to low to low to high may minimise response acquiescence or a 'yea-saying' bias (Heal and Sigelman, 1995; Streiner and Norman, 2008). No health-related studies have investigated the effect of changing categories within health outcome questionnaires. However response order was not varied in this outcome measure to avoid the potential that respondents would not realise such a change had occurred resulting in uninterpretable or incorrect responses (Streiner and Norman, 2008).

The use of five Likert response options is supported in the literature (Rattray and Jones, 2007). The ideal number of response categories has been reported as between five to nine (Streiner and Norman, 2008; Nishisato and Torii, 1970). Streiner and Norman (2008) recommend that providing more response options can increase an outcome measure's discriminative ability and reliability. However providing too many responses may unnecessarily increase confusion, making the measurement process more difficult and more time consuming (Preston and Colman, 2000; Considine et al, 2005). This was highlighted in Preston and Colman's (2000) study of 149 respondents who completed a self-administered retail survey and Considine et al's (2005) systematic review of outcome measure questionnaire design strategies. Both indicated that the provision of excessive response options can significantly increase measurement error and can create greater respondent dissatisfaction (Preston and Colman, 2000; Considine et al, 2005).

Within the health literature, four studies have compared the use of five-point Likert scale response options to four, seven and 10-point response options (Nagato et al, 1996; Garratt et al, 2011; Castle and Engberg, 2004; Østerås et al, 2008). Three studies have reported statistically significantly better response rates and questionnaire completion for the five-point method compared to the four-point (Østerås et al, 2008), seven-point (Nagato et al, 1996) and ten-point options ($p<0.05$; Garratt et al, 2011). However in contrast Castle and Engberg (2004) reported greater preference for the ten-point response format compared

to a five-point option. In their study of 2,450 elderly people who were surveyed on satisfaction, demographic characteristics and general health domains, 39% of the respondents stated that they preferred the ten-point response format and that this was less prone to a 'ceiling effect' when compared to the five-point response format. However this questionnaire assessed different domains and in an older population than this thesis' proposed outcome measure. Furthermore, given the balance of the other three studies which have assessed this area with younger respondents, the decision to adopt a five-point Likert scale option was made.

13.3.2.3 Total Score

Each questionnaire response option was numerically weighted. However, before allocating each individual activity a weighting, the total possible outcome measure score was determined. Previous literature has suggested that outcome measurements should be scored to a 'rounded' or even number to permit ease of calculation (Streiner and Norman, 2008; Vogh, 1999; Larson, 2002). However no studies have assessed the effect of using odd versus even final values for scoring health questionnaires. Accordingly, the researcher constructed trials of 50, 100, 200 and 250 points from the dataset. A final score of 250 was found most appropriate. This was because it permitted a sufficient interval between each activity strata, whilst providing a memorable final score for a single-construct i.e. patellar instability (Streiner and Norman, 2008). Combining the 19 items into a one-dimensional construct is supported in the literature. Carifio and Perla (2007), in their commentary on the common misconceptions regarding the Likert response format system, reported that summing eight or more items provided a reasonable level of interval data to provide an overall rating.

The final score was converted to a percentage as supported by various texts advocating the use of percentages for ease of interpretation (Larson, 2002;

Waltz et al, 2010; Steiner and Norman, 2008). No studies have compared the reliability, ease of use or interpretation of percentage versus raw numerical values. However, the adoption of a percentage value aided the management of missing responses. Individuals are only able to report instability symptoms if they have experienced this symptom during everyday activities. Individuals with the greatest instability may avoid higher-energy activities compared to those with less instability (Fisher et al, 2010; Wilson et al, 2011). It was therefore hypothesised that these individuals may not complete a number of questions, resulting in a lower score. Conversely, those who participate in sports may report higher instability symptoms since they participate in 'at risk' activities (Chapter 11). Finally, as a person recovers, participation in higher-energy tasks may increase. As a result this may be reflected in greater reported instability symptoms compared to their baseline measurements when they avoided such 'at risk' tasks. These potential scenarios could result in counter-intuitive scores which raise questions regarding the outcome's face validity (Portney and Watkin, 2009; Polgar and Thomas, 2000). To prevent this, a "don't do" response option was included and the questionnaire's total score divided by the maximum potential score of those activities actually participated. This is summarised below:

$$\frac{\text{Total score from participated items}}{\text{Sum of highest possible score from participated items}} \times 100$$

Using this calculation, it was possible to prevent the final score representing the degree of participation respondents engaged with the posed activities (Ludlow and O'Leary, 1999). The use of "don't do" options, to reduce the risk of missing responses, has been previously assessed in three studies (Rubin et al, 1995; Naeim et al, 2005; Holman et al, 2004). However no study has assessed

the validity of using "don't know" responses to calculate a percentage score. Instead the literature has reported how providing such a response option can be used to estimate a value through imputation (Rubin et al, 1995; Naeim et al, 2005; Holman et al, 2004).

It was decided that lower scores would indicate less instability symptoms. Streiner and Norman (2008) recommend that constructing outcome scores where the magnitude of a score directly correlates with the degree of disability is more intuitive. This was to reduce errors during the translation of results, thereby enhancing an outcome's reliability after completion (Streiner and Norman, 2008).

13.3.2.4 Item Response Weighting

The questionnaire needed to be able to discriminate between people who frequently experience patellar instability, those who only rarely experienced patellar instability and the continuum in-between. Previous authors (Nunnally 1970; Hirsch et al 2004) have demonstrated that providing different weights or scores to individual items within a questionnaire can facilitate its overall discriminatory value (Streiner and Norman, 2008).

Weighting each activity was justified since Nunnally (1970) in his commentary of outcome measure design recommended that in questionnaires of less than 20 items, weighting has been shown to have a greater effect on increasing discriminatory validity than when over 20 items are analysed. Three studies have assessed the use of item weighting in health outcome measures (van Loon et al, 2003; Hirsch et al, 2004; Letrait et al, 1996). Whilst van Loon et al (2003) and Letrait et al's (1996) studies reported no difference between using a weighted- and non-weighted response format, Hirsch et al (2004) reported that a weighted response analysis provided greater discriminatory ability in their questionnaire of 180 people with asthma. The weighting system was described

as an important methodological process to be able to discriminate between severity and presence of clinically important symptoms (Hirsch et al, 2004). Given this limited research in health-service survey designs, the use of weighting was therefore considered appropriate.

In this study, if each item was regarded as one point, people who experienced patellar instability during a higher range of activities were captured by a total overall score closer to 19 from the total 19 items posed, than those who experienced patellar instability during fewer activities. However this method of scoring is based on the assumption that each activity provided an equal chance of causing a patellar dislocation. From the results of the activity score (Chapter 11), those fewer and unfortunate people who experienced patellar instability during relatively sedentary activities presented with a greater frequency of overall patellar instability, and therefore greater severity of this symptom. Without weighting, any one of the relatively gentle activities scores would provide the same score value as another more vigorous activity. For example, an extreme sporting activity involving a higher degree of unguarded rotation is likely to be a problem for most people with patellar instability and so less discriminatory, whereas a more sedentary activity such as crossing one's legs was less likely to be a problem for most people, thereby providing greater discrimination of those with greater severity of symptoms.

In an attempt to overcome these issues, the weighting system was devised according to six strata. Using the six strata from the initial activity survey dataset (Chapter 11), each questionnaire item was weighted according to its relative association to symptoms of instability. Items associated more frequently with instability presided in a lower strata and were attributed a low score or weighting. Those activities that were less frequently associated with patellar instability were allocated a higher score. Therefore individuals who reported patellar instability during activities which rarely caused symptoms, as well as experiencing instability during the more frequently cited activities,

would report greater overall patellar instability, thus differentiating the frequency of instability symptoms. Weighing were allocated to ensure that the maximum weighed score equated to 250, which was justified earlier (Section 13.3.2.3).

13.3.2.5 Outcome Measure Presentation

Information was provided to respondents prior to completing the outcome measure. This was to familiarise themselves to the questionnaire's objectives and methods of completion. Without this information, they could be at greater risk of measurement error, inadvertently making mistakes when completing the questionnaire (Streiner and Norman, 2008). This information also specified that respondents should complete the questionnaire related to their current instability symptoms. This was important since asking individuals about their symptoms over a period of time can be influenced by recall error (Streiner and Norman, 2008).

The allocation of space to record basic demographic information such as the date, side of knee under assessment and respondent's name, address and hospital number was made to ensure that all important data was collected. The format and length of the outcome measure was limited to two sides of A4. This was justified as it is acknowledged that restricting the tool to a minimum length can reduce the cognitive effort required by respondents to complete a questionnaire (Streiner and Norman, 2008; De Velli, 1991; Hawthorne et al, 2006). Consequentially fatigue and measurement error could be minimised whilst maintaining the validity of the questionnaire (Oppenheim, 1992). De Vellis (1991), in his textbook on scale development, recommend that short questionnaires can minimise respondent fatigue but are less reliable, whilst longer questionnaires can improve reliability, but increase respondent fatigue. Therefore maximising one characteristic reduces the other (Selfe et al, 2001). The adoption of shortened questionnaires to utilise these proposed advantages

has been previously demonstrated by the Dimensions of Anger Reactions-5, the SF-12 and the Quick Disability of the Arm, Shoulder and Hand (DASH) measurement tools which have reported greater ease of completion and interpretation with no loss of validity compared to their originally longer formats (Hawthorne et al, 2006; Ware et al, 1996; Beaton et al, 2005).

Numbers representing the individual weighting for each response options were not presented on the new outcome measure. Previous literature suggested that respondents may use the weighted score numbers to help interpret the meaning of each item (Streiner and Norman, 2008; Christian and Dillman, 2004). By not providing this, respondents are unable to present themselves inaccurately and favourably through a social desirability bias (Streiner and Norman, 2008). This was typified by Christian and Dillman (2004) who reported that itemising the weighted score for each response significantly increased overall scores in a study of 1042 university students who completed a self-administered questionnaire. As a result, weighted scores were only available on a scoring sheet to calculate the final score for this patellar instability score.

13.4 Results

The ranked activities from the activity survey have been converted as described in Chapter 10 (Section 10.11) and their subsequent weighting are presented in Table 13.1.

The resulting outcome measure, the Norwich Patellar Instability (NPI) score (Figure 13.1) was constructed. This consisted of 19 items addressing the following domains: lower-energy activities (12 items), higher-energy activities (seven items) which were performed either uni-planar (14 items) or multi-directional and varus torsion activities (five items). The weighted score for each

response option is presented in Table 13.2.

13.5 Discussion and Recommendations for Future Research

By developing an outcome measure based on a cohort's experiences, the NPI score inherently possessed a degree of face validity since the inclusion and weighing of each item was based on the results of the activity survey (Chapter 11; Portney and Watkins, 2009). However further study examining other areas of validity, reliability and responsiveness is warranted to determine the appropriateness of this new outcome measurement.

The construction of the NPI score was based on an assumption that activities most commonly associated with patellar instability affect the majority of this population. This assumption was supported by previous epidemiological studies. Atkin et al (2000), Fithian et al (2004a) and Sillanpää et al (2008a) reported that sporting and higher-energy twisting activities are associated with patellar dislocation and instability, whilst uni-planar and less strenuous pursuits less frequently cause this injury (Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a). The weighting strategy was therefore designed to be responsive to differences in instability between activities. Further examination of the various forms of validity would determine whether these assumptions were founded.

In addition to the 19 activities evaluated during the activity survey, 21 additional activities were identified by different participants as potentially important (Chapter 11). These included skiing, walking in high heels and dancing. The most frequently cited additional activity, getting into/out of bed, was only acknowledged by four people (4% of the cohort). These activities were therefore considered as insufficient to generalise to the overall population and consequentially not included. However, to ensure content validity, a tool must demonstrate that it includes all potential items which refer to the subject

under investigation (Portney and Watkins, 2009; John and Benet-Martinez, 2000). Accordingly, further assessment is recommended to determine the

Table 13.1. Ranked activities related to frequency of perceived patellar instability reported by people with a history of recurrent patellar dislocation.

Activity	Frequency of Likert Response (Scored Conversion)					Mean (SD)	Rank	Maximum Weighted Score
	Always (4)	Often (3)	Sometimes (2)	Rarely (1)	Never (0)			
Twisting or changing direction during Sports or PE activities	120	78	30	4	0	46.4 (51.6)	1	5
Changing direction when running, such as cutting or slalom	108	69	28	7	0	42.4 (45.5)	2	7
Running in a straight line on uneven surfaces	92	78	32	8	0	42.0 (41.3)	3	7
Walking on slippery, wet or icy surfaces	64	75	50	11	0	40.0 (32.9)	4	7
Running sideways	100	63	20	9	0	38.4 (42.1)	5	10
Hopping	92	54	28	12	0	37.2 (36.7)	6	10
Jumping	76	54	36	18	0	36.8 (29.8)	7	10
Running in a straight line on even surfaces	88	39	40	14	0	36.2 (33.6)	8	10
Going down stairs	56	51	58	16	0	36.2 (26.5)	8	10
Squatting	68	60	28	24	0	36.0 (27.9)	10	10
Kneeling	76	48	34	18	0	35.2 (29.0)	11	10
Walking in a straight line on uneven surfaces	36	63	60	14	0	34.6 (27.7)	12	15
Climbing stairs	44	51	44	20	0	31.8 (21.3)	13	15
Stepping onto or over a high step	36	33	58	22	0	29.8 (21.2)	14	15
Crossing my legs when sitting	28	30	34	26	0	23.6 (13.5)	15	22
Walking in a straight line on even surfaces	20	18	54	25	0	23.4 (19.5)	16	22
Getting in and out of a car	16	9	56	22	0	20.6 (21.4)	17	22
Turning a heavy trolley round a supermarket aisle	28	21	36	11	0	19.2 (14.1)	18	25
Turning to look over my shoulder	16	18	38	23	0	19.0 (13.7)	19	25

Activity	Frequency of Likert Response (Scored Conversion)					Mean (SD)	Rank
	Always (4)	Often (3)	Sometimes (2)	Rarely (1)	Never (0)		
Twisting or changing direction during Sports or PE activities	120	78	30	4	0	46.4 (51.6)	1
Changing direction when running, such as cutting or slalom	108	69	28	7	0	42.4 (45.5)	2
Running in a straight line on uneven surfaces	92	78	32	8	0	42.0 (41.3)	3
Walking on slippery, wet or icy surfaces	64	75	50	11	0	40.0 (32.9)	4
Running sideways	100	63	20	9	0	38.4 (42.1)	5
Hopping	92	54	28	12	0	37.2 (36.7)	6
Jumping	76	54	36	18	0	36.8 (29.8)	7
Running in a straight line on even surfaces	88	39	40	14	0	36.2 (33.6)	8
Going down stairs	56	51	58	16	0	36.2 (26.5)	8
Squatting	68	60	28	24	0	36.0 (27.9)	10
Kneeling	76	48	34	18	0	35.2 (29.0)	11
Walking in a straight line on uneven surfaces	36	63	60	14	0	34.6 (27.7)	12
Climbing stairs	44	51	44	20	0	31.8 (21.3)	13
Stepping onto or over a high step	36	33	58	22	0	29.8 (21.2)	14
Crossing my legs when sitting	28	30	34	26	0	23.6 (13.5)	15
Walking in a straight line on even surfaces	20	18	54	25	0	23.4 (19.5)	16
Getting in and out of a car	16	9	56	22	0	20.6 (21.4)	17
Turning a heavy trolley round a supermarket aisle	28	21	36	11	0	19.2 (14.1)	18
Turning to look over my shoulder	16	18	38	23	0	19.0 (13.7)	19

Table 13.2. The weighted score designated for each response opinion on the Norwich Patellar Instability Score.

Activity	Response Option

	Always	Often	Sometimes	Rarely	Never
Twisting or changing direction during Sports or PE activities	5	4	3	2	0
Changing direction when running, such as cutting or slalom	7	5	3	2	0
Running in a straight line on uneven surfaces	7	5	3	2	0
Walking on slippery, wet or icy surfaces	7	5	3	2	0
Running sideways	10	7	5	3	0
Hopping	10	7	5	3	0
Jumping	10	7	5	3	0
Running in a straight line on even surfaces	10	7	5	3	0
Going down stairs	10	7	5	3	0
Squatting	10	7	5	3	0
Kneeling	10	7	5	3	0
Walking in a straight line on uneven surfaces	15	10	7	5	0
Climbing stairs	15	10	7	5	0
Stepping onto or over a high step	15	10	7	5	0
Crossing my legs when sitting	15	10	7	5	0
Walking in a straight line on even surfaces	22	15	10	7	0
Getting in and out of a car	22	15	10	7	0
Turning a heavy trolley round a supermarket aisle	25	22	15	10	0
Turning to look over my shoulder	25	22	15	10	0

Figure 13.1. The Norwich Patellar Instability (NPI) Score – Respondent Version.

Name/address/hospital no (affix patient label)	LEFT/RIGHT
	Date

Below is a list of activities which may cause your knee cap to feel like it will "pop out" of joint or feel unstable. Please read through each statement, ticking the box which best describes how often your knee cap feels like it will "pop out" of joint or feels unstable when you are doing each of the following activities. ***(Please tick one box for every question)***

1. Twisting/changing direction during sports/games

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

2. Changing direction when running

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

3. Running in a straight line on *uneven* surfaces

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

4. Walking on slippery, wet or icy surfaces

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

5. Running sideways

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

6. Hopping

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

7. Jumping

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

8. Running in a straight line on *even* surfaces

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

PLEASE TURN OVER

9. Going down stairs

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

10. Squatting

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

11. Kneeling

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

12. Walking in a straight line on *uneven* surfaces

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

13. Climbing stairs

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

14. Stepping onto or over a high step

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

15. Crossing your legs when sitting

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

16. Walking in a straight line on *even* surfaces

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

17. Getting into or out of a car

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

18. Turning a heavy trolley round a supermarket aisle

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

19. Turning to look over your shoulder

Always □ Often □ Sometimes □ Rarely □ Never □ Do not do □

importance of these additional activities to this population.

Although the NPI score presented some degree of construct validity, by being based on the results of previous individual's experiences, a formal assessment of the outcome's face validity would be appropriate. Further research to assess whether the questionnaire was optimally presented for people to accurately respond, whether the weighting of responses was considered appropriate and if the method of calculating the final scores and interpreting the results was appropriate is required. Only after this can the outcome measure be considered for widespread clinical adoption.

Criterion-related validity is the ability of an instrument to be effective in predicting a criterion or to be an indicator of a construct (Hulley et al, 2007). Criterion-related validity is subdivided into two types: concurrent validity which is the extent to which an instrument accurately estimates an individual's current state; and predictive validity which is the ability of a test to predict an individual's future outcome (John and Benet-Martinez, 2000). These can suggest whether a new outcome measurement can be used instead of an established reference test (Portney and Watkins, 2009). However, since no specific outcome measures have previously assessed this domain, the nearest reference test for the patellar instability population may be the dynamic MRI. Previous authors have suggested that patellar instability should be based on the assessment of the patella's dynamic functional control (Grelsamer, 2000; Donell, 2006; McConnell, 2007). Therefore only dynamic MRI assessment can effectively evaluate this construct (Draper et al, 2009; Powers et al, 1998; Powers et al, 2003). Further assessment to establish these key aspects of outcome validity is warranted.

Convergent validity assesses the degree to which two measurements, believed to reflect the same underlying phenomenon, yield similar results or correlate highly to one another (Hulley et al, 1997; Messick, 1995). Given the relative

paucity of assessment tools on patellar instability, convergent validity may be assessed in relation to overall knee function measured using a previously validated outcome such as the Kujala Patellofemoral Disorder Score (Kujala et al, 1993), lateral patellar displacement or through radiological measurements of anatomical features associated with patellar instability.

The mechanism of injury for a patellar dislocation is similar to an anterior cruciate ligament rupture (Grelsamer, 2000; Brukner and Khan, 2010). This was reiterated in the activity survey where respondents reported a greater association of instability symptoms on twisting and turning motions during sports (Chapter 11). With this similarity in mind, further discrimination of the NPI score, in individuals with tibiofemoral instability as a result of anterior cruciate ligament rupture should be conducted. This would determine how well the NPI score is able to differentiate between tibiofemoral and patellofemoral instability as part of discriminant validity (Portney and Watkins, 2009).

In addition to assessing a tool's validity, it is also important to assess its repeatability between people with similar characteristics (inter-rater reliability or test re-test) and data from the same person assessed over a number of times (intra-rater reliability; Bland, 2006). Responsiveness provides confidence that over time a change in NPI score would reflect a clinical change rather than measurement error. This would therefore be imperative before the tool could be adopted in widespread research and clinical practice.

An outcome measurement's responsiveness is its ability to detect a change when a change in a person's condition has occurred (Messick, 1995; John and Benet-Martinez, 2000). Questionnaires should be sensitive to detect a minimally important clinical difference (MICD) over time (Hays et al, 2005a). Knowledge regarding the MICD of a new measurement is essential to fully interpret its results (Hays et al, 2005a; Portney and Watkins, 2009). The MICD is also used to construct sample size power calculations (Bland, 2006). Future

study is therefore recommended to assess the responsiveness of the NPI score in FTPD cohorts following conservative and surgical interventions.

An instrument should possess high internal consistency (Portney and Watkins, 2009). This assesses the level of agreement between each item within the outcome measure. However perfect agreement between the items is considered inappropriate where the optimal degree of internal consistency is considered to be a Cronbach's alpha value of 0.7 to 0.9 (Zinbarg et al, 2006; Streiner and Norman, 2008). If perfect agreement was achieved each question would have assessed the same construct, unnecessarily gaining responses which have already been reported (Hulley et al, 2007; Hays et al, 2005b). By ensuring that some variation exists between items posed, the potential for ceiling and flooring effects can be limited (Portney and Watkins, 2009). This is important since ceiling and flooring effects would indicate insufficient variability in the activities posed, resulting in consistently high or consistently low scores (Messick, 1995). This would prevent the differentiation of symptoms within the target population limiting the usefulness of a measurement (Altman, 2009). With 19 different functional activities assessed, it would therefore be highly appropriate to assess the internal consistency of the NPI score.

Patellar dislocation has been reported in people from the age of 11 years upwards (Atkin et al, 2000; Fithian et al, 2004a). Responses were gained from this age group during the activity survey study (Chapter 11). The NPI score may therefore possess face validity in the paediatric population as well as adults. Bernston and Svensson (2001) and Ronen et al (2003) in their study of questionnaire outcome scores for paediatric populations acknowledged that children from the age of eight are able to complete Likert-response format outcome measurements with little difficulty. However further evaluation of the NPI score specifically with young people would be warranted given the typical epidemiology of FTPD and patellar instability (Atkin et al, 2000; Fithian et al, 2004a).

13.6 Summary

This chapter has described the construction of the NPI score. This new instrument requires further assessment before widespread clinical adoption is warranted for people following FTPD or recurrent instability symptoms. The first such assessment was part of the RCT presented in the following section.

Section Five

VMO vs. General Quadriceps following First-Time Patellar Dislocation: RCT

Chapter 14. Randomised Controlled Trial Methods

14.1 Introduction

The national survey demonstrated that strengthening exercises were a major component in the physiotherapy treatment of FTPD (Chapter 8, Section 8.5). Both the literature review and the national survey indicated that physiotherapists prescribe both general quadriceps and specific-VMO strengthening exercises to this population. The effectiveness (i.e. the change in the real world) or efficacy (i.e. the capability to produce an effect) of different physiotherapy interventions to treat people following FTPD is unknown (Chapter 5, Section 5.3). To begin to address this limitation a RCT was proposed to compare the clinical outcomes of these two exercises in a cohort who had experienced FTPD.

This chapter will outline and justify: the rationale for undertaking the study (Section 14.2), the study design (Section 14.3), its aims and objectives (Section 14.4), participant eligibility criteria (Section 14.5) and the sample size calculation (Section 14.6). Following this, the chapter will present the recruitment process (Section 14.7) the randomisation procedure (Section 14.8), the intervention (Section 14.9), the measurement outcomes used (Section 14.10), the follow-up periods (Section 14.11), the plan of analysis (Section 14.12) and finally the study's ethical issues (Section 14.13).

14.2 Rationale

The rationale for this trial was two-fold. Firstly quadriceps strengthening exercises are considered one of the principal physiotherapeutic treatments for people following FTPD (Mears and Cosgarea, 2001; Beasley and Vidal, 2004; Solomon et al, 2001; Aichroth, 1983; Howell, 2002). This was reiterated in the physiotherapy survey (Chapter 8, Section 8.5). Both the literature review and

the survey findings indicated that specific-VMO exercises can be used as an alternative to general quadriceps exercises (Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001; Chapter 8, Section 8.5). These exercises have gained acceptance based on an assumption that the VMO has a specific role in preventing excessive lateral patellar translation (Scudero and McCann, 2005; Solomon et al, 2001; Howell, 2002; McConnell, 2007). However debate remains over whether the VMO can be preferentially recruited (Post et al, 2003; King, 2000). The current evidence-base provided a limited indication that preferential VMO activation could be achieved through exercise (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997; Gregerson et al, 2006; Chapter 6, Section 6.9). However, no studies have assessed whether the VMO can be preferentially recruited in people following FTPD. Furthermore no studies have investigated whether this can impact on clinical outcomes in this population. It is therefore unclear whether physiotherapists should prescribe general quadriceps or specific-VMO strengthening exercises to these individuals. This single-blinded RCT was designed to answer this question.

Secondly, this clinical trial allowed the prospective examination of the NPI score by comparing it to other physiological and functional outcomes which have previously demonstrated validity and reliability in the FTPD population. Thus, the tool's convergent validity and internal consistency could be assessed (Aldridge and Levine, 2001; Buckingham and Saunders, 2004; Steiner and Norman, 2008). Furthermore the responsiveness of the NPI score could be evaluated by comparing the results collected during the trial's six month follow-up period.

14.3 Study Design

Randomised controlled trials are one type of experimental research design (Friedman et al, 1998). Modern RCTs can be traced to the work of R.A. Fisher

in the 1920s and 1930s who formalised the use of random allocation within agricultural research (Fisher, 1971). A RCT is an experiment where a cohort is randomly assigned to one of two or more interventions, whilst other interventional variables are controlled (Jadad and Enkin, 2007). The groups are assessed to observe for a difference in their outcome (Matthews, 2005; Piantadosi, 2005). These methods were developed since uncontrolled assessments are susceptible to bias, which can only be negated by the inclusion of contemporaneous control groups (Torgerson and Torgerson, 2008). Randomised controlled trials are therefore regarded as the 'gold-standard' for assessing treatment effectiveness (Portney and Watkins, 2009) and thus was adopted for this study.

A number of different RCT designs exist (Cleophas et al, 2009). This study adopted a pre-test post-test control group design. In this, one group is randomised to receive an experimental variable whilst the other acts as a control (Portney and Watkins, 2009). Both groups are tested prior to receiving their treatment (baseline measurements) and then assessed at subsequent time-points (Ho et al, 2008). The only difference between the groups should be the intervention which they receive. All other known variables are controlled. Any change detected between the groups from pre-test to post-test can thus be reasonably attributed to the study intervention (Portney and Watkins, 2009).

Randomised controlled trial approaches such as factorial design, where participants are randomised by various combinations of two or more variables under investigation, and nested designs, which assess treatment effect when there are variations in the interventions prescribed with the allocated groups, were considered. These were inappropriate since this study did not require the assessment of possible interactions between treatment effects by physiotherapists, but wished to evaluate the effectiveness of specific-VMO exercises compared to general quadriceps strengthening exercises. Two-way repeated measures or cross-over study designs were also inappropriate. These

rely on the ability of the participant to revert back to their baseline status during a washout period, thus treatment effect should therefore not carry-over onto a second experimental stage. This is a viable study design for some pharmacological studies where a wash-out period can be ensured (Delaney and Suissa, 2009). However the adoption of such an approach is not appropriate following muscle strengthening exercises as the return to baseline would require a period of atrophy, which would be unethical (Delaney and Suissa, 2009; Friedman et al, 1998).

This RCT adopted a superiority approach, justified since the research question sought to determine whether specific-VMO exercises were better than the established treatment of quadriceps strengthening exercises (Christensen, 2007; Gunsolley et al, 1998). The study did not aim to determine whether the two exercises had similar therapeutic properties. This would have suited an equivalence or inferiority trial design (Christensen, 2007; Gunsolley et al, 1998).

This was a pragmatic trial, as the study aimed to measure change which the intervention produced in routine clinical practice (Roland and Torgensen, 1998). Therefore the intervention, population, outcome measurements and trial procedures were expected to mirror clinical practice as closely as possible to be able to generalise the findings to practice (Hotopf, 2002; Roland and Torgensen, 1998). This was justified as the study sought to establish the effectiveness of specific-VMO exercises compared to general quadriceps exercises on patient-reported clinical outcomes in normal practice (Cook, 2009; Hotopf, 2002). This was essential to enhance generalisability and inform clinical work (Hotopf, 2002; Roland and Torgensen, 1998). This study did not aim to determine how or why the exercise programmes provided these outcomes. This would have suited an explanatory research design assessing the efficacy of the interventions (Cook, 2009; Hotopf et al, 1999; Jadad and Enkin, 2007). By adopting a pragmatic study design, fewer constraints were placed on

recruiting a very specific population or controlling other interventions provided (Roland and Torgensen, 1998; Friedman et al, 1998). Consequently it is more difficult to attribute the results of the trial to one treatment, in a specific population (Friedman et al, 1998; Hotopf et al, 1999). Nonetheless, the ability to obtain results which reflect normal clinical processes was more important in answering this research question.

14.4 Aims and Objectives

The aims of this study were to answer the following questions:

- Is there a difference in functional outcome between people prescribed a general quadriceps strengthening exercise programme compared to a specific-VMO strengthening programme following FTPD?

- Does the NPI score correlate to previously validated outcome measures used to evaluate people following FTPD?

- Is the NPI score responsive to change during the physiotherapy rehabilitation of people following FTPD?

14.5 Participants

Obtaining a representative sample to answer the research question is vital for the success of a RCT (Altman, 2009). To structure a sampling strategy, RCTs have adopted inclusion and exclusion criteria (Chow and Liu, 2004). Inclusion criteria permit the identification of participants which exhibit a sufficiently high rate of the study pathology to achieve adequate power to detect an important effect (Friedman et al, 1998). By narrowing the inclusion criteria, the ability to generalise results becomes limited (Friedman et al, 1998; Chow and Liu, 2004). Narrow inclusion criteria may also create recruitment difficulties (Cummings et

al, 2007). It has been recommended that exclusion criteria should be parsimonious as unnecessary exclusions can reduce generalisability (Cummings et al, 2007), which will result in an increase in the complexity and cost of recruitment (Cummings et al, 2007). Reasons to exclude someone from a trial include; when study treatment would be harmful with an unacceptable risk of an adverse event; the experimental treatment is unlikely to be effective due to a difference in a participant's pathology from the target population; the participant is unlikely to adhere to the intervention or complete the follow-up; or if practical difficulties are anticipated for some participants such as those with cognitive impairment who may find completing questionnaires, for example, difficult (Cummings et al, 2007). Since this study was a pragmatic clinical trial, the selection criteria chosen needed to reflect typical clinical practice (Cook, 2009; Roland and Torgensen, 1998). Therefore the criteria were sufficiently broad to ensure that a representative population was investigated. The following sections justify the eligibility criteria constructed for this trial.

14.5.1 Inclusion Criteria

The trial's inclusion criteria were: -

- **People aged 16 years or over referred to the out-patient physiotherapy departments at three hospitals in the East of England for physiotherapy following FTPD. Individuals needed to present with**:

(**a) a history of a single episode of patellar dislocation requiring reduction or having reported that their knee cap visibly "popped" out of joint, and**

(b) one of the following signs and symptoms of patellar instability: - (i) apprehension when a lateral-directed force was applied to the patella;

(ii) pain or tenderness along the medial retinaculum; (iii) abnormal patellar tracking or position e.g. lateralised, tilted, excursion such as J-sign, where the patella shifts laterally in terminal knee extension as it disengages from the femoral intertrochlear groove (Appendix 2).

The flexibility permitted in point (b) was appropriate given that there may be some natural differences in clinical presentation within the FTPD population (Woo and Busch, 1998; Mulford et al, 2007). The evidence remains limited regarding the reliability and validity of physical examination tests for people following FTPD (Sallay et al, 1996; Ando et al, 1993; Shakespeare and Fick, 2005; Smith et al, 2011b). However the three criteria used were justified four-fold. Firstly these tests have been the most widely adopted eligibility criteria in previous FTPD trials (Mäenpää et al, 1997; Mäenpää and Lehto, 1997b; Arendt et al, 2002), thus will facilitate a comparison to previous literature. Secondly a positive Apprehension test is the most frequently cited test within the literature for the diagnosis of patellar dislocation and in common usage in UK acute hospital physiotherapy departments (Chapter 8, Section 8.4). Its use in the trial represents normal clinical practice, conforming to the RCT's pragmatic nature. Thirdly pain or tenderness along the medial retinaculum (Bassett's sign) has demonstrated a sensitivity of 70% in people following patellar dislocation, providing some support for its inclusion on diagnostic accuracy (Sallay et al, 1996). Finally, although diagnostic accuracy has yet to be determined with this population, abnormal patellar tracking has been regarded as an important signs of patellar dislocation in textbooks and review articles (Petty and Moore, 2009; Magee, 2008; Brukner and Kahn, 2010; Malanga et al, 2003; Scudero and McCann, 2005).

Differentiating between individuals who experienced a FTPD compared to those following recurrent dislocations was based on two theoretical factors: Firstly people who experience recurrent patellar dislocations more frequently present with anatomical differences compared to those who experience a single

patellar dislocation (Mäenpää et al, 1997; Mäenpää and Lehto, 1997b; Dejour et al, 1994). Such differences can include trochlear dysplasia, a hypoplastic vastus medialis and patellar alta (Fucentese et al, 2007; Fulkerson, 1997; Bollier and Fulkerson, 2011; Singerman et al, 1994; Chapter 3, Section 3.4). Since the anatomy of people who experience recurrent patellar dislocation can predispose patellar instability, the treatment goals and prognosis are inherently different for these two groups (Beasley and Vidial, 2004; Mäenpää et al, 1997), thus they should be excluded.

Secondly anecdotally individuals who experience recurrent patellar dislocations are frequently referred to physiotherapy on numerous occasions, potentially over many years. Thus attitudes to physiotherapy may differ between those who have experienced a single patellar dislocation compared to recurrent events. This could be a confounding variable (Smith et al, 2010; Ogden, 2000) and has therefore been controlled in this trial.

Individuals with a history of PFPS, instability or subluxation in addition to an episode of frank dislocation were eligible. This was important to satisfy the pragmatic nature of this study by not being overly restrictive (Roland and Torgensen, 1998). However, individuals who had not experienced a patellar dislocation, but presented with PFPS or generalised patellar instability were excluded. This was considered essential as, although the PFPS population may report mild instability symptoms, their overriding symptom is pain (Donell, 2006). Accordingly people with PFPS were inappropriate for this trial which principally assessed instability.

The majority of patellae typically self-reduce following dislocation (Mäenpää et al, 1997), thus it was inappropriate to solely base diagnosis on radiological evidence of a dislocated patella. Furthermore no studies have evaluated whether the timing or method of reduction is a prognostic indicator for this population.

It was therefore inappropriate to exclude this subgroup from this pragmatic clinical trial.

Radiological investigations were not part of the eligibility criteria since plain radiographs of patellar dislocation and instability have a varying degree of reliability and validity between their measurements (Smith et al, 2011a). Whilst CT and MRI have demonstrated greater reliability than x-rays (Toms et al, 2009; Smith et al, 2011a), these investigations were not routinely conducted for individuals following FTPD in the participating hospitals. Since it is not typically performed in the clinical setting, the requirement of a positive MRI finding to warrant eligibility would not have adhered to the pragmatic nature of this trial (Hotopf et al 1999; Roland and Torgensen, 1998).

Patients younger than 16 years were excluded as the treatment approaches adopted by paediatric physiotherapists may differ to those of physiotherapists who treat adults (Crombie, 2007). Paediatric treatments often involved sports, games and play-therapy (Hartley, 2007). Whilst adult rehabilitation may also adopt some of these principles, adults receive more focused, specific exercise interventions (Hartley, 2007). The exercises, particularly those in the specific-VMO programme, may have been difficult for some children to understand and perform, since they required specific instructions on limb orientation. Therefore by including a paediatric population, the interpretation of the exercises may have been a major confounding variable.

People were excluded from the trial if they had undergone surgical treatment following a FTPD. Surgical intervention following patellar dislocation can provide different outcomes to conservative management (Smith et al, 2011c). Thus by removing this potential confounding variable, a difference between the groups could be attributed to the exercise treatments and not the surgical procedure undertaken.

Finally this study was multi-centred. The physiotherapy departments of five hospitals in the East of England were audited over a three-month period (January 2008 to April 2008) to assess the referral rates of people following FTPD. These ranged from none to 14 patients per month (Appendix 5). Given these small numbers, a multi-centre study design was most appropriate to ensure that the trial could be conducted within a reasonable timescale. Furthermore by being multi-centred, greater generalisations could be constructed from the results since the findings were based on three different hospital populations rather than one geographical population (Friedman et al, 1998).

- **Provide informed written consent.**

This is essential to ensure that before enrolling, individuals are fully informed about the aims, objectives and procedures in a study, plus plans for future dissemination of the results. This is in accordance with the Declaration of Helsinki (World Medical Association, 2000) and conforms to UK ethical standards (National Research Ethics Service, 2011).

14.5.2 Exclusion Criteria

The trial's exclusion criteria were: -

- **A history of two or more patellar dislocations on the knee which was referred to physiotherapy. This was to be either self-reported or documented in the medical notes and could have been experienced at anytime during a participant's lifetime.**

The justification for assessing FTPD rather than recurrent patellar dislocation has been previously stated (Chapter 10; Section 10.5.1).

- **People to be/or are immobilised for longer than four weeks from injury to their first physiotherapy appointment.**

People immobilised for longer than four weeks post-FTPD were excluded as prolonged immobilisation following injury can cause muscle atrophy, soft-tissue shortening and degrade cartilage nutrition (Shea et al, 2006). By limiting the period of immobilisation to less than four weeks, this source of intra-sample variation could be negated. Due to its potential detrimental impact on outcomes (Akeson et al, 1987; Booth, 1987; Kannus et al, 1992), this variable was controlled rather than ignored (Roland and Torgensen, 1998). However respecting this pragmatic design, the actual period of immobilisation between the limits of zero to four weeks was not controlled.

- **Meniscal, anterior cruciate ligament, posterior cruciate ligament, lateral collateral ligament or medial collateral ligament injury on the knee referred to physiotherapy, determined by a negative Lachman test, anterior and posterior draw, valgus and varus stress tests, and absence of tibiofemoral joint line tenderness.**

Individuals who experience a patellar dislocation may report general knee instability. The mechanism of injury associated with a patellar dislocation is considered similar to an anterior cruciate ligament injury (Grelsamer, 2000; Brukner and Khan, 2010). Accordingly, it was important to differentiate and exclude individuals with an anterior cruciate ligament or other soft-tissue injury compared to FTPD.

- **Gross osteoarthritic changes of the patellofemoral joint (Kellgren and Lawrence (1957) grade three or above) detected on plain x-ray.**

People with gross osteoarthritic changes were excluded as this population would be atypical for FTPD (Atkin et al, 2000; Fithian et al, 2004a). The prognosis and expectation of functional outcomes for FTPD may differ due to the degenerative nature of osteoarthritis (Hepinstall et al, 2011; Atkin et al, 2000; Fithian et al, 2004a). The potential for an atypical response in this subgroup therefore justified their exclusion.

14.6 Power Calculation

The power of a study is considered as the probability that a study of a given size could detect a difference of a given magnitude given that it exists (Altman, 2009). Studies which are insufficiently powered are unlikely to detect a clinically worthwhile difference between study interventions if a difference exists (Piantadosi, 2005; Altman, 2009). The greater the power, the larger the sample required provided that all other variables are held constant (Piantadosi, 2005). This therefore has cost and logistical consequences when conducting research.

The power calculation is based on the primary outcome adopted and the statistical model assumed (Altman, 2009). Since this study's primary outcome measure was a continuous outcome (Lysholm Knee Score), a sample size calculation was conducted for a normally distributed continuous dataset using the equation:

$$Std\ Diff = \frac{\Delta}{\sigma}$$

Where the:

Std Diff – is the standardised difference.

Δ – is the smallest clinically relevant difference between the two treatments. This has been considered as an arbitory value which may be difficult to define (Altman, 2009).

σ - is the standard deviation (SD) of the variable (in each group). This can be obtained from the variance in values for a given population under assessment taken from previous studies assessing the outcome of interest for this population, or by preliminary pilot or feasibility studies to specifically determine variance.

From this, a nomogram from Altman (2009) was used after considering α and $1-\beta$ values.

α – is the significance level which is an arbitrary value used to attribute the probability of the result being a chance finding. If a high level of significance is set, there is a greater chance that a difference will be seen between the interventions when this was actually due to chance. This is termed a type I statistical error (Bland, 2006; Simon, 2006).

$1-\beta$ – is the power of the probability that a given difference in means in a test will lead to a rejection of the null hypothesis (Portney and Watkins, 2009). A power figure has been arbitrarily recommended as 80% or higher (Altman, 2009). Therefore the chance of not identifying a difference between the groups under investigation, when such a difference exists, is 20% or lower. When the null hypothesis is not rejected when a real difference exists, then this probability of failing to reject a false null hypothesis is regarded as a type II statistical error (Portney and Watkins, 2009; Simon, 2006).

This study's power calculation was based on:-

- A difference of 15 points in the Lysholm Knee Score which is estimated to be clinically significant between individuals with or without patellar instability (Harilainen and Sandelin, 1993).
- A standard deviation of the Lysholm Knee Score after FTPD being 14 (Paxton et al, 2003).
- Power at 0.90 with a chosen five percent significance level.

Using the nomogram and this calculation, a sample size of 36 was required. The estimated sample size was increased by 40%. This was based on two factors. Firstly data which is not symmetrical requiring non-parametric analysis has lower power, particularly for studies with inherently lower sample sizes (Freidlin and Gastwirth, 2000). The sample size was therefore increased by 20% to compensate for this non-normally distributed dataset. Secondly to compensate for estimated potential dropout, the sample was again adjusted by 20%. This was justified since the literature has indicated that participant attrition in studies assessing the conservative management of patellar dislocation has varied from zero percent (Mäenpää et al, 2000; Camanho et al, 2009; Nikku et al, 1997; Nikku et al, 2005; Cash and Hughston, 1988; Savarese and Lunghi, 1990; Atkin et al, 2000; Hawkins et al, 1986; Mäenpää and Lehto, 1997a; Kiviluoto et al, 1986; Mäenpää et al, 1997) to 37% (Mäenpää and Lehto, 1997b). By adjusting for this, if participant drop-out occurs, the study would remain sufficiently powerful to detect a difference in outcomes. Following these adjustments, 50 people were required in total, 25 in each group.

This sample size was also practical within the study timescales which are presented in Appendix 28.

14.7 Recruitment

The recruitment process is summarised in a flow diagram in Appendix 30. Potential participants were initially approached via a letter. The covering letter (Appendix 31) and the patient information leaflet (Appendix 32) were included with the participating department's routine appointment letter. This provided information about the study and informed potential participants to expect a telephone call from the researcher who would answer any questions regarding the trial. This was included so that potential participants were not "cold" called. The participating physiotherapy department arranged the initial appointment in order to review an individual within four weeks from their injury. This time frame ensured that each patient was not immobilised for longer than four weeks to satisfy the eligibility criteria (Section 14.5.2).

A senior physiotherapist in each department notified the researcher of all FTPD referrals. They provided each potential participant's name and telephone number. Recruitment was conducted by the researcher since they could therefore provide the most comprehensive explanation of study's processes to potential participants. This was important to ensure that participants were fully informed about the study before deciding whether or not to enrol.

One week after the appointment letter was sent, the researcher contacted the individual by telephone. They explained the study design, objectives, procedures and application of results. Potential participants were provided with an opportunity to ask questions and were encouraged to read through the information leaflet (Appendix 32) before attending their first appointment. Participants therefore had a minimum of seven days to consult and discuss the information with their friends and family. This was important given that some individuals may have been anxious after their injury and may require this time to consider their participation (Hemsley et al, 2010). Furthermore it was

expected that a proportion of the cohort would be aged between 16 to 18 years. These people may have required time to discuss their potential participation with a parent/guardian or with family members. By providing a number of days, the individual had more time to pose any questions to these people or the researcher. Through these strategies, it was hoped that each individual could make a more informed decision on their enrolment.

During the first physiotherapy appointment at each participating hospital, each potential participant was assessed by a physiotherapist using their routine musculoskeletal assessment. A specific physiotherapy assessment procedure was not enforced in keeping with the pragmatic nature of this study. The physiotherapists were advised to pay particular attention to the study's eligibility criteria. If these were satisfied, the physiotherapist asked the individual whether they wished to enrol on the study. Those who agreed were asked to complete a consent form (Appendix 33). One copy of the consent form was provided to the individual, one was sent to the researcher, and one copy was included in the individual's medical notes. For individuals who did not wish to participate, usual rehabilitation determined by their treating physiotherapist was continued.

Recruitment was monitored by the researcher. Each department was asked to record all FTPD referrals. The researcher contacted each department every three weeks to ensure that this data was being collected. Thus all potentially eligible participants were recorded to monitor for selection bias.

14.8 Randomisation

Allocation to groups was based on randomisation to prevent allocation bias (Chow and Lui, 2004; Simon, 2006; Cummings et al, 2007). Literature suggests that characteristics such as age, gender and other demographics which could confound an observed association should be equally distributed if chance

variation does not occur (Cummings et al, 2007). Effective randomisation should ensure parity between the groups at the start of the study (Friedman et al, 1998). If equality exists, it is assumed that participants in either group have an equal chance of experiencing unexpected events such as a concomitant illness or injury during the course of the study. Between-group differences should therefore 'balance-out' during the trial (Portney and Watkins, 2009). Consequentially a treatment effect, if one exists, should manifest between the groups.

14.8.1 Methods of Randomisation

After completing the consent form, the participating physiotherapist telephoned the researcher. The researcher used opaque numbered sealed envelopes, assigned the individual to a coded number and allocated them to receive either a general quadriceps exercise regime and rehabilitation (Appendix 34) (the control group) or a specific-VMO exercise regime and rehabilitation (Appendix 35) (the experimental group). Envelopes were numbered so all could be accounted for at the end of the trial. Sealed and opaque envelopes were used so that trans-illumination through strong light could not occur. This prevented the researcher from identifying the group allocation before opening the envelope to minimising allocation bias (Cummings et al, 2007). This is important since investigators may be pressurised into influencing the randomisation process, particularly when an individual may appear particularly suitable for one treatment over another (Cummings et al, 2007; Chow and Lui, 2004). Randomisation was performed away from the clinical site, with the individual's clinical presentation and history unknown to the researcher. This information could therefore not bias the researcher whilst allocating participants.

Restricted randomisation was employed to ensure an equal number of participants were allocated to the two groups. Whilst Hewitt and Torgerson (2006) acknowledged that restricted randomisation may increase the risk of

subversion (conscious or unconscious) related to situations where allocation sequences are public knowledge or inadequate allocation concealment, this can prevented one group from being under-powered to answer the research question (Bland, 2006). Permuted block randomisation was not chosen since this method permits the prediction of subsequent allocations if a researcher became aware of the sequence and block size (Altman, 2009; Bland, 2006).

The randomisation process was stratified by site. Stratified randomisation was chosen over simple randomisation to ensure that each site had an equal chance of providing both interventions to their cohorts. With a small sample size, one site could solely provide one type of intervention. In such a case, the hospital provider may have become a confounding variable on outcome.

No individuals presented with bilateral FTPD. If this had occurred, only one knee would have been assessed in the trial. The side chosen would have been determined by the individual as the most functionally limiting. This criterion was required since as patient-reported outcomes of functional ability were being assessed, it was not be possible to differentiate between the outcomes of one limb to another.

14.9 Interventions

The participant's treating physiotherapist directed their rehabilitation in accordance with the guidelines specified in each treatment programme. The individual rehabilitation programmes are detailed in Appendix 37. These programmes were based on textbook and literature evidence and aimed at the reduction of pain, swelling, stiffness and increasing knee range of movement and strength post-FTPD (Howell, 2002; Burks, 1992; Post et al, 2003).

The specific-VMO exercises were identified through the literature which has investigated the preferential recruitment of the VMO as assessed by EMG in

populations with other knee pathologies (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006). As Chapter 6 (Section 6.9) summarised, these were the only exercises which have demonstrated an ability to preferentially recruit the VMO. Whilst no studies have assessed the preferential recruitment of VMO in those following FTPD, Chapter 6's findings provided the best indication of specific-VMO exercises for this study intervention. Their adoption was therefore justified in this study.

Immediately after randomisation, each individual was shown either their specific-VMO exercises or general quadriceps exercises and were instructed to commence these. Each was asked to record their exercise activity using an Exercise Diary (Appendix 36). The frequency and duration of physiotherapy sessions were decided by the treating physiotherapist. The individual's treating physiotherapist progressed their treatment as they felt appropriate.

The participating physiotherapy departments were involved in the development of the two treatment programmes. This was undertaken to increase the physiotherapist's confidence and compliance with the protocol. It also aimed to define a treatment programme which reflected current physiotherapy practice to enhance the study's external validity whilst maintaining its pragmatic nature (Piantadosi, 2005). As Appendix 34 and Appendix 35 demonstrate, in addition to the study interventions, physiotherapists were permitted to use treatments listed in the general rehabilitation programme. Each physiotherapist was asked to list which interventions were performed to determine whether there was any substantial difference in the rehabilitation programmes received by each group in addition to their allocated intervention (Appendix 37). An indication of which treatments should be listed in this check-list was gained through the retrospective notes audit from 20 previous patients who had sought treatment following FTPD (Appendix 38). Detailing these additional treatments was important as their use may have confounded the exercise interventions.

The hospital care between the point of injury to first physiotherapy appointment was standardised. The standard treatment for individuals following a FTPD in each hospital was a period of immobilisation in an extension splint followed by physiotherapy. This was not changed in this trial. However in accordance with the pragmatic nature of this study, the specific period of immobilisation was not controlled, as participants could be immobilised from one day to four weeks dependent on the referring consultant orthopaedic surgeon's recommendations thereby merely reflecting clinical practice (Altman, 2009).

It was the clinical decision of the treating physiotherapist as to when a participant was discharged from their care, reflected the pragmatic study design. Each individual was asked to record how often they continued their exercises post-discharge using the Exercise Diary at the final six-month assessment.

14.10 Measurement Tools

The primary outcome measure was:

- The Lysholm Knee Score (Appendix 39; Lysholm and Gillquist, 1982).

Secondary outcomes were:

- The SF-12 Health Survey (Appendix 40; Ware et al, 1996).
- The NPI questionnaire (Figure 13.1).
- The Tegner Level of Activity Score (Appendix 41; Tegner and Lysholm, 1985).
- Isometric knee extensor muscle strength at zero, 30°, 60° and 90° knee flexion, assessed using a hand-held dynamometer (Basic Force Gauge, Mecmesin, Slinfold, West Sussex, UK).

- Frequency of recurrent patellar dislocation, assessed by the frequency of patellar dislocations and number of dislocations requiring accident and emergency or healthcare management.
- The duration and frequency of out-patient physiotherapy treatment.
- Exercise compliance recorded using an Exercise Diary (Appendix 36).
- The number of complications or adverse events. This included the number of hospitalisations for recurrent patellar dislocation, hospitalisation for injury due to another reason, physical discomfort of other musculoskeletal regions during the intervention period until discharge from physiotherapy.

Whilst the first outcomes are assessments of treatment effectiveness, the latter three outcomes are assessments of intervention acceptability. This was considered important given that this study was the first trial assessing specific-VMO exercises and quadriceps strengthening programmes in this population. Therefore assessment of treatment acceptability was important since these may have related to outcome.

Patient-reported outcome measurements were used for three reasons. Firstly respecting the pragmatic nature of the trial, more patient-centred, quality of life measurements were indicated over objective, physiological measurements (Cook, 2009; Roland and Torgensen, 1998). Whilst such objective measurements may provide greater information on how the intervention worked, these would capture less information on the impact of interventions on the individual which this pragmatic trial aimed to assess (Torgerson and Roland, 1998; Piantadosi, 2005). Secondly the Lysholm Knee Score, SF-12 and Tegner Level of Activity score have all demonstrated good reliability and validity for the FTPD population, justifying their adoption (Paxton et al, 2003; Kiely et al, 2006). Thirdly Paxton et al's (2003) paper, the only study to assess the validity or reliability of outcome measurement in a FTPD cohort,

recommended that three different instruments should be used to assess outcomes: a knee-specific, an activity-level, and a general health measurement. The three tools selected in this RCT adhere to this recommendation and assess each of these domains to comprehensively evaluate clinical outcomes.

Other knee-specific scoring systems such as the Kujala Patellofemoral Disorder Score (Kujala et al, 1993) could have been adopted. However the Lysholm Knee Score was selected through its greater ability to discriminate between those with recurrent dislocation events and milder subluxation (Paxton et al, 2003).

Isometric knee extension strength was assessed using a hand-held dynamometer. This was used since the study interventions were strengthening programmes. Therefore a measurement to assess this specific domain was important. Secondly this outcome has previously demonstrated as being reliable and valid in the assessment of knee extension strength (Bohannon, 2001; Hayes and Falconer, 1992; Surburg et al, 1992; Bohannon, 1990). Isometric muscle strength was assessed at zero, 30°, 60° and 90° knee flexion. These increments were chosen to provide an indication of quadriceps strength at inner, mid- and outer-knee flexion ranges. Furthermore assessing a difference between the groups at 60° knee flexion was important as Tang et al (2001) and Basmajian et al (1971) reported that the VMO presents its greatest activity at this knee flexion angulation compared to the other vastii muscle. Therefore if a preferential VMO recruitment programme was effective in increasing VMO strength, it may be most obviously seen at this angle. The 30° measurement also had considerable importance as this angle has been cited as the position when the patella is most likely to dislocate (Colvin and West, 2008; Appendix 3). Assessing isometric knee extension in this range therefore evaluated the muscle's capabilities in this hypothetical 'at risk' position.

All muscle strength assessments were made with the participant's arms positioned across their body, seated on the edge of an elevated plinth, feet raised above the ground. Each was given verbal encouragement to push as hard as possible through the dynamometer. This formalised position was stipulated so participants were unable to gain leverage from their upper limbs or contralateral leg. This standardisation also aimed to reduce inter- and intra-rater variations in measurement technique and minimise measurement error.

The NPI questionnaire has been developed as the first self-administered questionnaire to assess perceived patellar instability (Chapter 13). This was therefore used to determine the intervention's abilities to affect an individual's perceived instability symptoms.

The number and the duration of physiotherapy treatments were recorded. This provided information on whether there was a substantial difference between the groups for this uncontrolled variable. This was important as it is unclear whether treatment intensity can influence outcomes. Exercise compliance was also evaluated using the participant-completed Exercise Diary (Appendix 36). Since exercise is a patient-centred treatment requiring the individual's active participation, the frequency of exercise was assessed to determine whether this could be attributed to any between-group variation in outcomes. Furthermore, if a difference was apparent, this may be attributed to the greater compliance of one exercise programme over another.

Finally the rate of complication was recorded. Complications may have included the number of hospitalisations for recurrent patellar dislocation or other injury, or physical discomfort from other musculoskeletal regions during the follow-up period.

All measurements were made by nominated physiotherapists in each participating centre. All assessors were blinded to participant allocation. This

was maintained to prevent ascertainment or assessor bias where one treatment arm may have been measured differently due to their allocation (Matthews, 2005; Piantadosi, 2005). It was not possible to blind clinicians to the treatment allocation. Knowledge of participant allocation was essential for the treating clinician to deliver the correct exercise programmes. Accordingly co-interventional bias may have been evident where a clinician could provide extra attention or a different level of treatment to participants (Cummings et al, 2007). To evaluate this, the frequency of treatments and sessions provided was assessed to determine if a differed occurred between the groups. Blinding of participants was not attempted. Individuals were made aware from the patient information leaflet (Appendix 32) that specific-VMO exercises were quadriceps exercises performed in different leg positions. From this, they could easily identify which group they had been allocated to. Secondly respecting pragmatic study principles, the study aimed to determine whether individuals derived benefit from their interventions (Cleophas et al, 2009). Therefore blinding them to group allocation would have been inappropriate since their attitudes and expectations towards their allocated treatment may have contributed to clinical outcomes.

Baseline measurements were collected by an assessor prior to randomisation. The same assessor collected all data for that participant throughout the study to maintain consistency. The assessors were not permitted to treat the same participant they assessed to maintain blinding. Each assessor was taught the assessment procedure by the researcher. This was conducted to standardise assessment methods between the blinded assessors from each centre. Additionally prior to recruitment, an assessment of one person's (volunteer physiotherapist from each centre) isometric muscle strength was made by the researcher and each nominated assessor for each study centre. This was performed to assess the intra- and inter-rater reliability of the isometric muscle testing procedure. The volunteer was assessed against the researcher to compare each isometric extensor muscle strength test on two occasions, 20 minutes

between each assessment. If this demonstrated poor intra- or inter-rater reliability (intra-class correlation coefficient results of 0.2 or less), the assessment methods were re-taught to improve data collection reliability.

The results of the intra- and inter-rater reliability scores are presented in Table 14.1 and Table 14.2, whilst the raw data is presented in Appendix 42. Based on Landis and Koch's (1977) categorisation, this overall indicated acceptable intra-rater reliability with moderate to very good agreement between the first and second assessments made. The agreement was very good between the two assessments from Centre One's assessor (ICC: 0.97; 95% CI: 0.64, 1.00). Intra-rater agreement was moderate to very good for each of the four assessors at Centre Two (ICC: 0.56-0.90). In Centre Three intra-rater agreement was moderate between the first and second assessments for the two assessors (ICC: 0.45-0.62).

Table 14.1. Table presenting the intra-class coefficient values from the evaluation of intra-rater reliability for the assessment of quadriceps extension strength.

Centre Number	Tester	ICC	95% CI
1	Assessor 1	0.97	0.64, 1.00
2	Assessor 1	0.56	-0.63, 0.96
	Assessor 2	0.79	-0.30, 0.99
	Assessor 3	0.90	0.10, 0.99
	Assessor 4	0.90	0.12, 0.99
3	Assessor 1	0.45	-0.71, 0.95
	Assessor 2	0.62	-0.57, 0.97

CI - confidence interval; ICC – Intra-class correlation coefficient

There was greater variation in respect to the inter-rater reliability findings. There was very good agreement between Centre One's assessor and the researcher (ICC: 0.88, 95% CI: -0.01, 0.99), and moderate agreement between the researcher and Centre Three's assessors (ICC: 0.58, 0.58). However, there was poorer inter-rater reliability for Centre Two's assessors. In this centre,

whilst Assessor One and Assessor Three reported substantial agreement to the researcher (ICC: 0.66, 0.61 respectively), Assessor Two and Four demonstrated poor agreement (ICC: <0.01). Given this poorer reliability, the measurement methods were re-instructed to these assessors in order to improve the standardisation of isometric muscle testing. Although the re-assessment of reliability was not formally assessed, Assessors Two and Four underwent further training until they and the researcher were satisfied that their measurement technique followed the standardised method.

Table 14.2. Table presenting the intra-class coefficient values from the evaluation of inter-rater reliability for the assessment of quadriceps extension strength.

Centre Number	Tester vs. Researcher	ICC	95% CI
1	Assessor 1	0.88	-0.01, 0.99
2	Assessor 1	0.66	-0.53, 0.97
	Assessor 2	<0.00	-0.91, 0.82
	Assessor 3	0.61	-0.58, 0.97
	Assessor 4	<0.00	-0.91, 0.83
3	Assessor 1	0.58	-0.61, 0.97
	Assessor 2	0.58	-0.61, 0.97

< - less than; CI - confidence interval; ICC – Intra-class correlation coefficient

14.11 Follow-up Periods

The two groups were evaluated at baseline (pre-randomisation), and then at six weeks and six months from commencement of their rehabilitation programme. This facilitated the collection of longer-term data whilst providing a reasonable duration between assessments to observe for a potential change in functional outcomes. A retrospective notes audit was performed in one participating hospital prior to commencing the study. This indicated that patients were reviewed for an average of eight weeks (range one to 28 weeks; Appendix 38). Accordingly a 28 week (six month) follow-up period from commencing rehabilitation in this study was deemed appropriate to provide sufficient time to

evaluate the functional outcomes of all participants after their physiotherapy discharge. These time-points were also chosen to avoid unnecessary inconvenience for individuals with too frequent re-assessment.

14.11.1 Baseline Measurements

Baseline data: gender; age; duration of knee instability; other joint disability of the symptomatic leg; contralateral patellar instability; disability of the contralateral leg; Beighton hypermobility score (Appendix 43) and isometric extensor muscle strength at zero, 30°, 60° and 90° knee flexion using the hand-held dynamometer were collected. Participants completed a Tegner Level of Activity questionnaire, a Lysholm Knee Score, SF-12, and a NPI questionnaire. Each was asked if there was a family history of patellar dislocation. These data were recorded on an individual data sheet (Appendix 44).

14.11.2 Six Week Assessment

Six weeks after commencing their physiotherapy rehabilitation, each individual completed a Lysholm Knee Score questionnaire, Tegner Level of Activity Score, SF-12, and a NPI questionnaire. Isometric knee extension strength was assessed in the same manner as baseline. Each participant's Exercise Diary was also collected. The individual was asked whether their patella had dislocated, and if so, when and how many times over the past six weeks. The number of 'did not attend' appointments and duration and frequency of physiotherapy appointments were recorded. A record was also made of any other complications which may have arisen during this initial rehabilitation period.

14.11.3 Six Month Assessment

The same assessment was performed six months after commencing the rehabilitation programme. Each Exercise Diary was collected and the

individual's medical notes were reviewed to determine whether they had attended the Accident and Emergency Department due to patellar dislocation and when they had been discharged from physiotherapy. The number of 'did not attend' appointments and duration and frequency of physiotherapy appointments were recorded.

All assessments were performed before the individual's physiotherapy appointment in the out-patient physiotherapy department of each participating hospital. Once an individual had completed their final assessment, all data sheets and Exercise Diaries were returned to the researcher for analysis.

14.12 Plan of the Analysis

14.12.1 Intentions to Treat and Per-Protocol Analysis

An intention-to-treat analysis method was adopted to minimise the risk of introducing subjectivity and analysis bias (Bland, 2006). This analysis ensures that participants are analysed by the intervention they were randomised to as opposed to the intervention which they actually received. Thus intention-to-treat analysis prevents the effects of crossover of participants between groups following randomisation. Consequently this limits the chance of a false positive result, enhancing the rigour of the analysis (Bland, 2006). Furthermore in light of the pragmatic study design, this approach reflects clinical practice where different treatments may be introduced at different stages within a patient's rehabilitation (Roland and Torgerson, 1998). Therefore this analysis method further enhanced the external validity of the trial (Cleophas et al, 2009).

A complete- or per-protocol analysis strategy, where individuals are analysed on the treatment they were assigned to at randomisation, was not performed (Shah, 2011). This was appropriate since the study sought to assess the effect of making the specific-VMO treatment available rather than necessarily receiving

the treatment. A per-protocol analysis would have been more applicable if the aims of this study were to determine how the exercises worked, or the safety of the exercises, since this would have analysed the actually treatment which individuals received.

14.12.2 Statistical Analysis

The formal *a priori* analysis plan is presented as Appendix 45. Statistical analysis of data has been broadly subdivided into two types (Dietrich and Kearns, 1986):

Descriptive statistics summarise or describe data. It is considered the simplest form of statistical analysis involving the collation and summary of data (Hulley et al, 2007).

Inferential statistics interpret data to make estimates, hypothesis testing, predictions or decisions from the study sample to a larger population (Chow and Lui, 2009; Hulley et al, 2007; Simon, 2006).

14.12.2.1 Descriptive Statistics

Baseline differences were assessed between the groups for demographic and clinical outcomes such as: age, duration of knee instability, other joint disability of the treatment leg, contralateral knee instability or disability, multi-joint problems, pre-rehabilitation isometric extensor muscle strength, hypermobility score, Tegner Level of Activity score, Lysholm Knee Score, SF-12 and NPI scores. This was performed by tabulating the data and comparing the two intervention groups in respect to their mean and standard deviation (SD) or median and inter-quartile range (IQR) data to provide an indication of central tendency and variance (Armitage et al, 2002; Portney and Watkins, 2009).

Mean and SD values for isometric extensor muscle strength, hypermobility score, Tegner Level of Activity score, Lysholm Knee Score, SF-12 and NPI scores were recorded at each follow-up period. The frequency of participant accruals to the trial was presented as a line graph per centre. The proportion of participants lost to follow-up was calculated as a percentage. The stratification of participants randomised to each group per centre was presented as a bar chart.

14.12.2.2 Inferential Statistics

Histograms and the Shapiro Wilk W test were used to confirm that the dataset was normally distributed at each time point for the primary and secondary outcome measurements. Accordingly parametric tests were the most appropriate inferential tests.

- *Baseline Measurements*

The difference between the two groups at baseline was assessed using the mean and SD values for all continuous outcomes such as age, duration of knee symptoms, isometric extensor muscle strength, hypermobility score, Tegner Level of Activity score, Lysholm Knee Score, SF-12 and NPI scores. All categorical data were analysed by their frequency of the event. This was used to compare the two groups in respect to other joint disability of the treatment leg, contralateral knee instability, disability of the contralateral leg and multi-joint problems.

Inferential analyses were adjusted for covariates. This was justified since the two reasons for adjusting analyses are to reduce the effect: of bias from differences in baseline; and when the covariate may correlate with outcome (Rochon, 1999). The RCT stratified its allocation by treatment centre. The site in which treatment was provided was considered a sufficiently important

variable to warrant stratification (Chapter 14, Section 14.8.1). Given this, all normally distributed outcomes were analysed with the adjustment by site. Those outcomes which presented with non-normally distributed datasets were not adjusted since it is not appropriate to adjust analyses for non-normally distributed datasets (Bland, 2006). All adjusted analyses were conducted using regression analyses as the Student T-test is not capable for assessing between group-differences with the adjustment of covariates (Bland, 2006).

A second adjusted analysis was conducted for baseline covariates. The baseline data indicated a baseline difference in Lysholm Knee Score. This difference was larger than the estimated clinically meaningful difference of 15 points (Harilainen and Sandelin, 1993). Furthermore, there was a difference of 11 days between the groups in the duration from injury to commencing physiotherapy. Therefore, if these were not adjusted for, the analyses may have been influenced by a bias in group imbalance.

- *Primary Analysis*

The primary analysis was an assessment of the Lysholm Knee Scores between the groups at six weeks using a regression analysis. The six week primary end-point was justified since the early results of clinical outcomes and function around the time of typical physiotherapy discharge were important.

The six week end-point was designed to determine whether there was a difference in outcome when these individuals were typically discharged from a hospital service. This six week period was defined as the threshold for participant discharge based from the retrospective notes survey of previous patients following FTPD from one of the participating sites (Appendix 38).

- *Secondary Analyses*

The difference in Lysholm Knee Score, Tegner Level of Activity score, SF-12 and NPI score results between the groups at six weeks and six months for these outcomes was performed using regression analyses.

The difference in isometric knee extensor strength between the groups at six weeks and six months was made using the regression analysis. A Spearman's Rank Correlation was performed to assess whether there was a correlation between exercise compliance and Tegner Level of Activity score, Lysholm Knee Score, NPI score, SF-12, isometric strength and rate of recurrent dislocation and duration between initial and second dislocation for each group. Similarly a within-group Spearman's Rank Correlation was undertaken to observe whether there was a relationship between the Tegner Level of Activity score, Lysholm Knee Score, or SF-12 and isometric knee extension results with the NPI score findings at each follow-up period for each group.

A Fisher's Exact Test was performed to assess whether there was a difference between the groups in the interventions prescribed to participants in addition to their allocated strengthening exercise. To determine whether there was a difference in treatment effect between the three study centres, an analysis of between-group differences was performed for each centre based on the primary and secondary analyses described above.

Finally a difference in NPI scores for each group between each of the follow-up periods was made using a Matched-Paired Student T-Test. The Cohan's D statistic was use to assess the effect size of the NPI score between the different follow-up periods. Through these two analyses, the responsiveness of the NPI score for individuals following rehabilitation after FTPD was made.

Internal consistency of the NPI score was assessed by comparing the relationship of the responses provided from the NPI's individual questions to

one another. This was analysed using the Cronbach's alpha coefficient. Its interpretation was based on the recommendation that Cronbach's alpha coefficient values between 0.7 and 0.9 are considered optimal (Streiner and Norman, 2008).

The proportion of respondents with the highest (ceiling) and lowest (floor) scores for each item and total scores were calculated from each time-point's NPI score dataset. A ceiling-effect assesses the proportion of respondents who report the highest possible response option. Conversely a floor-effect indicates the proportion of respondents which reported the lowest possible response option. Previous studies of musculoskeletal populations have concluded that a 30% threshold is advisable to indicate high floor or ceiling-effects (Kocher et al, 2004; Negahban et al, 2011). The appearance of ceiling or floor-effects can be a major weakness. Either floor- or ceiling-effects can impair the ability of an outcome to determine the central tendency of a dataset (Portney and Watkins, 2009). These can reduce the sensitivity of a score to distinguish between change in an individual's physical capabilities when they have recorded the highest or lowest possible score on an outcome measurement (Portney and Watkins, 2009). It is therefore important to assess these factors when assessing an outcome's ability to detect a meaningful difference (Streiner and Norman, 2008).

The level of statistical significance was set at 0.05. This was sufficient to indicate whether there was a difference between the groups. Confidence intervals are presented to provide an indication of the precision of the inferential statistical analyses. This is important as confidence intervals are advocated to present all plausible true values of a parameter, commonly within 95% boundaries (Armitage et al, 2002; Rothman, 1978; Gardner and Altman, 1989).

The statistical analyses were undertaken by the researcher who was not blinded to participant group allocation. All analyses were performed using STATA Version 11.0 (STATA Corp LP, Texas, USA).

14.12.3 Missing data analysis

It was planned that missing data would be estimated using multiple-imputation through STATA version 11.0. Using this strategy, missing data can be estimated by making repeated estimates from a model of the distribution of variables which have the missing observations (Mackinnon, 2010). This creates a number of complete datasets which are analysed in parallel to assess for a treatment effect (Mackinnon, 2010; Schafer, 1999). This has been typically used in studies where incompleteness in data has been attributed to participant drop-out, as in this study's case (Molenberghs and Kenward, 2007). This strategy is advantageous over a complete case analysis where all participants who did not provided complete data were omitted. If this was undertaken, it could permit greater researcher bias as data which is excluded from those lost to follow-up, may still have reported a treatment-effect (Altman, 2009).

A frequently recommended alternative for calculating missing data (but not used in this trial) was the last observation carried forward method (Molenberghs and Kenward, 2007). This method of calculating missing data is based on an assumption that the individual's measurements remain constant from their last measurement onwards. Such an assumption was a major limitation as it was not possible to predict how outcomes would change over time in this population (Rue et al, 2008). For this reason, the last observation carried forward method was not used.

14.13 Ethical Considerations

A number of ethical issues were considered during the design of this trial.

Before commencing the study, ethical approval was sought through the Norfolk Research Ethics Committee and the participating hospital's research governance committees (Appendix 46). This was essential to undertake a clinical trial in the UK's NHS to protect the safety of participants, researchers and fellow clinicians involved in the trial (Chapter 7, Section 7.12; Chapter 10, Section 10.12).

All data were collected on a pre-defined data sheet (Appendix 44). Using this, individuals were identifiable by code alone to protect anonymity. A de-coding form was stored in a locked cupboard at the researcher's place of employment. The data collection sheets were completed by the assessor and stored in a separate locked box in each participating physiotherapy department. This ensured that all data were stored together thereby reducing the potential for being mislaid. These sheets were also separate from the de-coding form to prevent breaking anonymity. By storing the assessment sheets separate to the treatment notes, the assessor was unable to un-blind themselves to treatment allocation. Once the individual was discharged by the treating physiotherapist, the data sheets and Exercise Diaries were mailed to the researcher. These were then stored in a separate locked cupboard in the researcher's place of employment. Once all data has been processed and the findings disseminated, all original data sheets and coding forms will be destroyed.

The design of this study ensured that individuals received either a specific-VMO strengthening programme with a general rehabilitation programme or a quadriceps strengthening exercise programme with a general rehabilitation programme. This was justified as a review of the literature (Chapter 5), findings from a retrospective notes audit at one of the participating hospitals (Appendix 38) and the national survey (Chapter 8) suggested that physiotherapists prescribe a variety of different treatments in addition to strengthening exercises for this population. It would have been unethical to withhold treatments which

are standard practice for the purposes of research (World Medical Association, 2000). Since all participants were allocated to a general rehabilitation programme, the difference between the groups was the type of strengthening exercises provided. Therefore no additional treatments were withheld from the study cohort which may have possessed a treatment effect.

14.14 Summary

This chapter has detailed the methodological approaches and justification for the design decisions made for this RCT. The following chapter will present the findings of this trial.

Chapter 15. RCT Results

15.1 Introduction

The last chapter presented the methodology decisions made when designing this RCT. This chapter will present this study's results. It will present the RCT's recruitment results (Section 15.2), loss to follow-up (Section 15.3), the analyses of the cohort's characteristics and baseline demographics (Section 15.4) and an analysis of the distribution of the dataset (Section 15.5). The findings of the primary (Section 15.6) and secondary (Section 15.7) analyses will be presented to answer the research questions. Finally the results of the validity and responsiveness analyses conducted on the NPI score will be discussed to begin to assess the behaviour of this newly developed outcome measure with this population (Section 15.8).

15.2 Recruitment and Randomisation

The raw data on the frequency of participant recruitment for each site is presented in Appendix 47.

During the planning of this trial, it was predicted that 50 participants would be recruited over a nine month period (Appendix 29). In reality, as Figures 15.1 to Figure 15.3 demonstrate, this was not achieved with each centre recruiting less than anticipated. Thirty people in total were approached to participate during a 12 month recruitment phase. Of these, three patients declined to participate after reading the patient information leaflet. Accordingly 90% of potential participants approached enrolled on the trial.

Figure 15.1. Line graph to illustrate the predicted and actual recruitment rate of participants from Centre One.

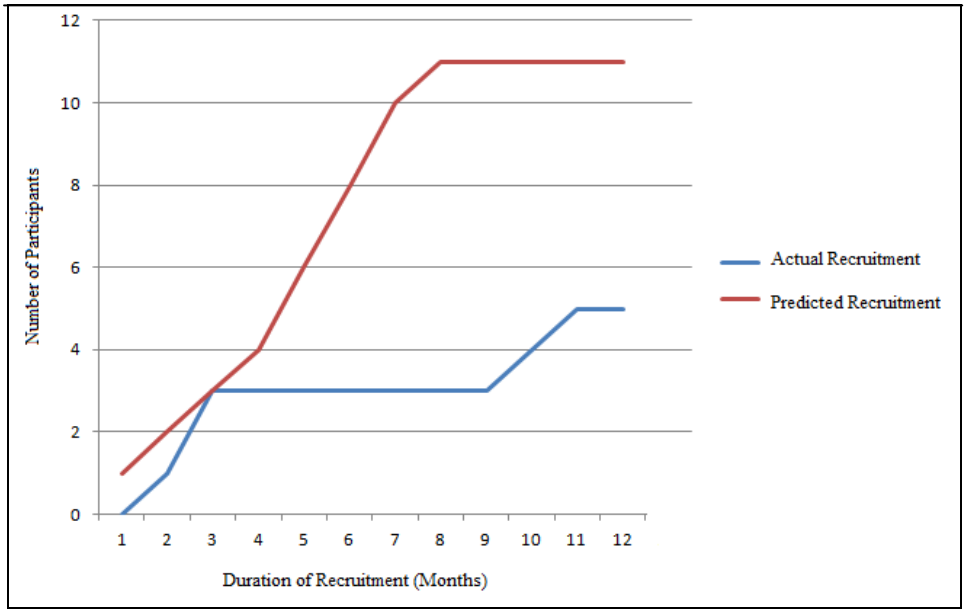


Figure 15.2. Line graph to illustrate the predicted and actual recruitment rate of participants from Centre Two.

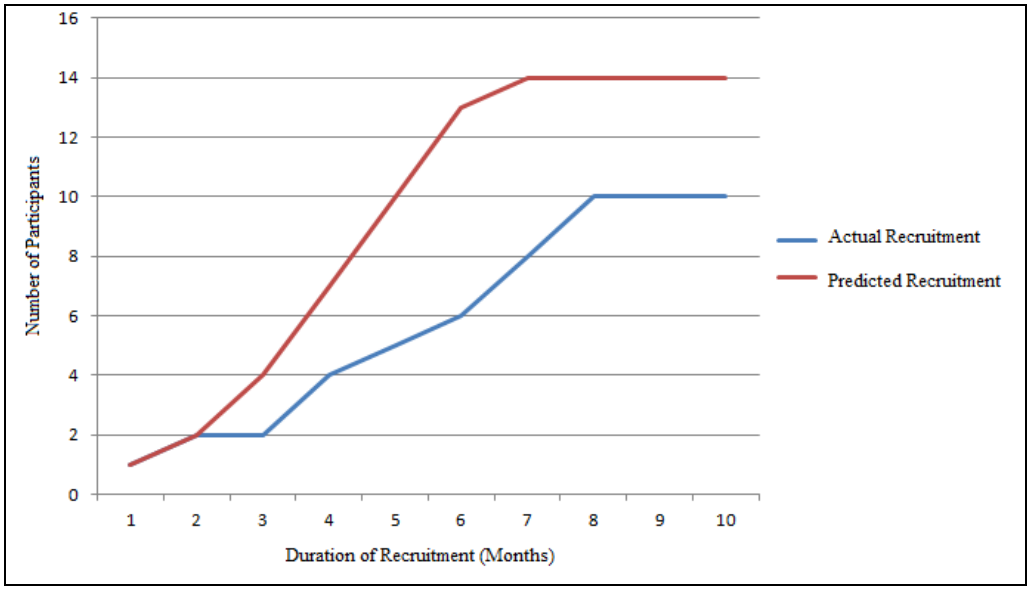
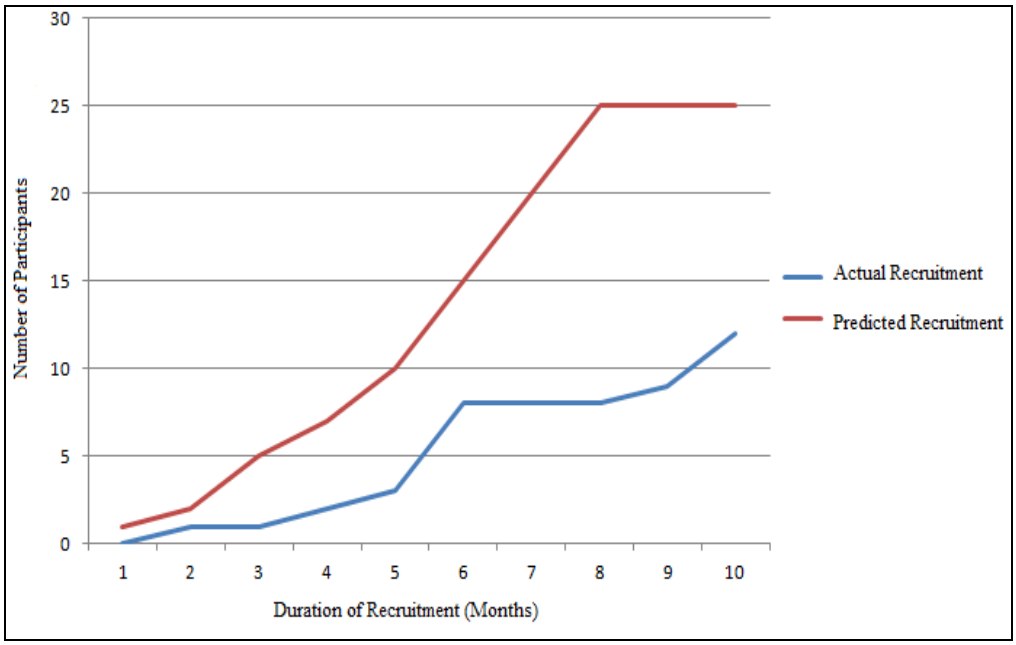


Figure 15.3. Line graph to illustrate the predicted and actual recruitment rate of participants from Centre Three.



The study Consort flow-chart is presented as Figure 15.4. As this illustrates, 15 individuals were randomised to the general quadriceps group whilst 12 were randomised to the specific-VMO exercise group. The stratification of the 27 participants by group allocation across the three sites is presented in Figure 15.5. This indicates that a relatively equal allocation of participants occurred across the two groups for Centre Two and Three suggesting successful stratification of intervention between the sites. However, this was not demonstrated for Centre One where four times as many participants were allocated to the general quadriceps exercises group compared to the specific-VMO exercise group (Figure 15.5).

Figure 15.4. Study Consort flow-diagram to depict the participant flow throughout the study.

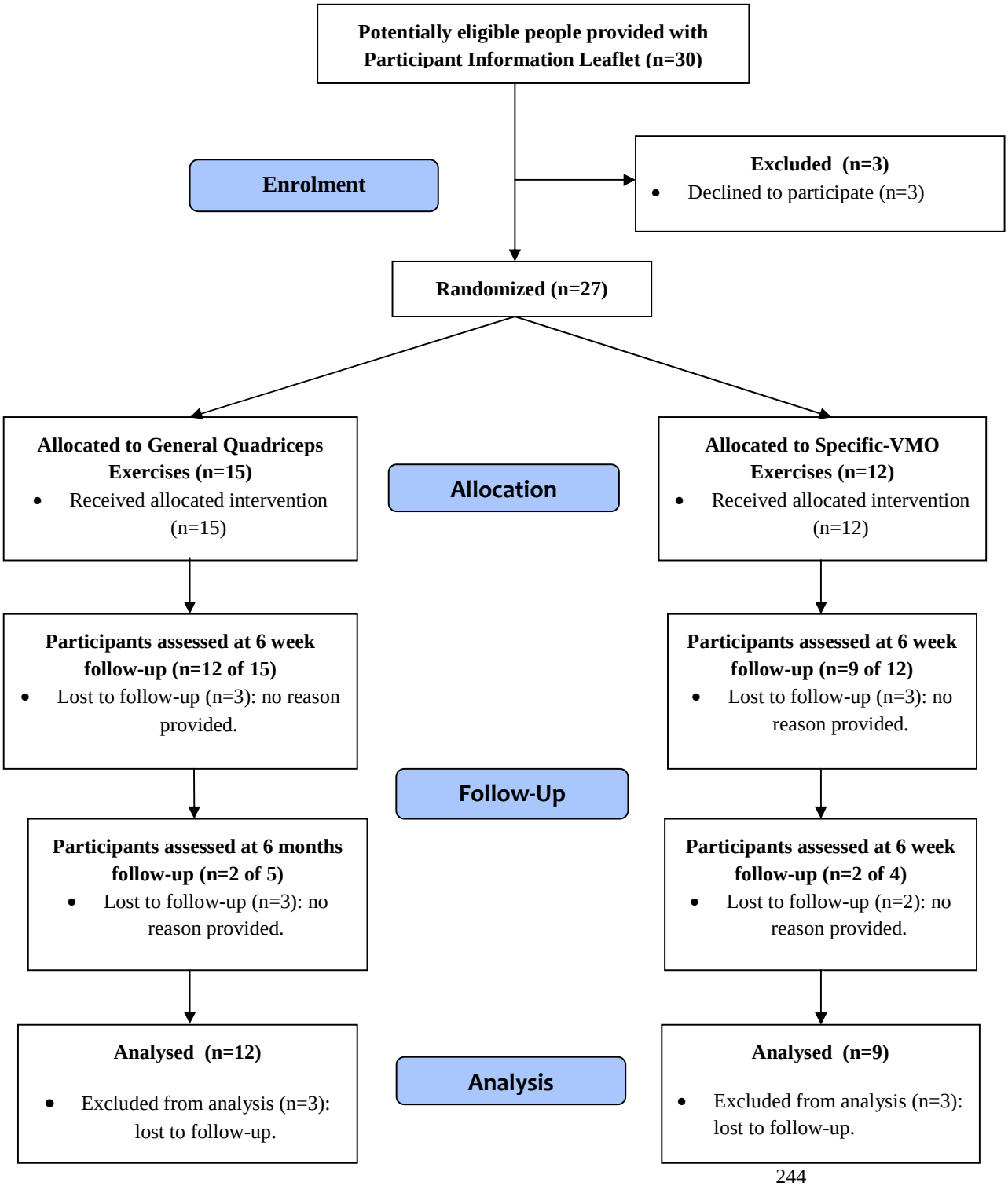
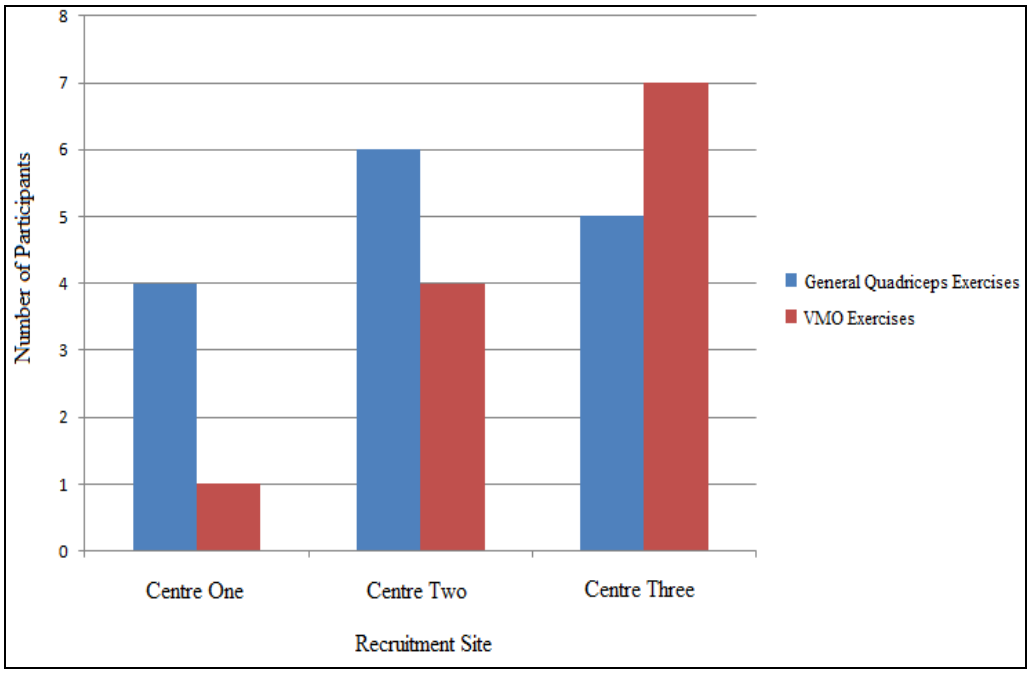


Figure 15.5. Bar chart to illustrate the stratification of participates allocated to the two intervention groups between the three study centres.



15.3 Loss to Follow-Up

As Table 15.1 summarises, 27 participants were recruited, 15 were allocated to the general quadriceps exercise group, 12 to the specific-VMO exercise group. At the six week follow-up, three participants were lost to follow-up from each group. This permitted a review of 12 participants in the general quadriceps group and nine in the specific-VMO group. Thus attrition rate at six weeks was 22%. Six month data were potentially available for five participants in the general quadriceps exercise group, with seven not reaching their six month follow-up point. This was available for four participants in the specific-VMO exercise group, with five not reaching their six month period following randomisation. Data was however only available for two participants in each group due to loss to follow-up. The dropout rate for the six month follow-up was therefore 56%.

Table 15.1 Table to present the baseline characteristics of those followed-up compared to those lost to follow-up at the six weeks assessment.

Characteristics	**Completed Follow-Up**	**Lost to Follow-Up**	**Student T-Test P-value (95% CI)**
	Freq/Mean (SD)	**Freq/Mean (SD)**	
N	21	6	NE
Age (years)	23.7 (1.7)	22.8 (2.3)	0.41 (-6.32,7.98)
Family Hx of Patellar Dislocation (yes)	2	0	1.00 (0.05,0.39) ‡
Gender (males/females)	14/7	3/3	0.64 (-0.35,0.46) ‡
Duration from injury to physiotherapy (weeks)	1.3 (0.1)	1.5 (0.2)	0.76 (-0.64,0.31)
Other MSK injury to the treatment leg (yes)	2	1	0.55 (-0.92,0.63) ‡
Contralateral PFI (yes)	4	1	1.00 (-0.58,0.41) ‡
Disability of the contralateral leg (yes)	1	0	1.00 (0.05,0.38) ‡
Multi-joint problems (yes)	2	0	1.00 (0.05,0.39) ‡
Beighton Hypermobility Score	3.4 (0.7)	0.3 (1.4)	0.49 (-2.87,2.97)
Isometric extensor muscle strength – 0° flexion (Newtons)	4.4 (0.9)	6.3 (2.7)	0.80 (-6.50,2.72)
Isometric extensor muscle strength – 30° flexion (Newtons)	10.5 (1.4)	10.8 (1.8)	0.55 (-6.28,5.58)
Isometric extensor muscle strength – 60° flexion (Newtons)	10.9 (1.4)	11.6 (1.9)	0.58 (-6.53,5.35)
Isometric extensor muscle strength – 90° flexion (Newtons)	10.4 (2.0)	11.5 (3.1)	0.61 (-9.71,7.41)
Tegner Level of Activity Score	2.1 (0.4)	2.0 (0.7)	0.45 (-1.50,1.69)
Lysholm Knee Score	39.6 (6.2)	43.3 (8.3)	0.62 (-29.56,22.04)
SF-12	31.2 (1.4)	31.8 (1.8)	0.58 (-6.42,5.23)
NPI score	32.6 (5.7)	43.8 (9.5)	0.82 (-35.51,13.22)

‡ - Fisher's exact test; CI – confidence intervals; Freq – frequency; MSK – Musculoskeletal; N - newtons; NE – not estimatable; NPI score – Norwich Patellar Instability Score; PFI – Patellofemoral Instability; SD – standard deviation; SF-12 – Short Form-12

Table 15.2 Table to present the baseline characteristics of those followed-up compared to those lost to follow-up at the six month assessment.

Characteristics	**Completed Follow-Up**	**Lost to Follow-Up**	**Student T-Test P-value (95% CI)**
	Freq/Mean (SD)	**Freq/Mean (SD)**	
N	4	5	NE
Age (years)	25.3 (6.0)	19.8 (1.4)	0.18 (-7.51,18.41)
Family Hx of Patellar Dislocation (yes)	1	0	0.44 (0.08,0.85) ‡
Gender (males/females)	1/3	0/5	0.44 (0.08,0.85) ‡
Duration from injury to physiotherapy (weeks)	13.3 (1.8)	30.2 (8.1)	0.94 (-39.09,5.19)
Other MSK injury to the treatment leg (yes)	1	0	0.44 (0.08,0.85) ‡
Contralateral PFI (yes)	1	1	1.00 (-3.37,0.83) ‡
Disability of the contralateral leg (yes)	0	1	1.00 (-3.37,0.83) ‡
Multi-joint problems (yes)	1	0	0.44 (0.08,0.85) ‡
Beighton Hypermobility Score	4.5 (1.7)	1.6 (0.9)	0.08 (-1.43,7.23)
Isometric extensor muscle strength – 0° flexion (Newtons)	5.0 (2.3)	9.9 (2.7)	0.89 (-13.57,3.85)
Isometric extensor muscle strength – 30° flexion (Newtons)	5.8 (1.3)	14.8 (3.7)	0.96 (-19.33,1.36)
Isometric extensor muscle strength – 60° flexion (Newtons)	6.5 (3.2)	15.2 (2.5)	0.97 (-18.13,0.61)
Isometric extensor muscle strength – 90° flexion (Newtons)	9.5 (5.4)	13.6 (3.9)	0.72 (-19.43,11.29)
Tegner Level of Activity Score	2.3 (0.9)	2.4 (0.9)	0.54 (-3.20,2.90)
Lysholm Knee Score	38.8 (18.4)	47.6 (13.9)	0.65 (-62.35,44.65)
SF-12	31.0 (5.9)	29.6 (2.4)	0.41 (-12.44,15.24)
NPI score	41.8 (19.6)	31.8 (8.7)	0.32 (-36.93,56.91)

‡ - Fisher's exact test; CI – confidence intervals; Freq – frequency; MSK – Musculoskeletal; N - newtons; NE – not estimatable; NPI score – Norwich Patellar Instability Score; PFI – Patellofemoral Instability; SD – standard deviation; SF-12 – Short Form-12

Literature was reviewed and statistical advice was sought regarding imputation for lost data. It was recommended that there was insufficient data to perform multiple imputatation to estimate missing data using STATA Version 11.0

(Hamer and Simpson, 2009). This analysis was therefore not performed. Only the original non-imputated dataset was analysed using intention-to-treat principles.

To estimate whether the effect of loss to follow-up may have impacted on analyses' findings, a comparison of the baseline characteristics of the followed-up and lost participants was undertaken for the six month and six week assessment (Table 15.1, Table 15.2). This indicated that there was no statistically significant difference between the groups in their characteristics of the lost participants and those followed-up at each of the assessments.

15.4 Cohort Characteristics

The baseline characteristics of the two intervention groups are presented in Table 15.3. The cohort of 27 participants consisted of 17 males and 10 females with a mean age of 24 years (SD: 7.4).

The groups were equally matched for a number of characteristics. There was a proportionally similar gender mix between the two groups with 40% of the general quadriceps group being female compared to 50% in the specific-VMO group. The mean Beighton score of the cohort was three (SD: 3.0). The mean values were similar between the groups for this measure of hypermobility (general quadriceps: 3.1, specific-VMO: 3.7). There was an equal distribution, one in each group, in respect to the number of participants who presented with multiple joint pathologies such as low back pain in addition to their FTPD. Similarly there was a relatively equal distribution of participants who presented with contralateral patellofemoral instability with or without a history of FTPD. Five participants in total reported contralateral patellar instability, two allocated to the general quadriceps group and three allocated to the specific-VMO exercise group.

Table 15.3. Table presenting the baseline characteristics for the study cohort and for each of the study intervention groups.

Characteristics	Entire Cohort	General Quadriceps Exercises	VMO Exercises
	Freq/Mean (SD)	Freq/Mean (SD)	Freq/Mean (SD)
N	27	15	12
Age (years)	23.5 (7.4)	23.1 (5.8)	19 (12.8)
Family Hx of Patellar Dislocation (yes)	2	0	2
Gender (males/females)	17/10	9/6	8/4
Duration from injury to physiotherapy (weeks)	21.6 (15.4)	26.8 (17.6)	15.2 (9.0)
Other MSK injury to the treatment leg (yes)	3	0	3
Contralateral PFI (yes)	5	2	3
Disability of the contralateral leg (yes)	1	1	0
Multi-joint problems (yes)	2	1	1
Beighton Hypermobility Score	3.4 (3.0)	3.1 (2.1)	3.7 (3.9)
Isometric extensor muscle strength – 0° flexion (Newtons)	47.6 (47.1)	47.8 (51.0)	47.3 (44.0)
Isometric extensor muscle strength – 30° flexion (Newtons)	103.3 (59.8)	99.8 (54.4)	107.6 (68.2)
Isometric extensor muscle strength – 60° flexion (Newtons)	108.9 (59.9)	115.1 (63.8)	101.0 (56.5)
Isometric extensor muscle strength – 90° flexion (Newtons)	104.2 (86.4)	110.0 (97.9)	97.0 (73.2)
Tegner Level of Activity Score	2.1 (1.6)	3.3 (1.6)	1.9 (1.4)
Lysholm Knee Score	40.4 (36.6)	47.3 (26.7)	31.8 (34.9)
SF-12	31.4 (6.0)	33.9 (5.5)	28.2 (5.1)
NPI score	35.1 (25.5)	32.5 (25.1)	38.3 (26.7)

Freq – frequency; Hx – history; NPI score – Norwich Patellar Instability score; PFI – patellofemoral instability; SD – standard deviation; SF-12 – short form-12; VMO – vastus medialis oblique

Baseline assessment of isometric muscle strength testing indicated no substantial difference between the groups for the strength measurement at zero and 30° knee flexion (Table 15.3). However, the general quadriceps exercise group presented with a higher baseline measurement for isometric knee

extension strength at 60° and 90° knee flexion by a mean difference (MD) of 14 and 13 Newtons respectively.

There were some other differences between the groups at baseline. The general quadriceps group presented with a higher mean age. This was 23 years (SD: 5.8) compared to 19 years (SD: 12.8) in the specific-VMO group. Two participants reported a family history of patellar dislocation and both were randomised to the specific-VMO exercise group. Three participants, all in the specific-VMO exercise group, presented with another musculoskeletal disorder on the same lower limb as their FTPD (one hip pain, two ankle sprains). Only one participant reported a contralateral musculoskeletal pathology (ankle pain); they were randomised to the general quadriceps group. There was a difference at baseline between the groups in respect to the time from injury to treatment. The general quadriceps exercise group presented with a longer duration from injury to treatment compared to the specific-VMO exercise group (mean difference 12 days; Table 15.3).

Although there appeared no large difference between the two groups in Tegner Activity score, there was a difference of 16 points in the Lysholm Knee Score and six points in the SF-12 indicating higher function and better general health for the general quadriceps compared to specific-VMO group at baseline (Table 15.3). The baseline NPI score which assesses perceived patellar instability supported this finding where participants in the general quadriceps exercise group reported less perceived patellar instability (mean: 32.5 points) compared to the specific-VMO group (mean: 38.3 points).

In summary, the baseline measurements for duration from injury to treatment and Lysholm Knee Score substantially differed between the groups. To account for this, the parametric inferential data analyses were adjusted for these two measures.

Table 15.4. Table to present the results of the analyses from the six week follow-up dataset.

Outcome	General Quadriceps Exc. Group	VMO Exc. Group	P-value (95% CI)	Adjusted P-value (95% CI)
	Freq/ Mean (SD)	Freq/ Mean (SD)		
Isometric extensor muscle strength – 0° flexion (N)	97.9 (41.2)	110.5 (39.7)	0.64 (-0.05,0.07)	0.71 (-0.07,0.10)
Isometric extensor muscle strength – 30° flexion (N)	166.6 (82.3)	183.6 (66.9)	0.90 (-0.04,0.04)	0.87 (-0.13,0.15)
Isometric extensor muscle strength – 60° flexion (N)	171.5 (86.2)	180.1 (51.5)	0.85 (-0.04,0.04)	0.52 (-0.09,0.18)
Isometric extensor muscle strength – 90° flexion (N)	181.0 (91.6)	191.0 (65.6)	0.99 (-0.03,0.03)	0.18 (-0.05,0.25)
Tegner Level of Activity Score	4.1 (1.8)	2.7 (1.7)	0.10 (-3.18,0.31)	0.03 (0.00,0.06)
Lysholm Knee Score	78.3 (18.5)	73.0 (22.8)	0.30 (-0.02,0.06)	0.02 (0.06,0.67)
SF-12	37.0† (32.8-41.0)*	38.0† (28.5-42.5)*	0.78 (-8.00, 5.00)**	NE
NPI score	20.3 (16.4)	14.1 (11.9)	0.49 (-0.02,0.01)	0.50 (-0.39,0.20)
Duration of physiotherapy (weeks)	6.0† (5.0-6.0)*	6.0† (4.5-6.0)*	0.74 (-1.00, 1.00)**	NE
Number of physiotherapy sessions	4.0† (3.0-5.5)*	3.0† (2.0-4.5)*	0.23 (-2.00, 1.00)**	NE
Duration participant continued with exercises (weeks)	6.0† (4.3-6.0)*	6.0† (3.0-6.0)*	0.45 (-2.00, 0.00)**	NE
Number DNAs	2	1	0.57‡	NE
Recurrent dislocation (freq)	0	1	0.43‡	NE
Duration to 1st recurrent dislocation (weeks)	0	3(actual)	0.25 (0.00, 0.00)	0.78 (-0.01,0.01)

† - Median; * - Inter-quartile range; ‡ - Fisher's exact test; ** Mann-Whitney U-test; % – percentage; CI – confidence intervals; DNAs – did not attend appointments; Exc – exercise; Freq – frequency; MSK - Musculoskeletal; N - newtons; NE – not estimatable; PFI – Patellofemoral Instability; SD – standard deviation

15.5 Assessment of Data Distribution

The results of the assessment of data normality in distribution for the six week and six month datasets are presented in Appendix 48. The results indicated that all outcome measurements assessed at six weeks were normally distributed except the SF-12, duration and number of physiotherapy sessions and duration participants exercised. The dataset was normally distributed for all outcome

measures at six months except Lysholm Knee Score, SF-12, duration and number of physiotherapy sessions and duration participants exercised.

When a Shapiro-Wilk W test probability value presented in Appendix 48 was less than 0.05, the outcome was assessed using a non-parametric inferential statistical test. When the Shapiro-Wilk W test probability value was greater than 0.05, the outcome was assessed using a parametric test. The results of these analyses are presented below.

15.6 Primary Analysis

There was a difference of five points between the groups in Lysholm Knee Score at six weeks, with a higher functional outcome for the general quadriceps exercise group (mean: 78.3) compared to the specific-VMO exercise group (mean: 73.0; Table 16.4). This difference did not reach statistical significance (p=0.30; 95% CI: -0.02, 3.04). However when the data were analysed to adjust for baseline differences, this did reach statistical significance (p=0.02; 95% CI: 0.06, 0.67).

15.7 Secondary Analyses

15.7.1 Lysholm Knee Score

At the six month follow-up, the general quadriceps exercise group continued to present with higher Lysholm Knee Score indicating superior functional outcomes in the specific-VMO exercise group. The mean difference between the study groups was 30 points. This did not reach statistical significance (p=0.68; 95% CI: 0.00, 0.00; Table 15.5).

The within-group analysis detected a statistically significant difference in Lysholm Knee Score between the baseline to six week findings in the specific-

VMO (p<0.01; 95% CI:-46.27, -21.40) and general quadriceps exercise groups (p<0.01; 95% CI: 22.43, 57.57). There was however no statistically significant difference between the six week to six month outcomes for this outcome measure in either intervention group (p≥0.32; Table 15.6).

Table 15.5. Table presenting the analyses of the six month follow-up dataset for each exercise group.

Outcome	General Quadriceps Exc. Group	VMO Exc. Group	P-value (95% CI)	Adjusted P-value (95% CI)
	Mean (SD)	Mean (SD)		
Isometric extensor muscle strength – 0° flexion (N)	92.1 (15.3)	119.1 (57.5)	0.59 (-21.22, 15.72)	0.91 (-2.17, 2.21)
Isometric extensor muscle strength – 30° flexion (N)	136.2† (136.2-136.8)*	157.1† (124.2-157.1)*	1.00 (1.00-1.00)**	NE
Isometric extensor muscle strength – 60° flexion(N)	199.9 (126.1)	186.4 (67.9)	0.91 (-43.09, 45.85)	0.39 (-2.73, 3.41)
Isometric extensor muscle strength – 90° flexion (N)	219.0 (143.5)	147.1 (2.0)	0.55 (-37.20, 51.88)	0.07 (-0.16,0.99)
Tegner Level of Activity Score	5.0 (2.8)	2.0 (2.8)	0.40 (-9.17, 15.17)	0.42 (-0.81,0.99)
Lysholm Knee Score	97.5† (95.0-97.5)*	67.5 (35.0-67.5)*†	0.68 (0.00-0.00)	NE
SF-12	43.0† (42.0-43.0)*	27.5† (12.0-27.5)*	0.44 (0.00, 0.00)	NE
NPI score	0.75 (1.1)	11.2 (8.9)	0.24 (-37.75, 16.85)	0.99 (-3.27,3.26)
Duration of physiotherapy (weeks)	6† (5.0-6.0)*	8.5† (8.0-8.5)*	0.15 (-7.31, 2.31)	NE
Number of physiotherapy sessions	4.0† (4.0-4.0)*	4.5† (4.0-4.5)*	0.42 (-2.65, 1.65)	NE
Duration participant continued with exercises (weeks)	8.5† (2.0-8.5)*	13.5† (12.0-13.5)*	0.53 (-33.70, 23.70)	NE
Number DNAs (freq)	0	0	1.00	NE
Recurrent dislocation (freq)	0	1	0.50‡	NE
Duration to 1st recurrent dislocation (weeks)	-	3	0.42 (-7.95, 4.95)	0.92 (-0.77, 0.76)

† - Median; * - Inter-quartile range; ‡ - Fisher's exact test; ** Mann-Whitney U-test; CI – confidence intervals; DNAs – did not attend appointments; Exc- exercise; Freq – frequency; N – newtons; NE – not estimatable; SD – standard deviation

Table 15.6. Table to demonstrate the within-group differences for each intervention group between each of the study follow-up periods.

Outcome	General Quadriceps Exc.		VMO Exc. Group	
	Mean Difference (SD)	P-value (95% CI)	Mean Difference (SD)	P-value (95% CI)
Baseline to 6 Weeks				
Isometric extensor muscle strength – 0° flexion (N)	58.7 (52.4)	<0.01 (-9.39,-2.60)	61.7 (53.9)	<0.01 (2.01,10.51)
Isometric extensor muscle strength – 30° flexion (N)	73.9 (64.3)	<0.01 (-11.71,-3.37)	68.6 (52.9)	<0.01 (2.80, 11.10)
Isometric extensor muscle strength – 60° flexion (N)	64.5 (54.1)	<0.01 (-10.09,-3.08)	71.5 (42.1)	<0.01 (3.99-10.66)
Isometric extensor muscle strength – 90° flexion (N)	82.8 (57.7)	<0.01 (-12.91,-4.71)	85.3 (6.9)	<0.01 (2.73,14.58)
Tegner Level of Activity Score	1.6 (1.8)	0.01 (-2.72,-0.45)	1.1 (1.6)	0.07 (-0.13,2.15)
Lysholm Knee Score	33.8 (19.6)	<0.01 (-46.27,-21.40)	40.0 (22.9)	<0.01 (22.43,57.57)
SF-12	3.3 (4.5)	0.03 (30.10,38.89)	5.8 (11.3)	0.04 (28.08,42.84)
NPI score	11.2 (24.5)	0.14 (-4.39,26.71)	20.0 (18.96)	0.01 (-34.59,-5.45)
6 Weeks to 6 Months				
Isometric extensor muscle strength – 0° flexion (N)	13.2 (9.0)	0.29 (-9.61, 6.91)	32.1 (106.1)	0.74 (-93.99,100.54)
Isometric extensor muscle strength – 30° flexion (N)	9.8 (0.0)	NE	29.0 (113.6)	0.78 (-101.23,107.15)
Isometric extensor muscle strength – 60° flexion (N)	12.3 (21.5)	0.57 (-18.44,20.94)	33.2 (115.2)	0.75 (-102.20,108.98)
Isometric extensor muscle strength – 90° flexion (N)	25.7 (18.6)	0.36 (-7.15, 5.55)	17.8 (31.3)	0.40 (-25.48,31.57)
Tegner Level of Activity Score	1.5 (0.7)	0.20 (-7.85,4.85)	1.0 (1.4)	0.50 (-11.71,13.1)
Lysholm Knee Score	25.0 (3.5)	0.50 (-29.27,34.27)	13.5 (10.6)	0.32 (-81.80,108.80)
SF-12	0.0 (4.2)	1.0 (42.00.44.00)	1.5 (2.1)	0.32 (12.0-14.0)
NPI score	4.9 (9.0)	0.58 (-85.53, 75.83)	8.9 (2.8)	0.14 (-33.63,15.93)

CI – confidence interval; N – newtons; NE – Not estimatable; SD – standard deviation

15.7.2 Tegner Level of Activity Score

On assessing between-group differences, the general quadriceps exercise group presented with higher mean Tegner Level of Activity Score compared to the specific-VMO group at the six week follow-up (mean: 4.1 versus 2.7) and six month follow-up (mean: 5.0 versus 2.0). This difference did not reach statistical

significance at the six week (p=0.10; 95% CI:-3.18, 0.31) or six month follow-up (p=0.40; 95% CI: -9.17, 15.17) on the unadjusted analyses. However the adjusted analysis indicated a statistically significant difference between the groups, but only at the six week follow-up (p=0.03; 95% CI: 0.00, 0.06; Table 15.4).

There was a statistically significant increase in reported Tegner Level of Activity Score from baseline to the six week assessment in the general quadriceps exercise group (p=0.01; 95% CI: -2.72, -0.45; MD: 1.6 points; Table 15.6). However there was no significant difference between these time-points in the specific-VMO group (median 1.5 to 2.7; p=0.07; 95% CI: -0.13, 2.15; MD: 1.1 points; Table 15.6). Furthermore there was no within-group statistically significant difference in Tegner Level of Activity Score between the six week to six month assessment for either group (p≥0.20; Table 15.6).

15.7.3 Short Form-12

There was a difference of one point between the median values of the two interventions at six weeks, with the specific-VMO group reporting slightly lower disability levels compared to the general quadriceps exercise group (Table 15.4). This did not reach statistical significance (p=0.78; 95% CI: -8.00, 5.00). However at six months, this trend in results had reversed where the general quadriceps exercise group reported a higher SF-12 score (MD=15.5 points) compared to the specific-VMO group (Table 15.5). However this was not statistically significant (p=0.44, 95% CI: 0.00, 0.00).

There was a statistically significant difference between the baseline and six week analyses for the SF-12 score in both the specific-VMO (p=0.03; 95% CI: 30.10, 38.89; MD: 3.3 points) and general quadriceps (p=0.04; 95% CI: 28.08, 42.84; MD: 7.0 points) exercise groups. There was no statistically significant

difference between the six week to six month dataset for either intervention group ($p \geq 0.32$), with a mean difference of zero points in the general quadriceps group and 1.5 points in the specific-VMO exercise group (Table 15.6).

15.7.4 NPI Score

At the six week follow-up, the general quadriceps group reported a higher NPI score compared to the specific-VMO group (mean: 20.3 versus 14.1). This was not a statistically significant difference on the unadjusted ($p=0.49$; 95% CI: -0.02, 0.01) or adjusted analyses ($p=0.50$; 95% CI: -0.39, 0.20). In contrast at six months data, the general quadriceps exercise group demonstrated a lower mean score compared to the specific-VMO group (mean: 0.8 versus 11.2). This was not a statistically significant difference ($p=0.24$; 95% CI: 37.8, 16.9). This remained not statistically significant when assessed through the adjusted analysis ($p=0.99$; 95% CI: 3.27, 3.26; Table 15.5).

There was a significant reduction in the NPI score from baseline to the six week assessment in the specific-VMO group ($p=0.01$; 95% CI: -34.59, -5.45). The mean difference between the two assessment periods was 20 points (Table 15.6). However this statistically significant within-group difference was not exhibited by the general quadriceps exercise group ($p=0.14$; 95% CI: -4.39, 26.71). This group reported a decrease in NPI score by a mean value of 11 points (Table 15.6). Although not reaching statistical significance ($p \geq 0.14$; Table 15.6) NPI scores reduced between the six week and six month analyses, indicating a reduction in perceived patellar instability.

15.7.5 Isometric Knee Extension Strength

There was a trend for greater isometric knee extension muscle strength at six weeks in the specific-VMO group compared to the general quadriceps exercise

group (Table 15.4). The mean difference between the groups ranged from nine Newtons (90° measurement) to 13 Newtons (30° measurement). None of the isometric knee extension strength measurements reached a statistically significant difference between the groups at the six week follow-up on the adjusted or unadjusted analyses (p=0.18 to 0.99; Table 15.4).

At six months, whilst mean isometric extension strength remained greater for the specific-VMO group at zero and 30° knee flexion measurements compared to the general quadriceps group (MD: 27.0 Newtons; 20.9 Newtons), greater extension strength was demonstrated at 60° and 90° knee flexion in the general quadriceps group (MD: 13.5 Newtons; 71.9 Newtons). Nonetheless these differences did not reach statistical significance on unadjusted and adjusted analyses at six months (p=0.55 to 1.00; Table 15.5).

Isometric knee extension muscle strength significantly increased from baseline to the six week measurement at all knee angle measurements for both the general quadriceps and specific-VMO exercise groups ($p<0.01$; Table 15.6). There was no statistically significant difference between the six week to six month assessment period in isometric knee extension strength for either intervention group ($p\geq0.29$; Table 15.6).

15.7.6 Duration of Exercise

There was no significant difference between the groups in respect to the frequency and duration in which participants exercised for at the six week assessment (p=0.45; 95% CI: -2.00, 0.00). The median value both groups reported using the Exercise Diaries was six weeks (Table 15.4). There was a difference between the groups at six months. Whilst the general quadriceps exercise group reported continuing their allocated exercises for a median of 8.5 weeks post-commencing rehabilitation, the specific-VMO group reported the

continuation of exercises for 13.5 weeks (Table 15.5). This between-group difference did not reach statistical significance (p=0.53; 95% CI: -33.7, 23.7).

15.7.7 Physiotherapy Intervention

The median duration of total physiotherapy treatment was six weeks for each group at the six week assessment. This indicated that the majority of participants were still under the care of a physiotherapist at this follow-up period. There was no statistically significant difference between the groups for this duration (p=0.74; 95% CI: -1.00, 1.00). The six month dataset indicated that participants were discharged later from physiotherapy in the specific-VMO group (median: 8.5 weeks) compared to the general quadriceps exercise group (median: 6.0 weeks). This difference did not reach statistical significance (p=0.15; 95% CI: -7.31, 2.31).

The number of physiotherapy appointments attended was broadly similar between the two groups. At the six weeks follow-up, the general quadriceps exercise group attended a median of four sessions, compared to a median of three in the specific-VMO group (Table 15.4). This was not statistically significantly different (p=0.23; 95% CI: -2.00, 1.00). The mean difference at six months was only 0.5 sessions (Table 15.5). This difference also did not reach statistical significance (p=.042; 95% CI: -2.65, 1.65).

At the six weeks assessment, one participant in the general quadriceps exercise group had not attended their physiotherapy appointments on two occasions; one participant in the specific-VMO group did not attend one of their physiotherapy appointments. This between-group difference did not reach statistical significance (p=0.57; Table 15.4). There was also no statistically significant difference between the groups in respect to the number of ‘did not attend’ appointments at six months (p=1.00; Table 15.5).

Table 15.7. Table to present the frequency of additional treatments prescribed and the analysis of statistical differences between the two exercise groups.

Interventions	General Quadriceps Exc. Grp	VMO Exc. Grp	P-value
Modified Wall Slide Exercise	0	12	<0.01
Isometric Quadriceps with hip rotation in semi-squatting position	0	12	<0.01
Leg Dips in Internal Femoral and Tibial Rotation	0	12	<0.01
Isometric Quadriceps and Tibial Internal Rotation	0	12	<0.01
Wall slide in neutral	15	0	<0.01
Isometric quadriceps in semi-squat neutral	15	0	<0.01
Leg dips in neutral	15	0	<0.01
Isometric quadriceps in neutral	15	0	<0.01
Knee Rom exercises	10	9	0.48
Ice	6	6	0.45
Ultrasound of medical retinaculum	3	1	0.39
Hamstring stretches	3	2	0.61
Calf Stretches	2	4	0.22
Glutei exercises	0	2	0.19
Proprioception exercises	5	4	0.66
Lateral retinaculum frictions	0	0	1.00
Medial Patellar Glides	0	2	0.19
Tibiofemoral Mobilisations	1	1	0.70
Inferential/Ultrasound combined	0	0	1.00
Acupuncture	0	0	1.00
Gym programme	6	6	0.45
Taping Techniques	2	1	0.59
Tubigrip and compression bandage	1	0	0.56
Straight leg raise	3	2	0.61
Inner Range Quad	3	2	0.61
Gait Re-education	2	3	0.39
Static Quadriceps in neutral	1	0	0.56
Running	0	1	0.44
Bike	1	0	0.56
Ankle ROM exercises	0	0	1.00
Plyometrics	1	0	0.56

Exc – exercises; Grp – group; ROM – range of motion

There was no statistically significant difference between the groups in the type of additional treatments prescribed with the exception of the study intervention ($p>0.05$; Table 15.7). The most frequently prescribed treatments in addition to

the allocated study exercises were knee range of motion exercises (n=19), ice (n=12), prescription of a gym programme (n=12) and proprioceptive lower limb exercises (n=9).

15.7.8 Complications

One participant experienced a recurrent patellar dislocation during the first six weeks post-randomisation. This participant had been randomised to the specific-VMO exercise group. The dislocation occurred three weeks after entering the trial. None of the four participants reviewed at six months had experienced a recurrent dislocation. There was no statistically significant difference in the frequency of recurrent dislocation between the study groups at six weeks (p=0.43) or six months (p=0.50). Similarly there was no significant difference between the groups in respect to the duration from FTPD to second dislocation event at six weeks follow-up (p=0.25; 95% CI: 0.00, 0.00) or six month follow-up (p=0.42; 95% CI: 7.95, 4.95). This was consistent between the adjusted and unadjusted analyses (Table 15.4; Table 15.5).

With the exception of one participant, no complications such as hospital or Accident and Emergency re-admission, tendinopathy or other musculoskeletal complications were reported by study participants at any follow-up period. One participant randomised to the specific-VMO exercise group was diagnosed with having a partial meniscal tear on the ipsilateral knee three months following trial enrolment. It remained unclear whether this was sustained prior or subsequent to randomisation. This participant underwent an arthroscopic meniscal debridement and at the time of writing currently continues her rehabilitation.

15.7.9 Effect of Duration of Exercise on Clinical Outcomes

There was no statistical relationship between the duration of exercises performed and clinical outcome measured by isometric extension muscle strength, Tegner Level of Activity Score, Lysholm Knee Score, SF-12, NPI score or the duration between the first and second dislocation at the six week follow-up. This was the case for both study groups (Table 15.8). A correlation of these variables was not performed using the six month dataset due to insufficient numbers to provide a meaningful estimate of such a relationship.

Table 15.8. Table to present the correlation coefficient analysis assessing the relationship between exercise frequency and clinical outcome between the two intervention groups at the six week follow-up.

Outcome correlated to frequency of exercise	General Quadriceps Exc. Group		VMO Exc. Group	
	Rho value (95% CI)	P-value (95% CI)	Rho value (95% CI)	P-value (95% CI)
Isometric extensor muscle strength – 0° flexion (N)	0.07	0.82 (-0.52,0.62)	0.23	0.54 (-0.51, 0.78)
Isometric extensor muscle strength – 30° flexion (N)	-0.07	0.82 -(0.62, 0.52)	-0.05	0.89 (-0.69, 0.63)
Isometric extensor muscle strength – 60° flexion (N)	0.17	0.61 (-0.45, 0.68)	0.07	0.85 (-0.62,0.70)
Isometric extensor muscle strength – 90° flexion (N)	0.19	0.55 (-0.43,0.69)	0.07	0.85 (-0.62,0.70)
Tegner Level of Activity Score	0.09	0.79 (-0.51, 0.63)	-0.16	0.68 (-0.75,0.57)
Lysholm Knee Score	0.05	0.87 (-0.54, 0.61)	-0.37	0.33 (-0.83,0.39)
SF-12	0.38	0.22 (-0.25,0.78)	-0.33	0.39 (-0.82,0.43)
NPI score	-0.41	0.19 (-0.80, 0.21)	0.11	0.78 (-0.60,0.72)
Duration between first and second dislocation (weeks)	NE	NE	0.30	0.43 (-0.46,0.80)

CI – confidence intervals; N – newtons; NPI score – Norwich Patellar Instability score; SF-12 – short form-12

15.7.10 Subgroup Analyses by Recruiting Site

Baseline comparability between the groups for each site is presented in Table 15.9. These reiterated the trends observed in the overall dataset with a difference between the groups in Lysholm Knee Score and duration from injury to commencing rehabilitation. However, unlike the overall dataset, Table 15.9 indicated that the Lysholm Knee Score was higher in the specific-VMO groups at Centre Two, in comparison to the other sites. The baseline data also indicated a difference between the groups for age and NPI score in Centre Two (Table 15.9), and NPI score in Centre One (Table 15.9). Centre Three reported an imbalance between the groups in respect to the Beighton Hypermobility score (Table 15.9) which was not demonstrated in the overall dataset.

The between-group difference was assessed for each site using the six week dataset. This indicated that there was no statistically significant difference for any outcome between the sites for each group ($p \geq 0.06$; Table 15.10). Only one variable presented with weak evidence of a statistical difference ($p=0.06$). The number of physiotherapy sessions attended was lower in Centre Three (mean: 2.7) compared to Centre One or Two (mean: 4.8; 4.8).

15.8. Analyses of the NPI Score's Properties

15.8.1 Convergent Validity

There was a trend for a greater convergence between the NPI score at each follow-up assessment compared to the baseline measurement dataset (Table 15.11; Table 15.12). For the overall cohort, when assessed at baseline, only isometric extension muscle strength measured at 60° and 90° knee flexion, SF-12 and the Lysholm Knee scores demonstrated a statistical association to NPI score (Spearman's Rho=-0.28 to -0.51; Table 15.11). When assessed by

Table 15.9 Table presenting the baseline characteristics for each of the three study sites for each of the study intervention groups.

Characteristics	Centre 1		Centre 2		Centre 3	
	General Quads Group	VMO Group	General Quads Group	VMO Group	General Quads Group	VMO Group
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
N (freq).	4	1	6	4	5	8
Age (years)	23.0 (16.5-36.3)	23.0 (NE)	22.5 (20.5-24.8)	32.0 (21.5-35.4)	21.0 (19.2-25.1)	18 (16.0-19.0)
Family Hx of Patellar Dislocation (yes)	0	0	0	0	0	2
Gender (males/females)	3/1	1/0	3/2	3/1	3/2	4/3
Duration from injury to physiotherapy (weeks)	4.5 (14.0-45.8)	27 (NE)	17.5 (7.3-32.8)	7.5 (4.0-9.5)	42.0 (21.5-50.5)	16 (14.0-28.0)
Disability of the treatment leg (yes)	0	0	0	3	0	0
Contralateral PFI (yes)	0	0	2	1	0	2
Disability of the contralateral leg (yes)	0	0	1	0	0	0
Multi-joint problems (yes)	0	0	0	1	1	0
Beighton Hypermobility Score	4.0 (2.5-5.5)	0.0 (NE)	3.0 (0.8-4.3)	0.0 (0.0-4.5)	2 (1.5-5.0)	7.0 (0.0-8.0)
Isometric extensor muscle strength – 0° flexion (N)	64.7 (51.0-100.0)	57.8 (NE)	0.0 (0.0-69.6)	41.2 (8.8-57.8)	69.6 (0.0-75.5)	57.8 (0.0-91.1)
Isometric extensor muscle strength – 30° flexion (N)	120.5 (59.8-155.8)	108.8 (NE)	44.1 (31.4-158.8)	80.4 (42.1-119.6)	106.8 (86.2-145.0)	83.3 (52.9-228.3)
Isometric extensor muscle strength – 60° flexion (N)	110.7 (43.1-176.4)	88.2 (NE)	54.9 (42.1-146.0)	78.4 (17.6-98.0)	144.1 (116.6-202-9)	105.8 (80.4-185.2)
Isometric extensor muscle strength – 90° flexion (N)	103.9 (5.9-219.5)	117.6 (NE)	10.8 (0.0-138.2)	41.2 (0.0-93.1)	201.9 (102.9-243.0)	118.6 (92.1-216.6)
Tegner Level of Activity Score	3.5 (0.8-4.8)	2.0 (NE)	1.5 (1.0-2.5)	1.5 (0.3-2.0)	4.0 (1.5-4.5)	1.0 (0.0-2.0)
Lysholm Knee Score	62.0 (18.5-88.3)	38.3 (NE)	20.0 (16.3-43.5)	29.5 (12.5-44.3)	64 (58.0-71.0)	15.0 (12.0-70.0)
SF-12	31.0 (31.0-43.0)	32.0 (NE)	31.0 (27.5-35.5)	31.0 (21.5-34.5)	38 (32.0-39.5)	27.0 (23.0-32.0)
NPI score	36.2 (8.1-66.6)	24.2(NE)	40.8 (7.9-51.6)	22.7 (11.9-62.5)	33.7 (6.1-39.4)	37.6 (16.5-66.4)

Freq – frequency; IQR – inter-quartile range; N - newtons; NE – not estimable; NPI score – Norwich Patellar Instability Score; PFI – patellofemoral instability; SF-12 – short form-12; VMO – vastus medialis oblique

Table 15.10. Table to illustrate the descriptive statistical analysis of the outcomes for each group from each of the three recruiting sites at six week follow-up.

Outcome	General Quadriceps Exc. Group			ANOVA (p-value)	VMO Exc. Group			ANOVA (p-value)
	Centre 1	Centre 2	Centre 3		Centre 1	Centre 2	Centre 3	
Mean isometric extensor muscle strength – 0° flexion (N)	106.8 (27.4)	89.2 (59.8)	199.0 (24.5)	0.29	72.5	105.8 (58.8)	120.5 (30.4)	0.32
Mean isometric extensor muscle strength – 30° flexion (N)	172.5 (37.2)	124.5 (68.6)	229.3 (123.5)	0.23	120.5	149.9 (60.8)	216.6 (62.7)	0.95
Mean isometric extensor muscle strength – 60° flexion (N)	204.8 (64.7)	108.8 (53.9)	232.3 (106.8)	0.54	93.1	170.5 (45.1)	202.9 (41.2)	0.90
Mean isometric extensor muscle strength – 90° flexion (N)	217.6 (89.2)	119.6 (65.7)	235.2 (97.0)	0.80	118.6	119.6 (65.7)	204.8 (58.8)	0.59
Mean Tegner Level of Activity Score	3.4 (1.3)	3.4 (1.3)	4.0 (1.7)	0.58	2.0	2.0 (1.7)	3.2 (1.8)	0.92
Mean Lysholm Knee Score	84.8 (20.9)	66.8 (16.7)	89.0 (9.5)	0.59	71.0	56.7 (24.8)	83.2 (19.9)	0.74
Mean SF-12	38.3 (5.9)	35.0 (4.7)	39.7 (3.2)	0.72	36.0	26.3 (13.2)	39.2 (6.5)	0.27
Mean NPI score	15.0 (13.5)	28.2 (18.8)	14.1 (15.3)	0.48*	24.6	14.1 (12.6)	12.0 (13.1)	0.66
Mean duration of physiotherapy (weeks)	5.0 (2.2)	5.8 (0.4)	5.3 (1.85)	0.86*	2.0	6.0 (0.0)	5.4 (0.9)	0.12
Mean number of physiotherapy sessions	4.8 (3.0)	4.8 (1.1)	2.67 (0.58)	0.06	3.0	5.0 (1.0)	2.4 (0.6)	0.35
Mean duration participant continued with exercises (weeks)	4.3 (2.6)	5.8 (0.4)	5.3 (1.2)	0.79*	2.0	14.1 (12.6)	4.2 (2.5)	0.16
Freq. of DNA	0	0	0	NE	0	2	0	0.33**
Freq. of recurrent dislocation	0	0	0	NE	0	1	0	0.64**
Duration to1st recurrent dislocation (weeks)	0	0	0	NE	0	3 (actual)	0	0.33**

Parenthesis signified standard deviation values. DNA – Did not attend; Exc – Exercise; N – newtons; NE – Not estimatable; NPI score – Norwich Patellar Instability Score; SF-12 – short form-12; VMO – vastus medialis oblique.

Table 15.11. Table to demonstrate the correlation between NPI score and outcomes between the two exercise groups at baseline.

Outcome correlated to frequency of exercise	Entire Cohort		General Quadriceps Exercise Group		VMO Exercise Group	
	Rho value	P-value (95% CI)	Rho value	P-value (95% CI)	Rho value	P-value (95% CI)
Isometric extensor muscle strength – 0° flexion (N)	-0.08	0.70 (-0.45,0.31)	-0.18	0.51 (-0.64,0.36)	0.03	0.93 (-0.55,0.59)
Isometric extensor muscle strength – 30° flexion (N)	-0.26	0.18 (-0.59,0.13)	-0.19	0.49 (-0.64,0.36)	-0.29	0.35 (-0.74,0.34)
Isometric extensor muscle strength – 60° flexion (N)	-0.38	0.05 (-0.67,0.00)	-0.31	0.26 (-0.71,0.24)	-0.39	0.21 (-0.79,0.24)
Isometric extensor muscle strength – 90° flexion (N)	-0.36	0.07 (-0.65,0.03)	-0.24	0.34 (-0.69,0.27)	-0.35	0.26 (-0.77, 0.28)
Tegner Level of Activity Score	-0.28	0.15 (-0.60,0.11)	0.03	0.91 (-0.49,0.54)	-0.68	0.02 (-0.90,-0.17)
Lysholm Knee Score	-0.51	0.01 (-0.75,-0.16)	-0.48	0.07 (-0.80,0.04)	-0.65	0.02 (-0.89,-0.13)
SF-12	-0.33	0.09 (-0.63,0.05)	-0.14	0.62 (-0.61,0.40)	-0.64	0.03 (-0.89,-0.10)

CI – confidence intervals; N - newtons; SF-12; Short form-12; VMO – vastus medialis oblique

treatment allocation, only the Tegner Level of Activity Score, the Lysholm Knee Score, and the SF-12 showed any statistical relationship to the NPI score in the specific-VMO group (Rho=-0.64 to -0.68). No clinical outcomes measured at baseline were demonstrated to be statistically related to the NPI score in the general quadriceps group.

Table 15.12. Table to demonstrate the correlation between NPI score and outcomes between the two exercise groups at six week follow-up.

Outcome correlated to frequency of exercise	**Entire Cohort**		**General Quadriceps Exercise Group**		**VMO Exercise Group**	
	Rho value	**P-value (95% CI)**	**Rho value**	**P-value (95% CI)**	**Rho value**	**P-value (95% CI)**
Isometric extensor muscle strength – 0° flexion (N)	-0.66	<0.01 (-0.85,-0.32)	-0.65	0.02 (-0.89,-0.12)	-0.73	0.03 (-0.94,-0.14)
Isometric extensor muscle strength – 30° flexion (N)	-0.58	0.01 (-0.81,-0.20)	-0.41	0.19 (-0.80,0.22)	-0.87	<0.01 (-0.97,-0.48)
Isometric extensor muscle strength – 60° flexion (N)	-0.66	<0.01 (-0.85,-0.32)	-0.62	0.03 (-0.88,-0.08)	-0.92	<0.01 (-0.98,-0.65)
Isometric extensor muscle strength – 90° flexion (N)	-0.66	<0.01 (-0.85,-0.32)	-0.58	0.05 (-0.87,10.01)	-0.70	0.04 (-0.93,-0.07)
Tegner Level of Activity Score	-0.53	0.01 (-0.78,-0.12)	-0.43	0.16 (-0.81,0.19)	-0.96	<0.01 (-0.99,-0.81)
Lysholm Knee Score	-0.68	<0.01 (-0.86,-0.35)	-0.63	0.03 (-0.88,-0.08)	-0.85	<0.01 (-0.97,-0.44)
SF-12	-0.79	<0.01 (-0.91,-0.55)	-0.78	<0.01 (-0.94,-0.38)	-0.87	<0.01 (-0.97,-0.48)

CI – confidence intervals; N - newtons; SF-12; short form-12; VMO – vastus medialis oblique

In contrast, isometric knee extension strength at 0°, 60° and 90° knee flexion, Lysholm Knee Score and SF-12 at the six week follow-up period demonstrated a statistically significant relationship to the NPI (Table 15.12). The isometric

knee extension strength at 30° knee flexion (Rho=-0.41, p=0.19), and the Tegner Level of Activity Score (Rho=-0.43, p=0.16) did not demonstrate this statistical relationship. There appeared a trend for a greater association between the outcomes and the NPI for the specific-VMO group compared to the general quadriceps exercise group (Table 15.12).

Due to insufficient data, the assessment of this relationship at six months was not analysed.

15.8.2 Internal consistency

The NPI score demonstrated high internal consistency between the 19 items (Table 15.13). Cronbach's alpha values of above 0.90 were reported at the baseline and six month analyses. The lowest value reported was 0.86 (lower confidence interval: 0.72), reported at the six week follow-up NPI score by the VMO group.

Table 15.13. Table to illustrate the results of the internal consistency analysis for the NPI at each follow-up period.

Follow-up Period	Entire Cohort	General Quadriceps Exc Grp (95% CI)	VMO Exc Grp (95% CI)
Baseline	0.95 (0.92,.0.98)	0.95 (0.91,0.99)	0.96 (0.92,1.00)
6 weeks	0.93 (0.90,0.96)	0.95 (0.91,0.99)	0.86 (0.72,1.00)
6 months	0.99 (0.99,0.99)	1.00 (1.00,1.00)	0.99 (0.96,1.00)

CI – Confidence intervals; Exc – exercise; Grp – group; VMO – vastus medialis oblique

15.8.3 Floor-ceiling effect

The NPI score baseline data indicated a high risk of a floor-effect, with a high proportion of the cohort reporting the lowest possible value to indicate no disability (Table 15.14). Specific questions where this was particularly evident included those related to walking in a straight line on an uneven (Question 5) or even surface (Question 16), getting in and out of a car (Question 17) and looking over a shoulder (Question 19). The baseline data suggested less of a ceiling effect. Nonetheless, questions related to descending stairs (Question 9), kneeling (Question11) and getting in and out of a car (Question 17) were reported as always causing patellar instability symptoms for 20% to 25% of the cohort.

The six week data reported no indication of a ceiling-effect (Table 15.15). However a higher proportion of the population reported no perceived instability symptoms, using the minimal response for a large number of questions (Table 15.15). Questions such as turning to look over a shoulder (Question 19) and walking in a straight line on an even surface (Question 16) again presented with a floor-effect similar to the baseline measurement. These questions were reported as not associated to any symptoms of patellar instability by 67% and 59% of respondents respectively.

Due to insufficient data, the assessment of a floor-ceiling effect was not analysed using the six month dataset.

15.8.4 Responsiveness

Whilst the NPI score demonstrated a responsiveness to change in the specific-VMO exercise group between the baseline to six week follow-up period ($p=0.01$; 95% CI: -34.59, -5.45), this was not demonstrated between the six

Table 15.14. Table to illustrate the assessment for a floor-ceiling effect from the baseline dataset for each group.

Quest.	NPI Score Item	Entire Cohort				General Quadriceps Exercise Group				VMO Exercise Group			
		Min Response: Floor Effect		Max Response: Ceiling Effect		Min Response: Floor Effect		Max Response: Ceiling Effect		Min Response: Floor Effect		Max Response: Ceiling Effect	
		Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%
1	Twisting or changing direction during Sports or PE activities	3	11	2	8	3	20	1	7	0	0	1	8
2	Changing direction when running, such as cutting or slalom	2	8	2	8	2	13	1	7	0	0	1	8
3	Running in a straight line on uneven surfaces	2	8	2	8	2	13	1	7	0	0	1	8
4	Walking on slippery, wet or icy surfaces	4	15	3	11	3	20	1	7	1	8	2	17
5	Running sideways	6	22	2	8	4	27	1	7	2	17	1	8
6	Hopping	4	15	2	8	3	20	1	7	1	8	1	8
7	Jumping	3	11	2	8	3	20	1	7	0	0	1	8
8	Running in a straight line on even surfaces	6	22	2	8	4	27	1	7	2	17	1	8
9	Going down stairs	8	30	4	15	5	33	1	7	3	25	3	25
10	Squatting	4	15	3	11	3	20	2	13	1	8	1	8
11	Kneeling	4	15	4	15	3	20	3	20	1	8	1	8
12	Walking in a straight line on uneven surfaces	8	30	4	15	7	47	2	13	1	8	2	17
13	Climbing stairs	7	26	3	11	3	20	1	7	4	33	2	17
14	Stepping onto or over a high step	8	30	4	15	5	33	2	13	3	25	2	17
15	Crossing my legs when sitting	5	19	2	8	3	20	1	7	2	17	1	8
16	Walking in a straight line on even surfaces	14	52	3	11	8	53	1	7	6	50	2	17
17	Getting in and out of a car	10	37	4	15	6	40	1	7	4	33	3	25
18	Turning a heavy trolley round a supermarket aisle	6	22	3	11	4	27	1	7	2	17	2	17
19	Turning to look over my shoulder	22	81	2	8	13	87	1	7	9	75	1	8
20	*Total*	2	8	0	0	*2*	*13*	*0*	*0*	*0*	*0*	*0*	*0*
21	*Percentage*	2	8	0	0	*2*	*13*	*0*	*0*	*0*	*0*	*0*	*0*

Freq – Frequency; Max – Maximum; Min – Minimum; NPI – Norwich Patellar Instability; PE – Physical education; Quest – Question

Table 15.15. Table to illustrate the assessment for a floor-ceiling effect from the six week follow-up period dataset for each group.

Quest.	NPI Score Item	Entire Cohort				General Quadriceps Exercise Group				VMO Exercise Group			
		Min Response: Floor Effect		Max Response: Ceiling Effect		Min Response: Floor Effect		Max Response: Ceiling Effect		Min Response: Floor Effect		Max Response: Ceiling Effect	
		Freq	%	Freq	%	Freq	%	Freq	%	Freq	%	Freq	%
1	Twisting or changing direction during Sports or PE activities	4	15	1	4	1	8	1	8	3	33	0	0
2	Changing direction when running, such as cutting or slalom	6	22	1	4	1	8	1	8	5	56	0	0
3	Running in a straight line on uneven surfaces	5	19	0	0	2	17	0	0	3	33	0	0
4	Walking on slippery, wet or icy surfaces	3	11	1	4	2	17	1	8	1	11	0	0
5	Running sideways	7	26	0	0	4	33	0	0	3	33	0	0
6	Hopping	9	33	0	0	5	42	0	0	4	44	0	0
7	Jumping	5	19	0	0	2	17	0	0	3	33	0	0
8	Running in a straight line on even surfaces	7	26	0	0	3	25	0	0	4	44	0	0
9	Going down stairs	8	30	0	0	4	33	0	0	4	44	0	0
10	Squatting	7	26	0	0	4	33	0	0	3	33	0	0
11	Kneeling	7	26	1	4	4	33	1	8	3	33	0	0
12	Walking in a straight line on uneven surfaces	12	44	0	0	7	58	0	0	5	56	0	0
13	Climbing stairs	9	33	0	0	5	42	0	0	4	44	0	0
14	Stepping onto or over a high step	11	41	0	0	6	50	0	0	5	56	0	0
15	Crossing my legs when sitting	13	48	0	0	6	50	0	0	7	78	0	0
16	Walking in a straight line on even surfaces	16	59	0	0	8	67	0	0	8	89	0	0
17	Getting in and out of a car	11	41	0	0	6	50	0	0	5	56	0	0
18	Turning a heavy trolley round a supermarket aisle	7	26	0	0	4	33	0	0	3	33	0	0
19	Turning to look over my shoulder	18	67	0	0	10	83	0	0	8	89	0	0
20	*Total*	1	4	0	0	*1*	*8*	*0*	*0*	*0*	*0*	*0*	*0*
21	*Percentage*	1	4	0	0	*1*	*8*	*0*	*0*	*0*	*0*	*0*	*0*

Freq – Frequency; Max – Maximum; Min – Minimum; NPI – Norwich Patellar Instability; PE – Physical education; Quest – Question

weeks to six month interval (p=0.14), or at any time period for the general quadriceps exercise group (p≥0.14). In the specific-VMO group, the Cohen's effect size for the baseline to the six week follow-up NPI score was 0.46 (Cohen's D=1.03), and 0.39 (Cohen's D=0.85) for the six week to six month dataset. The Cohen's effect size in the general quadriceps group for the baseline to six week follow-up was 0.24 (Cohen's D=0.48), and 0.40 (Cohen's D=0.87) for the six week to six month follow-up data.

15.9 Summary

This chapter has reported that whilst higher functional scores were reported in the general quadriceps compared to the specific-VMO group at six weeks, there was no statistically or clinically significant difference between the interventions for the other clinical outcome measurements reported. There was no statistically significant difference between the groups at six months. This chapter also highlighted that the expected recruitment rate and anticipated loss to follow-up did not behave as planned during the design of the study.

The purpose of the following chapter is to consider why such differences occurred and to discuss the clinical and research implications of the study's findings.

Chapter 16. RCT Discussion

16.1 Introduction

This study aimed to identify a difference in functional or clinical outcomes between individuals prescribed general quadriceps exercises compared to specific-VMO exercises following FTPD. The results indicated that whilst higher functional scores were reported in the general quadriceps group at six weeks, there were no statistically or clinical significant differences at six months.

This chapter will firstly examine possible explanations for the findings of each outcome measurement (Section 16.2), consider potential limitations to the study design which may have impacted on the results obtained, and will consider how these could be avoided in the future (Section 16.3). This chapter will also explore the clinical implications of these findings (Section 16.4), and will make recommendations for future study to build on this study (Section 16.5).

16.2 Explanations for the Findings

The study's primary outcome was Lysholm Knee Score at six weeks. The results indicated a difference between the groups, with lower disability in the general quadriceps compared to the specific-VMO exercise group. Whilst this was a statistically significant difference (p=0.02), the mean difference was only 5.3 points (Table 15.4). Although the MICD for the Lysholm Knee Score has yet to be formally determined in the FTPD population, this value has been documented as 8.9 points in the anterior cruciate ligament injury population (Briggs et al, 2009). The difference of five points identified may therefore not be clinically meaningful. There was a 30 point mean difference between the groups at six months (Table 15.5). Whilst being clinically meaningful (Briggs

et al, 2009), this did not reach statistical significance (p=0.68). The small sample which constituted the six month analysis may account for this finding, with a possible type II statistical error (Bland, 2006). This is justified given that the power calculation indicated that a minimum of 18 individuals would be required in each group to detect a statistical difference if one existed. The underpowered sample for this analysis was attributed to a high attrition rate where 56% of the potential cohort was lost to follow-up at six months. The reason for participant attrition was none attendance to their follow-up appointment. The reason why participants did not attend these review appointments was not determined. This limitation may have been the major contributing factor for why none of the six month analyses demonstrated a statistically significant difference between the groups. However, there was no statistically significant difference in baseline characteristics between those followed-up and those lost to follow-up at six weeks or six months (Table 15.1; Table 15.2). This therefore provides some assurance that the findings reported may have some representation to the overall cohort, rather than there being substantial differences between those who did, and those who did not attend their follow-up appointments.

There was a significant increase in both group's Tegner Level of Activity score from baseline to each follow-up period (Table 15.6). The mean differences between the groups varied from 1.4 to three points (Table 15.4; Table 15.5). Whilst not assessed in the FTPD population, a difference of one point has been recommended as the MICD for individuals following anterior cruciate ligament injury (Briggs et al, 2009). However, previous authors have speculated that a major limitation to the Tegner Level of Activity score is its inability to differentiate between individuals who can physically participate in higher level activities but consciously choose not to, and people who participate in higher level activities but experience physical limitations (Fuchs and Friedrich, 2000). These weaknesses have not been empirically investigated but were observed as

possible limitations to the Tegner Level of Activity score in Fuchs and Friedrich's (2000) reliability study of various knee and activity scores based on a cohort of 96 individuals with knee osteoarthritis. Nonetheless the Tegner Level of Activity score remains the only measure of physical activity which has been demonstrated to be reliable and valid for the FTPD population (Paxton et al, 2003).

No clinically or statistically significant difference was detected between the groups in respect to the SF-12 score at six weeks or six months (Table 15.4; Table 15.5). This was most notable at the six week follow-up with a single point difference between the groups (median: 37.0 versus 38.0). At six months this median difference was 15.5, a clinically meaningful value, given that the MICD for the SF-12 has been estimated as between three to five points for the general population and those following lower limb surgery (Drummond, 2001; Marsh et al, 2009). As discussed earlier, the small sample size constituting the six month analyses may have accounted for the non-statistically significant findings (Table 15.4; Table 15.5; Bland, 2006). The difference between the groups at six months reflected the overall trend in perceived functional outcomes where the general quadriceps group reported less disability compared to the specific-VMO exercise group (Table 15.5). Whilst an improvement in perceived general health after hospital discharge has previously been reported in cohorts following cardiac failure (Soriano et al, 2010) and colorectal surgery (Blazeby et al, 2010), this would not explain why there was a median difference of 15.5 between the groups at six months. Whether this was due to the intervention or a chance finding remains unclear since this analysis was underpowered.

There was no statistically significant difference in NPI score between the groups at six weeks ($p=0.50$) or six months ($p=0.99$). Participant's reported greater instability symptoms through the NPI score at baseline compared to six

weeks (p=0.03; Table 15.3; Table 15.4). This difference can be partly accounted through the design of the NPI questionnaire. The NPI questionnaire provides a "don't do" response. This response option was frequently used during the baseline assessment to indicate that participants were unable to perform many activities at this early stage prior to rehabilitation. This constituted 29% of possible responses. In contrast, at six weeks, respondents less frequently used this "don't do" response (22%), reporting participation in a greater array of activities. This may have conversely suggested that participants may experience greater instability symptoms with increased engagement with more physically demanding tasks potentially causing instability. However the findings indicated that patellar instability was less frequently reported at six weeks. This reflected the improvement in functional outcomes demonstrated through the Lysholm Knee Score and isometric knee extension strength (Table 15.5). This is also in agreement with previous literature on the early recovery of people conservatively managed following FTPD (Osterhues, 2004; Racouillat, 2007; Helgeson and Smith, 2008). All three previous single-subject case-studies detailing the early outcomes of physiotherapy for this population reported reduced subjective instability and enhanced recovery at five to nine weeks post-FTPD (Osterhues, 2004; Racouillat, 2007; Helgeson and Smith, 2008).

A secondary objective of this RCT was to assess the behaviour of the NPI score in relation to clinical measurements. The NPI score statistically correlated with all outcome measurements at six weeks (Table 15.12). There was no statistical correlation between the NPI score and baseline data (Table 15.11). This finding cannot be fully explained. However, as discussed above, as respondents frequently used the "don't do" option at baseline, the NPI score may not necessarily reflect the status of individuals who had recently experienced a FTPD. The "don't do" response was considered important to minimise the risk of respondents not completing every question posed (Chapter 13, Section

13.3.2.3). However this opinion may make the interpretation of the NPI score more difficult, particularly in those who are severely functionally limited.

The NPI questionnaire demonstrated a high degree of correlation between each of the 19 items posed (Cronbach's alpha: 0.86-1.00). A Cronbach's alpha value of 0.70 to 0.90 has been considered optimal to indicate that items which assess a similar domain do not repeat themselves (Streiner and Norman, 2008). However the NPI questionnaire frequently demonstrated a floor-effect (Table 15.14; Table 15.15). This was particularly apparent for less physically demanding activities such as getting into and out of a car and turning to look over a shoulder (Table 15.14; Table 15.15). Consequently, these items may reduce the NPI score's ability to demonstrate clinical changes (Streiner and Norman, 2008). It remains unclear whether this phenomenon would be present when assessed with different patellar instability populations such as those who have experienced recurrent patellar dislocation or those with severe trochlear dysplasia. In contrast, the current format of the NPI questionnaire presented with little evidence of a ceiling-effect. The NPI score may therefore be considered a suitable instrument to assess more functionally-capable respondents following FTPD.

The principal objective of a muscle strengthening exercise programme is to increase muscle strength (Brukner and Khan, 2010; Norris 2000). Numerous studies have demonstrated that isometric and isokinetic quadriceps exercises can significantly increase knee extension strength over three week (Ferber et al, 2011), eight week (Wong et al, 2009) and five month periods (Konishi et al, 2009). Whilst the specific-VMO exercise programme used in this study was based on EMG studies which have demonstrated an ability to preferentially recruit the VMO (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006; Chapter 6, Section 6.9), it was expected that this exercise

programme could also increase knee extension strength (Syme et al, 2009; Kirnap et al, 2005). Whilst not statistically significant, there appeared a small mean difference in isometric knee extension strength between the groups at six weeks, where the specific-VMO exercise group demonstrating higher strength compared to the general quadriceps group (MD: nine to 13 Newtons; $p \geq 0.18$). This trend was not apparent at six months (Table 15.5). At this later follow-up, isometric knee extension strength was greater in the specific-VMO group compared to the general quadriceps group only for the zero and 30° knee angulation measurements. The reverse was however reported at the 60° and 90° measurements. This difference did not reach statistical significance ($p \geq 0.55$; Table 15.5). The variation in results at six months based on knee angulation may be contrary to Tang et al (2001) and Basmajian et al's (1971) findings that the VMO demonstrates its greatest activity at 60° knee flexion. However this difference may be attributed to their findings being based on healthy participants or those diagnosed with PFPS rather than FTPD. Furthermore, whilst previous authors have acknowledged a relationship between EMG activity and muscle strength for healthy populations (Robbins et al, 2010; Fujita et al, 2011; Sedliak et al, 2008), it is unclear whether this remains representative in the FTPD population.

A change in isometric extension strength was plausible within the initial six week follow-up period. Previous studies which have assessed structural and metabolic changes in response to exercise have demonstrated that heat shock protein (HSP) 70, HSP60 and heat shock cognate 70 expression significantly increases which typically peak at 48 hours post-exercise to 210%, 170%, and 139% of pre-exercise levels respectively (Morton et al, 2006). This family of highly conserved cytoprotective proteins are important since they have a major role in maintaining muscle homeostasis, facilitate repair after injury, principally facilitating the cellular remodelling processes (Morton et al, 2009). With the limited expression of these proteins, muscle recovery would be severely

limited, demonstrated through a poorer training response (Morton et al, 2009). Exercise regimes have demonstrated greater muscle oxidative capacity through an improvement in adaptive signalling response of mitochondrial biogenesis (Wang et al, 2011). This was demonstrated in 10 healthy individuals following a resistance and endurance exercise programme compared to endurance exercises alone (Wang et al, 2011). The results suggested that resistance programmes are important in improving muscle capacity, and can demonstrate changes at a cellular level after commencing a training regime (Wang et al, 2011).

Resistance exercises have demonstrated the ability to increase muscle cross-sectional area as early as nine weeks after commencing an exercise programme (Moore et al, 2011). Furthermore, it is generally accepted that neural factors play an important role in muscle strength gains (Gabriel et al, 2006). In the early phases of training regimes, an increase in neural drive has been demonstrated to denote an adaptation of efferent neural output from the central nervous system to active muscle fibres, resulting in an increase in motor unit firing rate (Gabriel et al, 2006). Similarly Farthing et al (2007) explained that an increase in strength may be partly controlled by adaptations within the sensorimotor cortex, consistent with previous studies of motor learning during the first six weeks after commencing an isometric exercise programme (Farthing et al, 2007). Whilst justifying how isometric strength can increase from baseline, the above studies were undertaken on healthy people. It therefore remains unclear whether the increase in isometric muscle strength demonstrated in this study can be attributed to these previously demonstrated findings, or whether exercise response differs with HSP activity and enhanced inflammatory responses during early tissue repair following FTPD.

Only one participant experienced a recurrent patellar dislocation during the study period. This occurred three weeks after being randomised to the specific-

VMO exercise group. Given this, no statistically significant difference was demonstrated between the groups in recurrent dislocation events ($p \geq 0.43$). This low frequency may have been expected given the relatively short follow-up period adopted. The optimal follow-up period to assess recurrent patellar dislocation has been estimated by Mäenpää et al (1997) who recorded the time from primary to recurrent dislocation. They reported that the time between these events ranged from three weeks to 6.5 years in their observational study assessing treatment outcomes of 75 participants over a six to 25 year follow-up period. Participants most frequently experienced a second dislocation at two to three years post-FTPD.

The finding of a low recurrent dislocation rate is particularly important given that the VMO-specific exercise group performed their exercises in differing degrees of lower limb rotation. Since limb rotation has been associated with patellar instability (Atkin et al, 2000; Fithian et al, 2004b; Sillanpää et al, 2008a), the results suggested that specific-VMO exercises did not place the individual at greater risk of re-injury. Similarly only one participant reported a complication other than redislocation during the study. This individual, randomised to the specific-VMO group, was diagnosed with a partial medial meniscal tear at six weeks. They were unable to confirm whether this was sustained before or after commencing the study. Given this confusion and the finding that neither intervention was associated with any other complications, both the general quadriceps and specific-VMO exercises can currently be considered safe in clinical practice.

There was no significant difference between the groups in respect to the number of physiotherapy appointments attended or the duration of physiotherapy (Table 15.4; Table 15.5). At six months, the specific-VMO group had attended physiotherapy for longer than the general quadriceps group (median difference: 2.5 weeks; Table 15.5). This should be considered with caution given the small

number of participants involved in this analysis. The frequency and duration of physiotherapy were determined by the treating clinician. Thus, if a clinician believed that their patient required a greater duration of treatment, this was permitted and recorded. Such a difference could have reflected poorer clinical outcomes between these groups, or a difference in how well the exercises had been understood by participants. Anecdotally, the treating physiotherapists reported that the specific-VMO exercises were more difficult to teach. They reported that some participants found the replication of these exercises more challenging in different lower limb rotational positions. This may account for why physiotherapists saw their patients more frequently if allocated to the specific-VMO exercise group, to ensure correct exercise technique. No trials have been published assessing the effect of exercise complexity on compliance and outcome. However, previous textbook authors have acknowledged that more complex exercises can be more difficult to teach with a detrimental impact on compliance (Kisner and Colby, 2007). Both the duration and frequency of physiotherapy are important outcomes since they have cost implications for both physiotherapy services and individuals in receipt of treatment.

The duration participants continued their allocated exercises did not statistically differ between the exercise groups (Table 15.4; Table 15.5). Exercise compliance was therefore not a significant confounding variable. This may reflect an equal understanding between both groups in how to perform the exercises. It may also reflect an equally favourable perception toward their prescribed exercise's clinical merits. However, this was not formally evaluated and is therefore speculative. There was no statistically significant correlation between exercise duration and clinical or functional outcomes (Table 15.8). This may have been a consequence of a type II statistical error since previous studies have indicated that increased exercise frequency may correlate to improved outcomes in populations with osteoarthritis of the knee (Rejeski et al,

1997), young adults (Bickel et al, 2011) and older people with a history of cardiac failure (Evangelista et al, 2010).

There was no statistically significant difference between the two exercise groups in respect to the prescription of additional interventions with the allocated strengthening exercise programmes ($p \geq 0.19$; Table 15.7). This result validated the trial's adopted pragmatic design approach since no control was placed on which additional interventions could be used. These results also provided further indication as to which treatments physiotherapists prescribe to individual's following FTPD. The treating physiotherapists in this study most frequently prescribed knee range of motion exercises (70%), ice (44%), gym-based exercises (44%) and proprioceptive exercises (33%) in addition to the allocated strengthening exercise regime. These findings corresponded to the results of the national survey (Chapter 8; Section 8.5). However this survey indicated that reassurance and advice were the most commonly employed interventions; neither were recorded in this study. Whether this was a consequence of these not being pre-defined in the Treatment Log (Appendix 44) or whether the interventions were not provided by any of the treating physiotherapists, remains unclear.

16.3 Limitations of the Study

This study presented a number of limitations. Whilst every effort was made to minimise the potential for under-recruitment, bias, or confounders from influencing the results, these will have had some effect. Possible study weaknesses are examined below.

16.3.1 Recruitment

The anticipated number of participants was not recruited within the study period (Figure 15.1 to Figure 15.3). The power calculation indicated that 36 individuals were required to detect a statistical difference between the groups in Lysholm Knee Score at six weeks (Chapter 14, Section 14.6). It was expected that this number of people would be recruited within nine months. The underpowered cohort of 27 individuals may be a major factor to explain the non-statistically significant findings, most notably for the six month dataset (Table 15.5).

Strategies were used to attempt to prevent this under-recruitment. During the design phase, the frequency of FTPD referrals to each study centre was surveyed during three consecutive months. However, as Figures 15.1 to Figure 15.3 demonstrate, this survey did not reflect what transpired. With hindsight, although less practical, a survey over 12 months would have been more appropriate to provide more accurate referral behaviour. A longer survey could have eliminated possible seasonal variation in referral numbers since the survey was based on numbers referred during winter months only. However this is hypothetical since no studies have assessed the prevalence of FTPD between the seasons.

The recruitment period was increased from nine to 12 months to maximise recruitment within the time constraints of the PhD programme (Appendix 17). This recruitment period may have been further lengthened if not for unexpected delays in obtaining ethical approval. There was an additional one month delay as two centres requested “Research Passports,” not initially required when approvals were sought. An additional five month delay was also experienced in two of the three sites during the processing of the Site-Specific Research Governance approvals. These delays were attributed to the authorising

institute's processing time rather than the requirement for extensive amendments. Whilst this additional six months would have been insufficient to recruit the total number of participants required, it did prevent a greater number from being recruited, thereby reducing the power of the trial's findings (Bland, 2006).

Further strategies were adopted to enhance participant recruitment once it was apparent that the number of potentially eligible participants was lower than initially expected. Strategies included the use of study posters to remind each site about the study (Appendix 49), weekly email up-dates on recruitment rates sent to each site's Principal Investigator, and monthly recruitment graphs (Appendix 50). The researcher visited each site once every 12 weeks to deliver face-to-face teaching sessions on RCT design and recruitment and on topics surrounding FTPD. Previous studies have acknowledged these strategies as potentially beneficial. Monaghan et al (2007) assessed the effects of an enhanced communication and training package compared to standard information provision on the recruitment rates of 167 study centres across 19 countries participating in a RCT. Whilst there was no significant difference between these interventions in median number of participants recruited per centre between the groups (38 versus 37; p=0.68), the time taken to recruit the cohort was less in those centres who were provided with greater information on recruitment procedures (4.4 months versus 5.8 months). This did not however reach statistical significance (p=0.08). Campbell et al's (2007) systematic review of 114 studies also identified that trial newsletters or mail shots demonstrated significantly increased recruitment rates amongst study centres. This thereby supported the use of the monthly recruitment graphs and increased email correspondence with Principal Investigators.

16.3.2 Loss to Follow-Up

The large lost to follow-up was a major study limitation. The anticipated drop-out was 20% (Chapter 14, Section 14.6), based on the attrition rates from 27 studies which had assessed the conservative management of individuals following FTPD (Chapter 5, Section 5.3). In these studies, the proportion of participants lost to follow-up ranged from zero percent (Mäenpää et al, 2000; Camanho et al, 2009; Nikku et al, 1997; Nikku et al, 2005; Cash and Hughston, 1988; Savarese and Lunghi, 1990; Atkin et al, 2000; Hawkins et al, 1986; Mäenpää and Lehto, 1997a; Kiviluoto et al, 1986; Mäenpää et al, 1997) to 37% (Mäenpää and Lehto, 1997b). Marcacci et al (1995) however reported that 56% of their cohort was lost to follow-up. This study's findings may be attributed to the long follow-up period which averaged 30 years. Given this, whilst the six week attrition rate of 22% may be typical, the six month rate of 56% was not. When assessed further, the only major difference between the follow-up strategies employed in this RCT compared to the previous literature was the adoption of a multi-centre recruitment and data collection policy. All but two studies which have assessed the conservative management of people following FTPD were performed from a single-centre. Whilst Nikku et al's (1997; 2005) studies were multi-centred; they were based in two hospitals within the same city (Helsinki). In contrast, the three sites selected in this RCT were situated across the East of England, covering a greater geographical area than one city.

Multi-centre trials present greater logistical difficulties than single-centre studies (Friedman et al, 1998). Nonetheless, it was vital in this study to attempt to recruit sufficient participants within the permitted time-frames. However the multi-centred approach diminished the researcher's ability to directly manage recruitment and follow-up procedures. The researcher liaised closely with each clinical site to ensure that follow-up appointments were booked, and re-booked if participants did not initially attend. However, the role of the researcher may

have been a limiting factor contributing to attrition. Previous authors have recommended the employment of study trial managers to co-ordinate the day-to-day running of clinical trials (Campbell et al, 2007). A major role for these individuals is to ensure that all follow-up appointments occur in a timely fashion. Whilst every effort was made by the researcher to instil this within all study centres, the researcher was only able to visit each centre every 12 weeks. Although email contact was made weekly, this face-to-face contact anecdotally appeared to have a greater impact on ensuring study protocol compliance amongst the centres. This study may therefore have been ambitious for a part-time PhD student to design, manage and complete.

Strategies were adopted to maximise the attraction for participants to remain in the trial without coercion. Strategies included covering transport costs to follow-up appointments, minimising potential assessment fatigue by including infrequent and short follow-up appointments and providing individuals with a number of opportunities to ask questions about the study's procedures and FTPD. These were informed from previous findings on maximising the retention of participants in clinical trials (Caldwell et al, 2010; Watson and Torgerson, 2006; Goode et al, 2008).

Factors previously identified to enhance participant retention have included minimising the duration between baseline assessment and the first treatment, and to provide a structured advice intervention within the trial (Kalkhuis-Beam et al, 2011). Gifts or financial incentives were not provided in this study to retain participants as such incentives may coerce individuals into participation when they may not necessarily wish to (Tishler and Reiss, 2011). Furthermore, due to the costs associated, this strategy was not affordable. Five studies have assessed the effect of using incentives for enhancing retention of participants in prospective clinical trials (Henderson et al, 2010; Loftin et al, 2005; Boys et al, 2003; Katz et al, 2001; Burgess and Sulzer, 2011). All but one suggested that

incentives can significantly increase both recruitment and retention ($p<0.05$; Henderson et al, 2010; Loftin et al, 2005; Boys et al, 2003; Katz et al, 2001). In contrast, Burgess and Sulzer (2011) reported in their survey of 302 participants, that gifts did not influence an individual's decision on whether to participate or remain in a trial. However respondents to Burgess and Sulzer's (2011) survey were all enrolled into cardiovascular clinical trials in South Africa. It is unclear whether this trend is generalisable to UK participants who participate in orthopaedic or physiotherapy studies.

Social media networks and text-messaging have been used to improve trial retention of populations with known low retention rates. No studies have assessed the use of text-messaging on clinical trial retention in orthopaedic or physiotherapy studies. Text-messaging has however been shown to enhance follow-up retention in studies in ophthalmology (Brannan et al, 2011), smoking cessation (Free et al, 2011), low back pain (Kongsted and Leboeuf-Yde, 2010) and physical activity in adolescents (Lau et al, 2011). Whilst not assessed in physiotherapy trials, the use of social media has recently been investigated in one clinical trial. In a study of 1,588 people enrolled in a RCT testing the efficacy of Human Immunodeficiency Virus (HIV) prevention education using Facebook, Bull et al (2011) reported that this social network website was an effective means of communicating health promotion. They also recommended that whilst social networks are growing in popularity, conducting research on social media sites requires deliberate attention to consent, confidentiality and security problems (Bull et al, 2011). Further study is required to examine whether the use of social networking sites for data collection or the retention of participants is safe and appropriate in future clinical trials.

Internet or telephone follow-up may have reduced attrition. One study assessing the management of FTPD collected their mid-term data by telephone (Palmu et al, 2008). Four trials have assessed the used of text-messaging for data

collection rather than face-to-face methods in populations with irritable bowel syndrome (Kew, 2010), low back pain (Kongsted and Leboeuf-Yde, 2009), sexually-transmitted diseases (Lim et al, 2010), and to assess physical activity (Shapiro et al, 2008). All studies demonstrated a higher follow-up rate using text-messaging compared to face-to-face collection. Whilst these strategies may be valuable, particularly in collecting data from geographically disperse cohorts, they rely on mobile phone or internet access. Furthermore such methods are not feasibility for the collection of physical measurements which require manual testing such as isometric knee extension strength as used in this study.

16.3.3 Anatomical Confounding Variables

The integrity of the MPFL has been identified as a potential prognostic indicator for FTPD given its importance in maintaining lateral patellar restraint (Senavongse and Amis, 2005: Panagiotopoulos et al, 2006; Nomura et al, 2000). Individuals with a rupture of the MPFL possess a greater risk of patellar instability compared to those whose MPFL remain intact (Hautamaa et al, 1998; Conlan et al, 1993; Desio et al, 1998). Since the MPFL is not ruptured in all cases following FTPD, there may have been a difference between the groups in respect to the proportion of MPFL deficient knees (Sallay et al, 1996; Sanders et al, 2001; Shea et al, 2006; Balcarek et al, 2010; Sillanpää et al, 2009b). Sillanpää et al (2009b) reported that the location of a MPFL rupture is also a prognostic indicator following FTPD. In this study they compared the clinical outcomes at seven years with 53 people diagnosed with MPFL rupture at either the femoral origin, midsubstance, or at the patellar attachment using MRI (Sillanpää et al, 2009b). All were managed conservative with immobilisation and physiotherapy. The authors reported statistically significantly poorer outcomes in those with a femoral attachment MPFL rupture compared to a midsubstance or patellar attachment lesion ($p=0.05$). However

randomisation was not stratified for this variable in this thesis' RCT. This was because MRI was not normally undertaken as routine practice in the three study centres (Chapter 14, Section 14.5.1) and therefore confounded the pragmatic approach adopted by this RCT. Nonetheless the presence or location of MPFL rupture may have been a confounding variable.

As discussed in Chapter 3 (Section 3.4) there is a natural variation within the population in VMO muscle fibre orientation, its location of attachment to the patella, the presence of an individual innervation to the VMO, EMG activity, anatomical and physiological cross-section, and muscle fibre type. Since neither MRI, ultrasound nor muscle biopsy assessments were evaluated at baseline, these potential confounding variables could have contributed to intra-group differences. However, the importance of these variables on treatment prognosis is unknown as this has not been evaluated in the FTPD population.

There may have been an imbalance in the presence or location of a MPFL lesion or in differences in VMO anatomical composition between the groups given the small sample. The principles of randomisation suggest that with a sufficiently large sample, all known and unknown characteristics are equally distributed between treatment-arms, minimising the potential for baseline imbalances (Friedman et al, 1998; Matthews, 2005; Piantadosi, 2005). However, with the limited sample recruited, these anatomical factors may also have differed between the groups.

16.3.4 EMG Activity

The specific-VMO exercises selected aimed to preferentially strengthen the VMO and to normalise onset timing. The literature neither supports nor refutes that a difference exists in EMG activity in those individuals with FTPD compared to normal controls (Chapter 3, Section 3.4.3.2.2; Mariani and Caruso,

1979; Wild et al, 1982; Møller et al, 1986; Møller et al 1987). However textbooks and previous literature have supported their adoption (Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001). Furthermore the results of the national survey indicated that these exercises are adopted as a treatment for this population (Chapter 8, Section 8.5). No studies have assessed whether there is a difference in EMG onset timing between the VMO and vastus lateralis in the FTPD population (Chapter 3, Section 3.4.3.2.1). This study did not aim to assess why a difference may have occurred. This would have required an explanatory study design (Bland, 2006). Given that the ability of participants to preferentially activate the VMO was not assessed using EMG analyses, it remains unclear whether there was a difference within the specific-VMO group regarding how preferential VMO activation was achieved, if achieved at all. The ability to preferentially recruit the VMO was therefore a further potential confounding variable which could have been addressed through the use of biofeedback systems. However since these are not routinely used in NHS clinics, it was considered inappropriate to specifically include this adjunct in this pragmatic UK trial.

16.3.5 Hypermobility

Generalised joint hypermobility was assessed using the Beighton score (Hakim and Grahame, 2003). Whilst this was equal between the two groups at baseline (Table 15.3), a specific assessment of patellar hypermobility was not made. Nomura et al (2006) compared the assessment of generalised joint hypermobility with patellar hypermobility. They recruited 82 individuals with unilateral recurrent patellar dislocation and compared them to an asymptomatic age- and gender-matched cohort. The authors reported that manual patellar hypermobility was a significantly greater predictor of recurrent patellar dislocation compared to generalised joint laxity ($p<0.001$; Nomura et al, 2006).

However the manual assessment of patellar mobility has recently demonstrated poor intra- (Kappa=0.34; 95%: 0.16, 0.54) and inter-rater reliability (Kappa=0.11; 95% CI: -0.6, 0.27; Smith et al, 2011b). Therefore whilst potentially being a greater predictor, it remains unclear whether manual patellar mobility would be sufficiently reliable to be an accurate prognostic indicator to warrant its inclusion as a stratifying factor.

16.3.6 Outcome Measures

The outcome measures adopted in this study were reliable and valid for this population. Safe-guards were designed to ensure that the follow-up assessments were standardised between assessors, particularly for isometric knee extension strength. The intra- and inter-rater reliability of this measurement was assessed before commencing the study. The results indicated acceptable agreement within- and between-assessors (Chapter 14; Section 14.10). Nonetheless factors such as how participants were instructed and the position of the dynamometry probe on the limb required standardisation across the seven assessors. Given that data were collected over 12 months, these may have varied between the assessors and sites over time. This was not formally assessed. In an attempt to minimise variability, one assessor could have been used throughout. However, due to the multi-centre nature of the study, and the limited funds available, this was not possible. This potential variation should be considered when reviewing the isometric knee extension strength results.

16.3.7 Feasibility Study

Previous authors have highlighted the importance of conducting a pilot or feasibility studies (van Teijlingen and Hundley, 2002). Feasibility studies can inform the sample size calculation for a given treatment effect; recruitment rates; the appropriateness of the selected outcome measurements; and determine

the validity of the study's eligibility criteria (van Teijlingen and Hundley, 2002). Although an assessment of potential recruitment rates was undertaken (Appendix 5), on reflection, a formal feasibility study should have been conducted prior to commencing this trial. The logistical problems principally surrounding the recruitment and retention of participants could have been accounted for before commencing this RCT. Consideration of the merits of feasibility studies should be made when designing future RCTs in this population. In this respect, the following chapter will further explore how such a feasibility study may be conducted based on the findings of this thesis (Chapter 18).

16.4 Clinical Implications

This RCT aimed to determine whether general quadriceps or specific-VMO exercises should be prescribed to individuals following FTPD. At the time of designing the study protocol, this had not been previously undertaken with any population diagnosed with a patellofemoral joint disorder. However since conducting the trial, two studies have addressed this clinical question with PFPS populations (Bennell et al, 2010; Syme et al, 2009). Bennell et al (2010) allocated 60 pain-free individuals with a history of PFPS and a delay (greater than 10 milliseconds) of VMO to vastus lateralis EMG activity during stair-stepping, to a specific-VMO exercise and rehabilitation regime or a general quadriceps exercise and rehabilitation programme. The specific-VMO exercises consisted of isometric 'VMO' contraction exercises at 90° knee flexion, mini-squats to 40° knee flexion in lower limb neutral, isometric VMO contraction exercises with the hip joint in abduction and external rotation in standing and step-dip exercises in lower limb neutral rotation. All exercises were performed with a dual-channel surface EMG biofeedback unit assessing VMO and vastus lateralis activity. The general quadriceps exercises consisted of static quadriceps exercises in full knee extension, straight leg raises to 30°

hip flexion, inner range quadriceps exercises and isokinetic hip abduction exercises in side-lying. The authors reported no statistically significant difference between the two exercise interventions in respect to EMG onset timing ($p=0.76$) or quadriceps strength after 14 weeks ($p\geq0.14$).

Secondly Syme et al (2009) performed a single-blind RCT with 69 people diagnosed with PFPS. The cohort was allocated to either (1) a specific-VMO retraining programme and rehabilitation, (2) a general quadriceps strengthening and rehabilitation programme or (3) a no-treatment control group. The specific-VMO retraining programme consisted of exercises designed to "selectively activate and retrain" the VMO with a dual-channel surface EMG biofeedback unit. The general quadriceps exercises were "based on concentric, eccentric and proprioceptive rehabilitation principles" (Syme et al, 2009). The authors did not specify the type of exercises included in either regime. They reported no statistically significant difference between the specific-VMO and general quadriceps exercise groups for clinical or patient-reported outcome measures at the final eight week follow-up ($p\geq0.27$).

However these papers present two significant limitations. Firstly whilst Syme et al (2009) suggested their study was a pragmatic trial, this may be questioned since the duration and frequency of treatment provided was controlled, thus not permitting flexibility which would normally be demonstrated in clinical practice. Secondly, whilst it is unclear whether patellar taping was routine practice in the participating treatment centre, all participants in Syme et al's (2009) study received patellofemoral taping techniques. This was justified by the authors who suggested that the weight of evidence supporting the use of taping was "irrefutable", making the denial of taping to all participants unethical (Syme et al, 2009). However the mechanism of taping, through potential proprioceptive feedback, may have inadvertently influenced VMO

activity in the general quadriceps as well as the specific-VMO group, thus confounding the results (Gilleard et al, 1998; McConnell, 1986).

The results of both studies concur with this trial's findings that there is little clinical or statistical difference between individuals prescribed general quadriceps exercises compared to specific-VMO exercises. However there were major interventional differences between these three studies. For instance, whilst the exercises performed in Syme et al's (2009) study were not clearly described, both trials stated that all participants used EMG biofeedback units whilst exercising. This adjunct may have acted as a confounding variable compared to exercising without such feedback units (Robertson et al, 2006). Additionally the specific-VMO exercises prescribed in Bennell et al's (2010) study were performed with the lower limb in external rather than internal rotation in contrast to this trial. This contradicts the current evidence-base on preferential VMO recruitment (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006; Chapter 6, Section 6.9). Furthermore, given that the PFPS population present with different clinical features to FTPD cohorts (Boden et al, 1997; Donell, 2006), it would be inappropriate to generalise the findings of these studies to the FTPD population. Nonetheless the trend that clinical outcomes do not differ for people prescribed specific-VMO over general quadriceps exercises is largely reaffirmed by the findings of these studies. This therefore raises questions regarding any assumptions that there is a superiority of one intervention over another.

The NPI score is the first formally constructed outcome measurement of perceived patellar instability. It has demonstrated a degree of convergent validity to other clinical outcomes for individuals who receive physiotherapy following FTPD (Chapter 15, Section 15.8.1). The score has demonstrated its responsiveness to change, significantly demonstrating an initial increase in

instability followed by a decrease over time. However concern remains regarding the use of the "don't do" response option and a high floor-effect. Given this, further study may be warranted to investigate the behaviour of the NPI score before clinical adoption. Strategies to develop this new outcome measure are presented in the following section (Section 16.5).

16.5 Recommendations for Future Study

The major limitation to this study was its underpowered cohort. The first recommendation for further study is therefore to recruit all 50 participants as initially planned (Chapter 14, Section 14.6). This will ensure that subsequent analyses are sufficiently powerful to better answer the research question.

On reflection of the study processes, this RCT has demonstrated the importance of feasibility studies to inform the design of definitive trials. Future studies on this population should include the conduct of a feasibility study to particularly assess potential recruitment rates and the retention of participants. Other factors of importance which could be assessed during this proposed feasibility phase include the assessment of minimal differences between study groups for each outcome to better inform power calculations, the identification of logistical problems surrounding randomisation and data collection, as well as the acceptability of trial interventions to both participants and treating physiotherapists. Such information which was not available in this study, could better inform the design of future trials to negate a number of methodological problems which arose. This will be further explored in Chapter 18.

The rationale for undertaking this study was based on clinical equipoise regarding which exercise programme should be prescribed to individuals following FTPD. The national survey indicated that both general quadriceps and specific-VMO exercises are used clinically (Chapter 8, Section 8.5). Whilst

specific-VMO exercises are used, there remains limited evidence on whether there is a difference in VMO:vastus lateralis EMG activity or onset timing in people following FTPD, or whether this can be altered through exercise. Further study is therefore warranted to explore the influence of VMO:vastus lateralis EMG activity and onset timing to assess the mechanisms surrounding exercise's potential effects on this population. This may also provide a scientific rationale for the reported use of specific-VMO exercises in clinical practice.

The specific-VMO exercises were selected on an assumption that they could preferentially recruit the VMO (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006; Chapter 6, Section 6.9). Previous papers by Bennell et al (2010) and McConnell (2007) have suggested that these exercises should be performed in conjunction with an EMG biofeedback system. Such units are aimed to increase visual and audio feedback of VMO recruitment to assist in the "retraining" of this muscle's activity (Robertson et al, 2006). No studies have specifically assessed the effectiveness or efficacy of this intervention following FTPD. Four studies have assessed the effectiveness of EMG biofeedback units with PFPS populations (Yip and Ng, 2006; Ng et al, 2008; Crossley et al, 2002; Wise et al, 1984). These have all demonstrated an improvement in early clinical outcomes (Yip and Ng, 2006; Ng et al, 2008; Crossley et al, 2002; Wise et al, 1984). However these studies are based on small sample sizes, using treatment regimes which incorporated taping techniques in addition to exercise. Consequently the effectiveness of biofeedback alone remains unclear for PFPS and FTPD populations. Further study to assess EMG biofeedback is therefore required before considering its use as an adjunct to exercise.

As acknowledged, the adoption of exercises performed in internal rotation was recommended by the available literature (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006; Chapter 6, Section 6.9). Whilst literature has concentrated on VMO:vastus lateralis onset timing, the importance of this with the medial:lateralis hamstrings had not been assessed until recently. In the only study published to assess this phenomenon, Patil and colleagues (2011) investigated the EMG activity of the hamstring complex in 20 individuals diagnosed with PFPS compared to 17 healthy controls. The authors reported that biceps femoris contracted significantly earlier in those with PFPS compared to healthy controls ($p=0.04$). The authors hypothesised that this was meaningful since altered activation patterns in the hamstring complex may produce excessive external rotation of the tibia on the femur resulting in lateral patellar tracking (Patil et al, 2011). Further study to assess the role of the hamstring muscle complex on FTPD is indicated. Specifically study should be directed to determine whether specific-VMO exercises prescribed in this study, particularly those performed with concurrent semitendinosis/semimembrinosis contraction, influences the onset timing of semitendinosis/semimembrinosis compared to the biceps femoris. This may be an additional factor to hypothetically account for any difference in functional or clinical outcomes following these exercises.

It was assumed that there was a difference in the anatomy and clinical features of FTPD compared to those following recurrent patellar dislocations (Chapter 14, Section 14.5.1). This was based on the assumption that these cohorts may present with a different proportion of individuals with a MPFL rupture, trochlear dysplasia and hypermobility, with different attitudes toward physiotherapy. This was hypothetical and should be examined through anthropological assessments and epidemiological study designs. As only FTPD was evaluated due to these hypothetical differences, further study is

recommended to explore whether a difference exists in outcomes between individuals treated with general quadriceps exercises compared to specific-VMO exercises following recurrent patellar dislocation in order to answer this secondary question.

A number of variables were uncontrolled, the impact of which remains unclear. These included the period between injury to treatment and the form of immobilisation. Respecting the pragmatic nature of this study, no control was placed upon whether participants were initially immobilised in a cast, brace or knee sleeve. The limited literature remains unclear as to whether these factors are clinically important (Mäenpää et al, 1997; Kilviluoto et al, 1986; Chapter 5, Section 5.2). Further study to explore the optimal form and duration of immobilisation and whether there is a relationship between these factors and outcome is justified.

The number of outcome measures utilised in this RCT were controlled to reduce the burden placed on participants. This was justified to minimise participant fatigue and enhance trial recruitment and retention (Williamson et al, 2007). Nonetheless a number of important outcome measurements were not assessed. These included the time to return to work, participant confidence, and treatment satisfaction. These latter two outcomes are justified following the findings of the national survey (Chapter 8, Section 8.7). Patient satisfaction was reported as the most frequently used outcome measure by NHS physiotherapists treating FTPD (Chapter 8, Section 8.7). By assessing these outcomes, future RCTs would better reflect the clinical practices of NHS physiotherapists to enhance external validity (Portney and Watkins, 2009). Finally, the assessment of return to work is important due to the economic implications work absence places on individuals and employers. This is particularly important for this population who are typically of working age (Atkin et al, 2000; Fithian et al, 2004b).

The NPI score demonstrated convergent validity through a correlation with clinical outcomes. The results indicate that the NPI questionnaire possessed a high floor-effect, where a high proportion of respondents reported the lowest possible score for a number of less physically demanding activities such as getting into and out of a car and turning to look over their shoulder. A high floor-effect can lower the capacity of a score to detect a MICD in status (Binkley et al, 1999). Future study is therefore recommended to assess the appropriateness of including these questions. The current questionnaire should however be further explored with other cohorts including those following recurrent patellar dislocation or those with identified MPFL rupture or severe trochlear dysplasia. This would indicate whether specific questions are required to distinguish between different severities of patellar instability. If these too demonstrated that lower-energy activities are frequently cited as asymptomatic, then consideration to removing these items may be appropriate.

Previous literature has suggested that shorter, more concise questionnaires result in higher response rates without loss of validity or reliability (Hawthorne et al, 2006; Ware et al, 1996; Beaton et al, 2005). As cited in Chapter 13 (Section 13.3.2.5), questionnaires such as the DASH and SF-12 have been shortened to maintain validity, reliability and responsiveness whilst reducing respondent burden. Two of the assessing physiotherapists in this study anecdotally acknowledged that they felt the NPI score was burdensome. Whether this was a widely held belief is unclear as this was not specifically assessed. However calculating the NPI score was time-consuming, particular when respondents frequently used the “don’t do” response. This may detract from the ease to which the NPI score can be completed, reducing attraction for clinical adoption. Nonetheless with increased computer and handheld tablet usage in clinical practice (Vezyridis et al, 2011; Keddie and Jones, 2005), this may be less of an issue in the future. Nonetheless future simplification of the

calculation method may be required to enhance the accessibility of NPI score data.

16.6 Summary

The findings of this RCT indicated that whilst there was a difference in Lysholm Knee Score and Tegner Level of Activity score between the exercise groups at six weeks, there was no statistically or clinical significant difference for other measures. The results provided some support that the NPI score correlates with clinical outcomes, and is responsive to change. However the NPI questionnaire presented with a floor-effect, suggesting that some questions may be redundant in the FTPD population. A number of potential methodological limitations were identified. These were principally pertaining to low recruitment rates and loss to follow-up. Both limited the confidence which could be placed in the findings. Further study to assess these outcomes with a larger dataset continues in order to address this limitation.

This trial did provide some important and new information. In addition to the clinical findings detailed above, the RCT has provided an indication on how long people following FTPD attend NHS physiotherapy services and the duration with which they continue with their exercise programmes. The results have also indicated that whilst six week data is readily available for this population followed-up as part of a clinical trial, other strategies may be required to successfully collect longer-term data. The standard deviation values recorded for the assessed outcomes will also help with the construction of future power calculations. Furthermore this study has identified that the referral rates for FTPD were lower than previously anticipated. Accordingly multi-centre trial designs will be required to sufficiently recruit sufficient numbers of participants for future RCTs assessing FTPD cohorts.

The final chapter will now consider how all three studies in this thesis relate to the evidence-base. It will also identify future clinical and research implications, principally in the form of a feasibility study, to take this thesis's work forward.

Section Six

Overall Thesis Conclusions

Chapter 17. Thesis Conclusions (Research and Clinical Implications)

17.1 Introduction

The objective of this PhD was to examine the physiotherapy management of people following FTPD. The literature review identified that there was a paucity of evidence surrounding how physiotherapists assess, treat and evaluate individuals following this injury. The three studies presented in this thesis have begun to address this limitation.

The purpose of this chapter is to examine how this thesis has contributed to the current knowledge-base, and to consider where future research should be directed to improve the understanding of FTPD. This chapter has been subdivided to review the aims of the programme of study (Section 17.2), to summarise its results (Section 17.3), to consider the clinical implications of these findings (Section 17.4), to acknowledge areas for future research to better understand this condition (Section 17.5) and to reflect on the researcher's personal journey during this PhD (Section 17.6).

17.2 Aim of the Thesis

The aim of this PhD was to investigate the physiotherapy management of people following FTPD. The literature review identified a weak evidence-base both in its size and quality. Three key limitations were identified. Firstly, it was unknown how physiotherapists assessed, treated or evaluated their patients following FTPD. Whilst 27 papers have been published detailing the conservative treatment of people following FTPD, only three, all single-case study designs, had specifically outlined physiotherapy interventions (Helgeson and Smith, 2008; Osterhues, 2004; Racouillat, 2007). None of these were from

the UK. Given this, a national survey to assess how people are managed by physiotherapists in UK NHS hospitals following FTPD was warranted. These findings also informed the design of the following two studies, ensuring that these related to normal clinical practice in the UK.

Secondly, prior to this thesis, it was not known which physical activities were associated with symptoms of patellar instability. Whilst previous authors had suggested that twisting and turning motions during sports were frequently associated with patellar dislocation (Atkin et al, 2000; Fithian et al, 2004a; Sillanpää et al, 2008a; Hsiao et al, 2010), no studies had assessed what specific activities these related to. Furthermore the literature review identified that no outcome measure existed to formally assess symptoms of patellar instability (Chapter 4; Smith et al, 2008). Given that this is the primary complaint for this population (Donell, 2006), the construction of an outcome measure from this survey's findings was warranted before future clinical trials could be conducted.

Both the literature review and the national survey (Section 3) indicated that exercise was the corner-stone of physiotherapy for individuals following FTPD. These exercises were principally quadriceps or VMO strengthening exercises. It also identified that physiotherapists prescribed both types of exercises. Thus whilst clinically adopted, the literature review could provide no evidence for support or rejection of the prescription of one exercise over another. Furthermore the literature review identified that no clinical trials had compared these two physiotherapy interventions to one another in order to assess efficacy or effectiveness. Consequently, there was no evidence upon which physiotherapists could base their clinical-decision making for the rehabilitation of people following FTPD.

These studies therefore aimed to begin to develop the evidence-base on this poorly researched area. All were novel and have developed new knowledge on the physiotherapeutic management of this population.

17.3 Summary of Findings

The first study indicated that FTPD was not a common musculoskeletal disorder managed by NHS physiotherapists. It constituted an average of two percent of respondent's caseloads. The results suggested that physiotherapists most commonly assess for quadriceps or VMO capacity, patellar maltracking, excessive patellar glide or effusion in their patients following FTPD. The most common treatments prescribed were reassurance, proprioceptive exercises, knee motion, quadriceps and specific-VMO exercises. Based on these findings and the literature review, UK acute hospital NHS physiotherapists were adopting interventions which have not been scientifically investigated. This provided a strong rationale for the conduct of the subsequent two studies undertaken.

The second study concluded that sporting and multi-directional twisting activities were associated with greater symptoms of patellar instability compared to lower energy, uni-planar activities. Females and those without a family history of patellar instability more frequently experienced symptoms of patellar instability compared to males, or those with a family history. The 19 activities identified as symptomatic were used to construct the NPI score which was designed to assess perceived patellar instability.

The RCT reported that whilst there was statistically significantly better functional scores for people prescribed general quadriceps exercises compared to specific-VMO exercises in respect to Lysholm Knee Score at six weeks, this was not a clinically significant difference. There was no statistical or clinically significant difference between the groups for other secondary outcome

measurements collected except Tegner Level of Activity score at six weeks. This study also demonstrated that the NPI questionnaire was responsive to change, and correlated to clinical measurements at the six week assessment. However, it reported high floor-effect, indicating that further assessment of all 19 items, with different patellar instability populations, is warranted to improve the ability to detect a clinically meaningful difference for different severities of patellar instability. Furthermore this multi-centre pragmatic RCT presented a number of major limitations, principally surrounding lower than expected recruitment rates and a high loss to follow-up.

17.4 Implications of Findings

This work has implications for a variety of different individuals including physiotherapists and orthopaedic surgeons, people who have experienced a FTPD, healthcare commissioners and researchers. The key implications of the thesis will be considered for each of these groups.

17.4.1 Implications for Physiotherapists

Physiotherapy is considered the primary management strategy for individuals following FTPD (Grelsamer, 2000; Cofield and Bryan, 1977; Cash and Hughston, 1988). The national survey indicated that physiotherapists largely adopt interventions which cannot be supported by an empirical evidence-base and patient satisfaction was considered the principal means of assessing treatment outcome. There was little reported use of formal outcome measurement tools. Standard six of the Chartered Society of Physiotherapy's (CSP) core standards states that published, valid, reliability and responsive outcome measures should be used to evaluate changes in patients' health (Chartered Society of Physiotherapy, 2005). The construction of the NPI score

may provide such a pertinent outcome measurement for physiotherapists to evaluate their patients against following FTPD.

A second objective of this study was to increase awareness of FTPD amongst NHS musculoskeletal physiotherapists. The limited use of patellar-specific assessment and treatment modalities recognised by the survey was partly attributed to the relatively small number of people following FTPD seen by this group of physiotherapists within their typical caseload (Chapter 8, Section 8.3). By increasing awareness of the pathology through the use of a national survey, it was hoped that this may stimulate physiotherapists into further considering their management strategies for this population. In addition, the subsequent publication of the results of this survey and a systematic review on the physiotherapy management of FTPD in the Physiotherapy journal (Smith et al, 2011d; Smith et al, 2010), was aimed to further enhance an awareness of FTPD.

Over the past five years, 10 papers have been published from this thesis (see: *Publications arising from this thesis*). Given the acknowledged limited literature surrounding this topic, this has substantially contributed to the available evidence-base. Whilst it is hoped that this has better informed physiotherapists and other groups, the success to which this has been achieved is unknown.

17.4.2 Implications for Orthopaedic Surgeons

The national survey indicated that orthopaedic surgeons are a key member of the multi-disciplinary team in the management of FTPD (Chapter 8, Section 8.8). The national survey and RCT provided information regarding how physiotherapists manage this population. Whilst this may be of interest to orthopaedic surgeons, the construction of the NPI score may be the key finding for this group. Since orthopaedic surgeons are involved in the management of

people treated conservatively and surgically who present with patellar instability, this outcome measure may have considerable ability to assess treatment outcomes.

17.4.3 Implications for Individuals who have Experienced a FTPD

Two potential major implications have arisen from this thesis for people treated by physiotherapists in the UK following FTPD. Firstly, each of the 10 papers published from this thesis are accessible to the general public and may better inform individuals who have experienced a FTPD about their management.

Secondly the NPI score and the findings of the RCT may directly impact on clinical practice where patients may experience a difference in care provision. For example, rather than assessing treatment outcomes through subjective questioning, individuals may be asked to complete a NPI questionnaire. Similarly, there is now some evidence to address the previous clinical equipoise between general quadriceps exercises and specific-VMO exercises. Through this, some clinicians may alter their exercise prescription.

17.4.4 Implications for Healthcare Commissioners

Both the results from the RCT and the NPI score's construction could be of interest to healthcare commissioners involved in deciding the provision of care for people following FTPD. The results of the RCT indicated that people following FTPD improved during physiotherapy irrespective of the strengthening exercises performed. This supports the provision of physiotherapy for this population. The results of the national survey and RCT provide an indication of the frequency and duration of physiotherapy treatments received by this population and provides further insight into the typical management required for these individuals. From these, the costs incurred to

healthcare providers can be better estimated. Finally the NPI score, may eventually be used as a valid tool to evaluate this population. Since it has not been previous possible to assess this domain in a reliable fashion, may provide a means to evaluate different services to benefit commissioning services.

17.4.5 Implications for Researchers

The thesis provides a series of key findings. Firstly, the literature review presented the strengths and weaknesses of the available evidence-base, prioritised areas for future study, and can be used as a resource on-which subsequent research conducted can be based. By identifying what interventions are performed by UK physiotherapists, future researchers can better plan clinical trials to reflect typical UK practice. Thus the external validity of such studies can be enhanced, and increase the rigor of the future evidence-base.

The RCT was the first clinical trial undertaken to assess different physiotherapy interventions with participants following FTPD. The limitations identified included problems with recruitment and retention, and the need for prior feasibility studies. These lessons can therefore better inform future researchers. Given this, the RCT presented in this thesis may become a resource for any future researcher considering conducting a multi-centre RCT with this population.

Finally, after further assessment, the NPI score may be used as an outcome measure of patellar instability. This could be added to the recommended battery of outcome measurements required to assess this population including a knee-specific, general health and activity-specific outcome measurement (Paxton et al, 2003). Based on these, all important clinical domains following FTPD can be evaluated.

17.5 Areas for Future Study

Whilst this thesis has advanced the knowledge on the management of FTPD, a number of key areas for future study have been raised.

17.5.1 Feasibility Study

The RCT demonstrated a variety of methodological limitations which may be partly attributed to uncertainity during the planning of the trial. This therefore threatened teh success of the RCT. As discussed in **Chapter 16** (**Section 16.3.7**) feasibility studies can more accurately inform the sample size calculation for a given treatment effect; recruitment rates; the appropriateness of the selected outcome measurements; and determine the validity of the study's eligibility criteria for example (van Teijlingen and Hundley, 2002). Therefore the formal conduct of such a study is considered imperative before further study is undertaken examining the clinical outcomes of physiotherapy interventions for people following FTPD. **Chapter 18** outlines a proprosal for such a study.

17.5.2 Effectiveness of Proprioceptive Exercises

The literature review highlighted that people following FTPD demonstrate poorer knee proprioception compared to those who have not sustained this injury (Jerosch and Prymka, 1996a; Jerosch and Pryka, 1996b). The national survey reported that proprioceptive exercises were prescribed by 99% of respondents. In support, the RCT reported that proprioceptive exercises were frequently prescribed to both trial exercise groups. Given these, future study is warranted to identify which exercises may effectively increase knee joint proprioception in this population. This is further explored in Chapter 18 where,

reflective of this finding, a proprioceptive treatment arm has included to begin to assess this area.

17.5.3 Standardised Assessment Procedures

The national survey indicated that physiotherapists adopt a variety of different assessment methods to diagnose FTPD. Furthermore, as highlighted in the RCT (Chapter 14, Section 14.5), controversy exists regarding how best to clinically examine this population. The diagnosis of this pathology is essential to differentiate between other patellofemoral disorders such as PFPS or patellar tendinopathy. Whilst a previous study has attempted to standardise the assessment used by orthopaedic surgeons for individuals following FTPD (Smith et al, 2011b), this has not been conducted with physiotherapists. Further examination is therefore required to ascertain the reliability of common clinical assessment methods used by physiotherapists to diagnose FTPD. Following the identification of the most accurate methods, consensus should be gained from panel groups of experts in this field to construct guidelines on what physiotherapy assessments should be endorsed to examine people with suspected FTPD.

17.5.4 Recurrent Patellar Dislocation

This thesis was based on an assumption that differences exist in the anatomical morphology and health-beliefs of individuals who experience recurrent patellar dislocation compared to those following FTPD. This was based on literature suggesting that people who experience recurrent patellar dislocations more frequently present with anatomical features such as trochlear dysplasia, a hypoplastic vastus medialis and patellar alta, compared to those who experience a single patellar dislocation (Mäenpää et al, 1997; Mäenpää and Lehto, 1997a; Dejour et al, 1994; Fucentese et al, 2007; Fulkerson, 1997; Bollier and

Fulkerson, 2011; Singerman et al, 1994; Chapter 3, Section 3.4). Secondly, anecdotally individuals who experience recurrent patellar dislocations are referred to physiotherapy on numerous occasions, potentially over many years. Given this, it was hypothesised that attitudes and health-belief towards physiotherapy may differ between those who experienced a single patellar dislocation compared to recurrent events (Smith et al, 2010; Ogden, 2000). This however remains hypothetical. Future study is required to determine the validity of these assumptions. Nonetheless since both factors may be important variables, they were distinguished as two separate populations. Given these potential differences, it remains unclear how different the findings of the three studies would have been if assessed with a recurrent dislocation population. Since the evidence-base surrounding the management of this population also possesses inherent weaknesses similar to that of the FTPD population, further study to assess the optimal management strategy for this group of complex individuals is warranted.

17.5.5 NPI Score

The results from the RCT indicate that the NPI score possessed a degree of convergent validity to clinical outcomes at six weeks, however it also exhibited a high floor-effect. This may limit the ability to detect a MICD, particularly in people with less severe symptoms. Further study is warranted before the NPI score can be clinically adopted. This should determine the convergent validity of the tool to other outcome measurements which assess similar domains over a longer follow-up period. To assess whether the tool is specific to the patellar instability population, examination of the applicability of the NPI score to other populations such as those following anterior cruciate ligament rupture, PFPS or with osteoarthritis of the knee is recommended. Additional examination is also warranted of whether the floor-effect reported in the RCT was typical. This should be conducted with cohorts which present with more severe patellar

instability such as those awaiting surgery or those with trochlear dysplasia. This could determine whether items attributed to the floor-effect, should be removed from a second version of the NPI score. Subsequently further evaluation of the MICD would be valuable for clinicians to understand the clinical meaning of the results obtained. This would be the first outcome measure where a MICD has been determined for the FTPD population.

17.5.6 Prognostic Indicators

The literature review identified that rupture of the MPFL at the femoral attachment (Sillanpää et al, 2009b), patellar hypermobility (Nomura et al, 2006) and family history of patellar dislocation (Palmu et al, 2008) are the only demonstrated prognostic indicators for the conservative management of FTPD. A wealth of additional characteristics such as an individual's gender, age, weight, method of delivery at birth or method and duration of immobilisation following initial injury have not been examined in this population. Information on these epidemiological characteristics would be valuable for two reasons. Firstly, the identification of all potential prognostic indicators could better inform researchers as to which variables should be stratified during randomisation. Hence, known variables could be balanced between the groups to prevent baseline imbalances, thus enhancing the ability to detect a real difference between groups (Friedman et al, 1998). Secondly knowledge on significant prognostic indicators can enable the development of well-informed treatment algorithms. The activity survey identified that age, family history and gender may be important characteristics in perceived patellar instability (Chapter 11, Section 11.6). These should be examined in relation to their association with physiotherapy treatments to determine whether they are important or not. As the literature develops, an evidence-based treatment algorithm may then be constructed to determine the optimal management of this population.

17.6 Personal Reflections on the PhD

My personal goals in undertaking this PhD were two-fold. Initially, from a clinical perspective, I wished conduct a series of studies to better inform my understanding on themanagement of patients who I treated following FTPD. Secondly the PhD was designed to develop my understanding of research methods in research synthesis, survey design and randomised controlled trials. Previous literature has acknowledged that both objectives were realistic and appropriate for a PhD student (Mullins and Kiley, 2002).

On reflection, whilst this PhD has been a challenge from logistical, time-management and academic perspectives, I feel that both study objectives have been met. Clinically, my understanding of this pathology, how people are managed, how to grade activities related to symptoms and how to evaluate outcomes has been developed. Secondly, the past six years has provided a foundation in research methods which will facilitate further study to answer the questions which remain and have been raised during this PhD. Finally, the studies undertaken, and particular the RCT, have developed my aptitude for clinical research which I intent to purse during post-doctoral work.

17.7 Conclusions

This study has fulfilled its objective of developing new knowledge on the physiotherapy management of people following FTPD. It has identified current physiotherapy strategies used and proposed a new means of evaluating patellar instability. Lastly, it has begun to examine what the optimal rehabilitation is for this population. Key problems relating to the recruitment and retention of people following FTPD were identified and should be considered when designing future studies with the FTPD population. Further study examining the properties of the NPI questionnaire, the identification of important prognostic

indicators, and the effectiveness of other commonly used physiotherapy interventions is recommended with the aim of eventually being able to develop a treatment algorithm to inform how best to assess, treat and evaluate people following FTPD. By collectively examining the findings of the three studies, and considering how they relate to the current knowledge, their importance has been demonstrated. This is set against a number of areas for continued research and it is hoped that through further exploration, the optimal methods for managing people following FTPD can be determined.

Many of the methodological limitations may have been avoided if a feasibility study had been conducted prior to this RCT. Furthermore, on reflection, this chapter has highlighted a number of methodological and design uncertainities which surround the RCT presented in Part 4 of this thesis. In recognition of this, the following chapter will further explore the rationale for feasibility studies, and will describe the design and justification for the methodological approaches adopted.

Chapter 18. Feasibility Study Design

18.1 Introduction

The previous chapter acknowledged that this thesis's RCT presented with a number of limitations. These included uncertainties regarding the optimal means of identifying participants, which outcome measurements to assess, acceptability of trial interventions and a high participant attrition rate after six months. A feasibility study could have highlighted these limitations. This study design would have informed whether different methodological approaches would have been more successful for a larger-scale study. The purpose of this chapter is therefore to design such a feasibility study.

This chapter has been divided into three phases: a pre-study focus group, the feasibility trial itself, and a post-study focus group. With these over-arching phases, the chapter will include discussion on the purpose of feasibility studies (Section 18.2), the rationale for this feasibility study (Section 18.3), its objectives (Section 18.4), and study design (Section 18.5). Following this, the chapter will describe and justify the approaches taken when designing the pre-study focus group (Section 18.6), the feasibility trial (Section 18.7) and the post-study focus group (Section 18.8) phases.

18.2 Purpose of Feasibility Studies

Feasibility studies are designed to assess the feasibility and acceptability of study procedures. They provide data in order to inform the design and conduct of a larger-scale trial. These studies address the main uncertainties or 'threats' to the success of a future trial (Medical Research Council, 2008). Accordingly methodological problems such as poor acceptability and reduced compliance to a trial's protocol, difficulties in delivering an intervention, recruitment,

retention and unexpected small effect sizes can be tested. These features, all demonstrated in this thesis's RCT (Chapter 14, Chapter 15), could have been identified through a feasibility study (Medical Research Council, 2008).

Previously the terms 'pilot' and 'feasibility' study designs have been used interchangeable within the literature. However this has been clarified more recently. Arain et al's (2010) systematic review of 54 pilot/feasibility studies identified a number of major differences between the two terms. Pilot studies were more frequently seen as 'miniature RCTs', randomising participants and including a control group comparison (Arain et al, 2010). Studies labelled as 'feasibility' were more flexibility in their methods compared to 'pilot' studies, assessing areas such as screening programmes, examining different outcomes or intervention delivery methods, to evaluate study feasibility and acceptability (Arain et al, 2010). Therefore the purpose of a feasibility study is to better understand all 'known' uncertainties to design a more rigorous subsequent RCT. Once determined, a pilot study may be designed based on these findings, to explore any 'unknown' uncertainties with the trial design, before commencing on a larger-scale. Accordingly, feasibility studies are considered particularly valuable when designing pragmatic multi-centre Phase III RCTs examining complex interventions due to methodological and logistical complexity associated with these trials (Medical Research Council, 2008).

The literature strongly recommends that feasibility trials should not be confused with other trial designs (Hagen et al, 2011; Thabane et al, 2010; Bowen et al, 2009; Leon et al, 2011; Lancaster et al, 2004). Such designs include proof-of-concept studies, which assess intervention safety, dosage and responsiveness, acting as Phase I or II designs (Jadad and Enkin, 2007). Similarly, internal pilot studies should be considered differently. In such 'adaptive trial' designs, changes are made to a definitive study design during the conduct of that definitive trial (Thabane et al, 2010). This may take the form of an *a priori*

interim analysis, stopping a trial early due to safety concerns and serious adverse responses, or to recalculate a sample size based on sufficient early data to provide a more reliably powerful indication of effect size (Thabane et al, 2010). This does not usual address any other design uncertainties such as recruitment, intervention or data collection processes unlike an external pilot or feasibility study (Thabane et al, 2010).

Feasibility studies cannot assess treatment efficacy nor formally evaluate the reliability or validity of outcome tools. Feasibility studies cannot determine optimal intervention dosages (treatment intensity, frequency, duration), safety of an intervention or outcome measurement's psychometric properties, but should be conducted prior to commencing a feasibility study (Bowen et al, 2009). Such studies require sufficiently powerful samples, adequate follow-up periods, whilst imposing greater control for confounding or co-interventional factors (Jadad and Enkin, 2007).

It has been suggested that feasibility studies are vital but often 'skipped' to the detriment of larger-scale trials (Eldridge et al, 2004; Hagen et al, 2011; Treweek and Sullivan, 2006). Nonetheless feasibility study design has received little attention within the literature (Thabane et al, 2010). Ten papers have been published regarding feasibility study methodology (van Teijlingen and Hundley, 2001; Hagen et al, 2011; Thabane et al, 2010; Bowen et al, 2009; Leon et al, 2011; Lancaster et al, 2004; Shanyinde et al, 2011; Arain et al, 2010; Taylor, 2007). No book chapters have been specifically written on this topic (Thabane et al, 2010). Furthermore no agreed published guidelines exist to inform the design of these studies (Bowen et al, 2010). The methodological approaches described in this chapter are therefore based on this available literature.

18.3 Rationale for the Proposed Feasibility Study

Chapter 16 (Section 16.3) outlined the thesis RCT's limitations. These included: unexpectedly low participant identification and subsequent recruitment; higher than anticipated loss to follow-up; limited information regarding the reliability of the hand-held dynamometry; no previously reported indication of the MICD for any of the outcome measurement; and limited consultation with important stakeholders to inform study design. Further exploratory study is therefore warranted to better inform a larger-scale trial on this topic to prevent these weaknesses being future 'threats'.

The RCT reported no statistically significant difference between the general quadriceps and specific-VMO exercise groups at six weeks for all outcomes except Lysholm Knee Score and Tegner Activity Level score ($p>0.05$; Chapter 15). As discussed in Chapter 3, Chapter 6 and Chapter 16, this may be attributed to the questionable existence of the VMO muscle and the ability to preferentially activate VMO with exercise. Seven studies indicated that the VMO could be preferentially recruited through a variety of lower limb quadriceps exercises (Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997b; Miller et al, 1997c; Gregerson et al, 2006). However, the majority (13 studies) reported that such preferential activity could not be achieved (Chapter 6, Section 6.9). Furthermore, the evidence-base in this field demonstrated poor methodological quality (Chapter 6, Section 6.9). Nonetheless the findings of the national survey indicated that both general quadriceps and specific-VMO exercises are widely used in NHS practice (Chapter 8, Section 8.5). These exercises are also advocated in textbook and review literature (Cherf and Paulos, 1990; Scuderi and McCann, 2005; Post et al, 2003; Burks, 1992; Howell, 2002; Solomon et al, 2001). Given this, there appears a conflict between the research literature and clinical practice, thus a pragmatic rationale for investigating specific-VMO and

general quadriceps exercises in this study. However, no studies prior to this thesis have been conducted. Thus, with hindsight, a feasibility study was justified to ensure the feasibility of these interventions as part of a clinical study.

The literature review identified that previous exercise programmes, whilst providing acceptable outcomes in functional improvements, still fail to prevent recurrent disability in a proportion of the FTPD population (Chapter 5, Section 5.4.6, Section 5.4.7). The activity survey reported that people most commonly experience symptoms of patellar instability whilst participating in sporting or multi-directional twisting activities compared to lower energy, uni-planar activities (Chapter 11, Section 11.4). Neither the previous literature nor the national survey determined exercise frequency, dosage or the level of joint loading prescribed to people following FTPD. Given the association of higher-loading activities with greater perceived patellar instability, exercises progressing to these higher loading levels may, hypothetically, be indicated to 'train' the patellofemoral joint to resist lateralisation during these greater forces (Kisner and Colby, 2007). The exercises prescribed in this thesis's RCT did not stipulate a specific loading progression. Loading and exercise progression was decided by the treating physiotherapist. By not standardising this progression, it may be interpreted that the minimal difference reported between the specific-VMO and general quadriceps exercise groups in this trial at six weeks could be attributed to insufficient progression of loading (Chapter 15, Section 15.6, Section 15.7). However, since this has yet to be investigated, this remains hypothetical.

Given the originality of these exercises, and the number of 'unknowns' regarding the intervention, this feasibility study will begin to explore the acceptability of progressive loading exercises as part of each exercise regime. This is warranted under feasibility trial conditions since the tolerance,

acceptability and logistics in delivering, receiving and recording such a progressive exercise programme has not been previously examined in this population. Thus this may act as a 'threat' to the success of a larger trial if not examined in this context. Furthermore, since this form of exercise progression has not been investigated, it is important to determine whether the interventions provide a 'risk' to participants. The activity survey reported that activities which load the patellofemoral joint increase participant's instability symptoms (Chapter 11; Section 11.4). Therefore increased loading may, hypothetically, place participants at greater risk of instability and dislocation events. This therefore stresses the importance of investigating this exercise progression using a feasibility trial approach.

One study has previously investigated proprioception following recurrent patellar dislocation (Jerosch and Prymka, 1996a). This was an observational study of 30 healthy controls and nine individuals following recurrent patellar dislocation. The researchers reported that, when measured using a passive reproduction joint position sense method, a statistically significantly greater angle reproduction error (i.e. poorer proprioception) was detected in those who had experienced recurrent patellar dislocations compared to healthy controls ($p<0.05$; Jerosch and Prymka, 1996a). However, this study presented a number of limitations. Firstly the findings were based on only nine people, therefore questioning the representation of this cohort to the wider patellar dislocation population. Furthermore the authors did not match the groups to ensure comparability for important variables such as age, gender or hypermobility score (Fithian et al, 2004a; Atkin et al, 2000; Sillanpää et al, 2008a; Hsiao et al, 2010). Consequently these findings should be viewed with caution as these are known confounding variables to joint position sense measurement (Toledo and Barela, 2010; Gribble et al, 2009; Rombaut et al, 2010; Fatoye et al, 2009). Finally, neither this nor any other studies have assessed proprioception following FTPD, or the effectiveness of proprioceptive exercises in this

population. Nonetheless, the national survey indicated that the second most commonly prescribed exercises for this population were proprioceptive exercises, where 95% of respondents reported using these exercises for 75% or more of their typical caseloads (Chapter 8; Table 8.2). Given that proprioceptive exercises were widely adopted, there again appears clinical equipoise between clinical practice and an insufficient evidence-base. Thus justifying the conduct of a feasibility study to begin to explore the optimal study design to assess the effectiveness of this intervention.

Given the principles for conducting a feasibility study, as stated in Section 18.2, the title of this study is therefore: a pragmatic, multi-centre feasibility RCT to compare the functional outcomes of a specific-VMO exercise, a general quadriceps strengthening and a proprioceptive exercise programme following FTPD.

18.4 Objectives

The objectives of this study are to:

- Explore the rationale for this trial and its design with all major stakeholders prior to feasibility testing
- Estimate participant recruitment rates and retention
- Identify any difficulties with the screening, recruitment and randomisation procedures
- Determine the optimal content and delivery of study interventions
- Estimate the MICD of outcome measurements
- Identify difficulties in collecting or storing outcome data
- Estimate the completeness of outcome data
- Estimate effect sizes and variability

- Explore the experiences and perceptions of all major stakeholders to the trial design and procedures

The importance and methods used to address each of these objectives will be examined in the following sections.

18.5 Study Design

The various aspects of the proposed feasibility study design are presented as Figure 18.1.

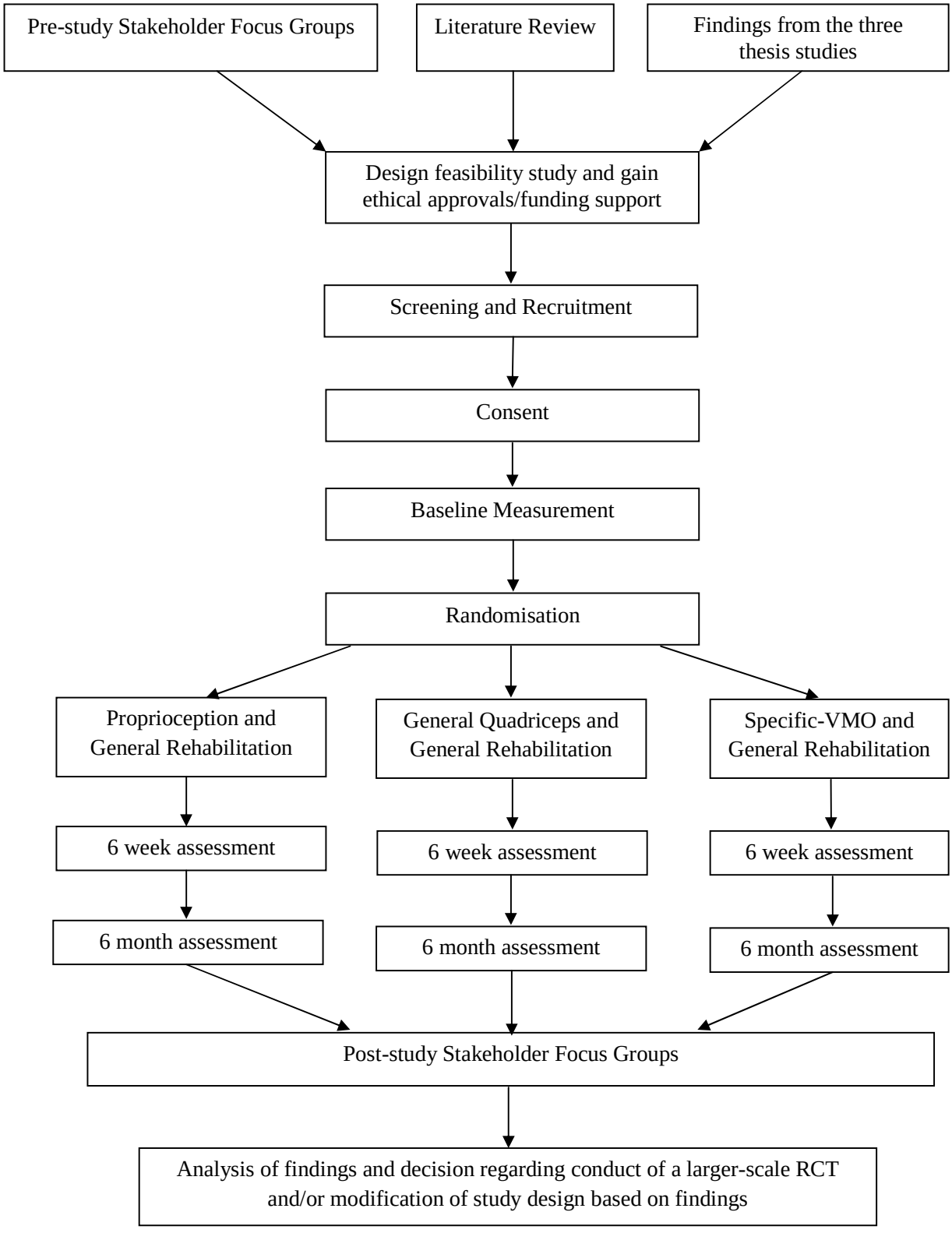
Acknowledging the paucity of evidence regarding the reliability and MICD of outcome measurements used for this population, the originality of the interventions tests, and the other methodological limitations highlighted in the previous RCT, a feasibility study rather than a pilot study was warranted to address the breath of uncertainty.

In recognition of the Medical Research Council's (2008) framework for designing studies using complex interventions, this feasibility study has been divided into three phases: a pre-study focus group, a feasibility trial, and a post-study focus group. These will be described and discussed chronologically in the following sections.

18.5.1 Sources of information to inform the initial feasibility trial design

The study design will be informed through two sources. Firstly, the previous evidence-base and this thesis's findings have been examined to inform the trial's interventions, population, outcome measurements and design. Using this, the development of ideas surrounding the treatment of people following FTPD was formulated, to begin to construct theories on how the interventions would

Figure 18.1. Flow chart depicting feasibility study structure



expect to behave. This is in accordance with the Medical Research Council's (2008) framework for the design and conduct of investigations into complex interventions.

The second source to inform trial design will be a focus group of key stakeholders. Consultation with clinicians and service managers when devising a feasibility study has been advocated as paramount to ensure that study processes are feasibility prior to testing (Medical Research Council, 2008). Thus this will be specifically performed within the pre-study focus group interviews. The rationale and processes surrounding this phase of the feasibility study are presented below.

18.6 Phase 1: Pre-Study Focus Groups

This focus group will be an interpretative qualitative investigation. This has been suggested as an important step when planning a feasibility study (van Teijlingen & Hundley, 2001). They propose that data collection methods such as individual or focus group interviews should be undertaken with various stakeholders to inform the methodological decisions taken prior to a trial.

18.6.1 Participants

Two pre-study focus groups will assist to inform the design of this feasibility study. These consultations will include patients who have experienced a FTPD and subsequent rehabilitation and/or their parents/family members (n=6), physiotherapists (n=4), health-service managers (n=2), a NHS commissioner (n=1), researchers (n=2) and a medical statistician (n=1). This sample is representative of each of the important study decision-makers and each of the key stakeholders involved in the conduct of the trial. The inclusion of a NHS commissioner is to better understand what they expect from the trial to inform

their decision on service outcomes and commissioning. Therefore this will help maximise the impact and usefulness of the eventual study findings.

18.6.2 Sampling

Clinicians, health service managers, commissioners and researchers will be purposively sampled from the sites involved in the proposed study to provide a representative range of views and opinions. Through this patients will be identified using a maximal variation sampling strategy according to key variations in characteristics (Vitcu et al, 2007). This is to achieve greater representation of this population and ensure that previous patients included in the focus group will vary in age, gender and location of treatment.

18.6.3 Data Collection

The focus groups will be divided to explore the attitudes and experiences of previous patients and their parents/family, with a separate focus group conducted with health professionals and research team members. This is to enable patients and their family to freely express their views of their physiotherapy experiences. Additionally, by gauging the experiences of patients first, these findings will then be further explored with the clinicians and researchers, providing an iterative approach for the second focus group.

All focus groups will be audio recorded and led by an experienced qualitative researcher. Areas will be explored using a topic guide which will include trial rationale, the processes involved with a clinical study and then consideration of the dissemination and impact of the study findings. These are summarised in Table 18.1.

Table 18.1. Topic guide for participant and researcher/clinicians/commissioner pre-study focus groups.

Participant Focus Groups	Researcher/Clinician/Commissioner Focus Group
Rationale	
- Is it important to assess the effectiveness of three different exercises following FTPD?	- Is this trial warranted based on clinical practice and service provision? - Is the FTPD population the most important population to assess this trial with?
Recruitment	
- What are the barriers to initial participation? - When should initial contact be made to join the trial? - What information should be in a Participant Information Leaflet? - What is the role of friends/family/carers in the consideration on enrolment? - How long is required to make a decision on trial participation?	- What criteria would best identify FTPD patients? - What criteria would accurately exclude other pathologies such as PFPS? - How would participant screening be best performed i.e. through medical notes, a screening questionnaire or face-to-face with physical examination? - What are the best sources to recruit participants following FTPD?
Randomisation	
- What do participants understand by random allocation? - What information is needed to explain randomisation?	- What are the usual processes between initial review and allocating treatment? - How long is this process? - When would it therefore be best to randomise participants? - Would this be best performed by web-based/telephone based means? - Are these patients seen at weekends or Bank Holidays?
Intervention	
- How easy is it to adhere to an exercise regime? - Is there any discomfort during a patients last rehabilitation with exercises? - Did you perceive any benefit from exercises? - How are exercises best delivered and informed e.g. demonstration and exercise sheets or alternative?	- How do physiotherapists teach exercises? - What is the typical range of frequency, dosage and progression of the study exercise? - How are these and their progressions documented? - Which other interventions to physiotherapists prescribe in addition to exercises? - How do physiotherapists decide on which co-interventions to exercise to prescribe? - Where are physiotherapy interventions

	provided? - What are physiotherapists attitudes towards exercises progression? - How often and over what period do physiotherapists treat people following FTPD?
Outcome Measurements	
- How do patients know if they are getting better or not? - How frequently do patients consciously measure this? - What outcome measurements would be important to include in a study of recovery following FTPD? - How would patients prefer to be measured e.g. through internet methods/postal/telephone/face-to-face methods?	- How do physiotherapists currently assess the outcome of patients following FTPD? - Have physiotherapists any experience of using dynamometry or assessing proprioception? - What outcome data would be required to implement a change in clinical practice?
Follow-Up	
- What are the barriers to continued participation for follow-up? - How long do patients think is required to determine if you are better or not? - Would an incentive improve patient's interest in continuing to be followed-up in a study? - If patients missed an appointment, how would they like to be reminded of this to attend a second appointment?	- How long do physiotherapists typically follow their FTPD patients up for? - Do physiotherapists have a high "do not attend" rate in physiotherapy departments for people following FTPD? - Why do physiotherapists think this population do not attend follow-up appointments if this is a problem? - What could facilitate the prevention of this?
Analysis/Dissemination	
- Would patients like to be able to see the results of a study, and how would it be best to present these results? - Do patients think other people would be interested in seeing these results?	- Could the present study design have sufficient impact to change national/international policy? - If not to the above, how could this be facilitated?
Study Management	
	- How could communication be maximised within study sites and between the overall research team and the study sites? - Is there sufficient safe space for the storage of equipment or data in each centre?

18.6.4 Data Analyses

An inductive qualitative analysis approach will be used to identify themes emerging from the data. Potential themes, which may arise, are: recruitment, randomisation, outcome measures, interventions, follow-up study procedures, analysis methods and study management logistics. However, this will remain unknown until data is analysed.

Since this pre-study focus group has yet to be conducted, the protocol which follows is based on previous literature, the experiences drawn from the other studies in this thesis and the methodological literature.

18.7 Phase 2: Feasibility Trial

It is anticipated that the proposed feasibility study will be a single-blind three-armed pragmatic multi-centre RCT. This will allows the comparison between a specific-VMO exercise and rehabilitation programme, to a general quadriceps exercise regime and rehabilitation programme, to a lower limb proprioceptive exercise programme and rehabilitation regime, whilst limiting the influence of bias and random error (Jadad and Enkin, 2007).

18.7.1 Participant Eligibility Criteria

The inclusion criteria for this study will consist of:

- People aged sixteen or over referred to the participating centres' out-patient physiotherapy departments following conservative management of a FTPD and present with:

(1) a history of patellar dislocation requiring reduction, or having reported that their knee cap visibly "popped" out of joint.

and

(2) one of the following signs and symptoms of patellar instability:- (a) apprehension when a lateral directed force is applied to the patella; (b) tenderness along the medial retinaculum; (c) abnormal patellar tracking or position e.g. lateralised, tilted, excursion such as J-sign, where the patella shifts laterally in terminal knee extension as it disengages from the femoral intertrochlear groove.

- Provide written informed consent.

Exclusion criteria will consist of:

- Inability to undertake the assessment and treatment procedures.
- A history of two or more patellar dislocations on each knee, either self-reported or documented in the medical notes, during a participant's lifetime.
- Meniscal, anterior cruciate ligament, posterior cruciate ligament, lateral collateral ligament or medial collateral ligament injury on the knee referred to physiotherapy, determined by a negative Lackmans test, anterior and posterior draw, valgus and varus stress tests, and absences of tibiofemoral joint line tenderness.
- A large osteochondral fracture detected on plain radiograph (anteroposterior, lateral and skyline view) requiring operative intervention.

- Previous surgical intervention for patellar stabilisation on the injured knee referred to physiotherapy.
- Allergy to adhesive tape used in the joint position sense assessment procedure.

The justifications for these have been previously explained in Chapter 14 (Section 14.5). The maintenance of these eligibility criteria to this feasibility study is justified, particularly on pragmatic trial principles. For example, pragmatic criteria were justified to identify the FTPD population. Through these principles the recruitment strategy aims to identify a cohort which is reflective of the 'normal' clinical environment to enhance external validity and therefore more heterogeneous than in explanatory trials (Helms, 2002). Exclusion criteria such as gender, co-morbidities including hypermobility or severity of injury will not be controlled. In contrast, explanatory trial designs place greater restriction on cohort characteristics, aiming to recruit a more homogeneous group of individuals (Alford, 2007; MacPherson, 2004). This is required in Phase II studies where trials aim to assess treatment efficacy through ideal, highly controlled, optimal conditions, rather than assessing effectiveness during normal clinical interactions and processes (Alford, 2007; MacPherson, 2004). A secondary benefit to adopting a pragmatic approach is that by placing less restriction on participant eligibility, recruitment rates may be enhanced. This may be particularly advantageous since the previous RCT demonstrated major difficulties with recruitment (Chapter 15, Section 15.2).

Even with pragmatic designs, some exclusion criteria are necessary and will be employed in this pragmatic feasibility study. Participant's aged under 16 will be excluded based on the principle that this population may find the specific-VMO and proprioceptive exercises technically difficult to perform. Furthermore the method by which there exercises are prescribed may not necessarily reflect the

'play-based' exercises typically taught to a paediatric population (Hartley, 2007; Crombie, 2007).

People following recurrent patellar dislocation events are excluded based on the previous assumption that those who have experienced recurrent dislocations may present with different patho-anatomical features, particularly MPFL rupture (Chapter 14; Section 14.5). These individuals with previous experience of physiotherapy interventions, may also have significantly different health beliefs and perceptions towards their intervention. This may act as a confounding variable (Ogden, 2000; Smith et al, 2010; Chapter 14; Section 14.5). Therefore the FTPD and recurrent patellar dislocation populations have been considered distinct, warranting their current separation in this trial.

In order to explore the feasibility of the eligibility criteria, each participating centre will complete a screening log (Appendix 51). This will identify the number of potentially eligible and non-eligible participants referred to each site. It will identify how restrictive each of the exclusion criteria are in limiting recruitment. The screening log will also be compared with each institution's referral numbers. This will assess for possible disparity between the two to evaluate sampling bias. If such a difference was evident, further modification to a definitive trial's design would be required to clarify participant identification and screening methods.

18.7.2 Sample Size

There is unanimous agreement amongst the 10 papers which have outlined methodological approaches to feasibility studies that sample sizes, for this study design should not be based on a power analysis (van Teijlingen and Hundley, 2001; Hagen et al, 2011; Thabane et al, 2010; Bowen et al, 2009; Leon et al, 2011; Lancaster et al, 2004; Shanyinde et al, 2011; Arain et al, 2010; Taylor,

2007). Instead the number of participants required should be based on an estimation to ensure a sufficient and representative cohort is recruited to assess study processes, without unnecessarily over-recruiting to cause undue inconvenience (Leon et al, 2011; Julious, 2005; Shanyinde et al, 2011). Since the degree of uncertainty being assessed by feasibility studies vary dependent on the topic and level of previous knowledge, there has been considerable variability within the literature with regards to their recommended size. A minimum of 24 to 30 participants has been advocated for most interventional feasibility RCTs (Browne, 1995; Shanyinde et al, 2011; Julious, 2005). However, recently Sim and Lewis (2012) suggested that the majority of feasibility studies require a sample of 55 participants for a two-arm RCT (28 per group). They suggested that a smaller sample would give greater imprecision to the estimate of a population's standard deviation value, so ill-informing a future trial's sample size (Section 18.15.1).

Based on this recommendation, in addition to the degree of uncertainty regarding the acceptability of each of the interventions and their progression, a sufficiently large sample is warranted. Accordingly, a cohort of 84 participants, 28 per group, will be recruited to this three-arm multi-centre feasibility RCT.

18.7.3 Participating Sites

Given the sample size stated above, and the problems with recruiting participants demonstrated in the previous RCT, where three sites recruited a maximum of two participants per month (Chapter 16, Section 16.3), 10 sites will conduct this trial to facilitate the recruitment of approximately nine participants per month. Through this, recruitment is estimated to be achievable within 10 months. However this is an estimation and an objective of this feasibility study is to better inform predicted recruitment rates.

The 10 sites will be identified by contacting all NHS hospitals in London, the East and South East of England to enquire whether they would be interested in participating. Furthermore, each of the Comprehensive Local Research Networks within these regions will be contacted to liaise with their local physiotherapy departments to gauge interest. Through this, only those interested sites will be approach. Once confirmed, one physiotherapist from each centre will be designated as a site's Principal Investigator. Their role will be to liaise with the research team and locally co-ordinate the study. They will contribute throughout the feasibility study design to provide a further level of approval with the proposed study procedures prior to feasibility testing, in an attempt to enhance protocol compliance.

The justifications for conducting a multi-centre RCT are based on the benefits this provides to facilitate greater recruitment within a period of time and enhancing study generalisability to other clinical centres and population catchments (Chapter 14, Section 14.3). The feasibility study will be conducted at sites which would be potentially interesting in participating in a larger-scale trial, if indicated, at the end of the feasibility study. This firstly, will provide an indication of how representative the sites are to the typical FTPD population based on the epidemiological evidence-base (Chapter 3, Section 3.3). Secondly, it will indicate the success with which sites recruit participants and further test their adherence to the study protocol. Thirdly, by including multiple sites, the logistics of a multi-centre trial can be ascertained.

18.7.4 Recruitment

Previous literature has highlighted the importance of assessing recruitment processes across all participating sites to optimise the efficiency of future larger-scale trials within study time-frames (Lancaster et al, 2004; Fletcher et al, 2012). This is considered essential given the problems with recruitment

seen in this thesis's RCT (Chapter 16, Section 16.3). This is particularly important since failure to recruit sufficient numbers, with subsequent loss of statistical power, has been cited as a principal reason for abandoning a trial prematurely (Ross et al, 1999).

The procedures for participant recruitment will largely mirror that of the methods adopted in the previous RCT (Chapter 14, Section 14.7). Accordingly, each site's Principal Investigator will screen all new physiotherapy referrals for potentially eligible participants using the pre-defined eligibility criteria. This will be recorded using the screening log (Appendix 51).

A physiotherapy appointment will be made by the participating department. A covering letter (Appendix 52) and Participant Information Leaflet (Appendix 53) will be included with the potential participant's posted physiotherapy appointment letter. This will inform each potential participant that a feasibility study examining the rehabilitation of people following FTPD is being undertaken within their physiotherapy department. The participating physiotherapy department will arrange the initial appointment to review the potential participant within a week from being referred to their department.

Potential participants will be specifically informed that this study is a feasibility study. This has been highlighted of key importance by Thabane et al (2010). They detailed that since these studies may not lead to further studies dependent on results, and do not assess treatment effectiveness or efficacy, disclosure of the objectives of this type of trial should be explicit to ensure that potential participants are fully aware how the findings are to be used (Thabane et al, 2010). This is in accordance with the Declaration of Helsinki (World Medical Association, 2000).

Potential participants would have a minimum of seven days to read through and discuss their participation with their friends and family. This was felt important given that some individuals may be anxious after the trauma of a FTPD, and may require time to consider participation. Furthermore, some of the participants may be aged 16 to 18 years. Accordingly, these potential participants may require time to discuss their potential participation with a parent or close family member before making their decision.

When a potential participant attends their first physiotherapy appointment, they will be assessed by their treating physiotherapist using the physiotherapist's routine musculoskeletal assessment. Particular attention will be paid to whether the potential participant satisfies the eligibility criteria. If these are satisfied, the physiotherapist will ask the potential participant whether they would like to participate in the trial and if so, informed consent will be taken. One copy of the completed Consent Form (Appendix 54) will be given to the participant, one will be sent to the Chief Investigator whilst one will be included in the participant's medical notes. If the potential participant declines to participate, their treatment will continue as normal.

Each participant's referring clinician and the participant's registered General Practitioner will be notified by letter of their inclusion (Appendix 55; Appendix 56). These letters will be sent by the research team. The assessment of timeliness of each of these procedures will be evaluated through the recruitment log (Appendix 57).

18.7.5 Randomisation Procedure

Once the participant has been consented and enrolled, the treating physiotherapist will telephone the Chief Investigator, who, using a sealed envelope system off-site from the trial centres, will assign the participant a

coded identifying number to allocate them to an intervention. Using this method of randomisation, the impact of selection bias will be limited (Jadad and Enkin, 2007).

Allocation will be stratified by location, thus each department will contribute an equal number of participants to each of the three treatment-arms. Stratifying by centre will prevent a 'clustering effect' from occurring which can lead to reduced statistical power and therefore potentially misleading conclusions (Tangri et al, 2010; Andersen et al, 1999). Whilst methodologists such as Parzen and colleagues (1998) recommend that stratification should be kept at a minimum to reduce unnecessary complexity in a randomisation protocol, the results of the feasibility study will be used to predict whether baseline imbalances occur. Whilst it is acknowledged that the risk of this occurring is increased in small sample sized studies, the recruitment of 84 participants may partly negate this complication. If imbalance does occur, the importance of such factors will be considered in relation to the previous literature, and this may indicate a requirement to stratify further in a more definitive trial to minimise this threat in the future (Bland, 2006).

18.7.6 Interventions

Three study exercises interventions will be investigated in this trial. The description of these interventions and their rationale is presented below:

18.7.6.1 Proprioceptive Exercise Intervention

No studies have been published assessing the efficacy or effectiveness of proprioceptive exercises for people following patellar dislocation. Limited literature exists on the use of proprioceptive exercises for people with other patellofemoral joint pathologies. One Cochrane review has evaluated exercise

interventions prescribed to people with PFPS (Heintjes et al, 2003). In this review of literature published to December 2001, of the 12 papers identified, three reported incorporating proprioceptive exercises (Dursun et al, 2001; Clark et al, 2000; Gobelet et al, 1992). On review of these original papers, Gobelet et al's (1992) proprioceptive exercise was performed on an isokinetic seated dynamometer which is not commonly used in clinical practice within the region this feasibility study will be conducted due to its expense. The other studies reported that 'proprioceptive exercises' were prescribed but did not describe what these specifically consisted of (Dursun et al, 2001; Clark et al, 2000). No information on frequency, duration or dosage was provided.

Subsequent to this Cochrane review, two additional RCTs have assessed exercises incorporating proprioceptive activities for people diagnosed with PFPS (van Linschoten et al, 2009; Bily et al, 2008). Van Linschoten et al (2009) reported that their cohort received "balance exercises" but did not provide further detail on this intervention. Bily et al (2008) documented that their cohort were also prescribed "balance exercises" which consisted of standing on one leg for two minutes, progressed at eight weeks to being perform in a "tip-toe" position. Both trials and those reported in Heintjes et al's (2003) review incorporated their proprioceptive exercises as part of an intervention 'package'. Therefore it is not possible to specifically determine the efficacy or effectiveness of the proprioceptive-based exercises for these cohorts.

Given the dearth of literature detailing what exercises should constitute a proprioceptive exercise regime, the literature pertaining to anterior cruciate ligament injuries was examined. This is appropriate since both anterior cruciate ligament and FTPD populations report 'knee' instability. Furthermore, the age, gender and mechanism of injury in both populations has been acknowledged as similar (Chapter 4; Section 4.4).

The anterior cruciate ligament evidence-base is divided into exercises prescribed to (1) surgically and (2) non-surgically reconstructed populations. Four trials have compared the use of proprioceptive exercises compared to strengthening exercises for non-surgically managed anterior cruciate ligament rupture (Ageberg et al, 2001; Beard et al, 1994; Fitzgerald et al, 2000; Zatterstrom et al, 2000). They reported that proprioceptive exercises provide superior results in respect to one leg hop test findings (Ageberg et al, 2001), Lysholm Knee Score results (Beard et al, 1994) and reduced risk of recurrent instability episodes during sporting pursuits (Fitzgerald et al, 2000).

Three trials have been published comparing the effectiveness of proprioceptive exercises compared to strengthening regimes following anterior cruciate ligament reconstruction. Whilst Liu-Ambrose et al (2003) reported a greater percentage in isokinetic knee extension torque ($p<0.05$), there was no statistically significant difference to other functional outcomes between the exercise interventions in this study ($p>0.05$). Similarly, Cooper et al (2005) reported no significant difference between their proprioceptive and balance exercise programme versus their strengthening programme in respect of hop-test results, strength or functional outcomes ($p>0.05$). However both trials recruited small, underpowered samples ($n=10$ and 29 respectively). Additionally they evaluated outcomes during a limited follow-up period (12 and six weeks respectively). Therefore the ability to generalise these findings for longer-term results is questionable, whilst potentially committing a type II statistical error (Bland, 2006). More recently, Risberg and colleagues reported their six month (Risberg et al, 2007) and two-year (Risberg and Holm, 2009) results of a RCT comparing a neuromuscular exercise programme versus a traditional strength training programme with 74 people following anterior cruciate ligament reconstruction. They reported no significant difference in proprioception, hop-test, balance or muscle strength tests between the groups ($p>0.05$), but a significant improvements in Cincinnati Knee Score at six

months and in global functional score and pain levels in the proprioceptive training compared to the strengthening regime group at two years ($p<0.05$). Therefore, although not consistent, there is evidence to suggest that proprioceptive exercises may provide some additional functional benefit, in some outcomes, over strengthening exercises alone.

A major strength of the literature regarding anterior cruciate ligament compared to PFPS populations is the clearer depiction of the prescribed exercise regimes. Consequently the proprioceptive intervention in this feasibility study was based on these regimes which were clearer to interpret and is based on a more rigorous evidence-base than the PFPS literature. The intervention is presented as Appendix 58.

18.7.6.2 General Quadriceps Exercise Intervention

The general quadriceps strengthening regime is presented as Appendix 59. These specific exercises were justified since they have been recommended for people following FTPD within the textbook literature (Scuderi and McCann, 2005; Brukner and Karim, 2001; Burks, 1992). Secondly these strengthening/recruitment exercises were reported as used in NHS practice through the national survey (Section 8, Section 8.5), thus enhancing external validity of this decision. Further justification for these exercises has been provided in the previous RCT (Chapter 14, Section 14.11).

18.7.6.3 Specific-VMO Exercise Intervention

The specific-VMO exercise programme is presented as Appendix 60. These exercises were chosen for three reasons. Firstly, these have been previously cited within textbook literature for this population (Scuderi and McCann, 2005; Brukner and Karim, 2001; Burks, 1992). Secondly, although methodologically

limited and contracted by a larger evidence-base, limited previous literature provided some suggestion that these exercises may preferentially recruit the VMO compared to other types of exercise (Smith et al, 2009; Hodges and Richardson, 1993; Lam and Ng, 2001; Willis et al, 2005; Laprade et al, 1998; Miller et al, 1997; Gregerson et al, 2006). Finally, the national survey indicated their clinical application in current NHS practice (Section 8, Section 8.5). More detailed justification for the adoption of these exercises was outlined in the previous RCT (Chapter 14, Section 14.11).

18.7.6.4 Exercise Loading Progression

The major difference in the exercise regimes prescribed in this feasibility study compared to the thesis's RCT is in relation to exercise progression and loading. Further direction on loading progression of these exercises has been stipulated for all three exercise interventions (Appendix 58 to Appendix 60). This is warranted since the activity survey reported that higher-level loading activities were associated with greater perceived patellar instability (Chapter 11, Section 11.4). Thus rehabilitation at greater loading-levels may, hypothetically, better address recurrent instability symptoms (Section 18.3). Furthermore, Herrington and Pearson's (2006) electromyographic study of 10 asymptomatic participants reported that increasing the level of load from 25% to 50% to 75% of maximum isometric voluntary contraction significantly increased quadriceps activity ($p=0.001$). Thus through exercise progression, VMO and VL activity may increase (Herrington and Pearson, 2006). However given the pragmatic nature of this trial, the exact number of repetitions, speed and use of weights, and when these should be progressed will be determined by each physiotherapist based on the participant's clinical presentation (e.g. strength, pain severity and swelling) and their response to the exercise load. This approach has been previously advocated by Crossley et al (2008) and Gaffney et al (1992) in the rehabilitation of people diagnosed with PFPS. However this has not been

evaluated in the FTPD population. This feasibility study will therefore begin to assess the effect of loading on clinical outcomes for these three exercise interventions.

Leon et al (2011) acknowledged that some feasibility studies only evaluate the feasibility of experimental interventions (i.e. specific-VMO and proprioceptive exercises) and neglect to assess the control intervention (i.e. general quadriceps strengthening). However, by doing so, intervention fidelity to *all* treatments remains unknown. Furthermore, since there was similar loss to follow-up between the specific-VMO exercise and general quadriceps exercise programmes in the thesis's RCT (Chapter 15; Section 15.11), further exploration of the delivery and acceptability of each intervention, in addition to the clarity in higher-level loading instructions as stipulated in this proposal, is warranted through a feasibility study approach.

As acknowledged, no studies have previously assessed the efficacy or effectiveness of these three exercise regimes with the FTPD population. This is a major limitation when designing a Phase III feasibility study. As stated earlier, a feasibility study is an inappropriate study design to assess the efficacy of an intervention (Section 18.2). However, an efficacy study specifically assessing the optimal dose-response of each intervention and their loading progression would be required prior to conducting a feasibility study. In its absence, there would be insufficient information to deliver a Phase III feasibility trial with sufficient rigor. This Phase II study would therefore be conducted to inform the design of this feasibility study.

18.7.6.5 Co-Interventions

As Appendix 58 to Appendix 60 demonstrate, in addition to the three study interventions, physiotherapists will be permitted to prescribe other treatments or

co-interventions. In clinical practice, physiotherapists use multiple interventions to treat people following FTPD (Chapter 8, Section 8.5). The national survey provided an indication as to which treatments are commonly conducted in NHS practice. However, the frequency to which co-interventions are used may differ between the three intervention groups. To examine this, each physiotherapist will be required to list which co-interventions are used using the intervention checklist (Appendix 61). It will also determine whether other interventions are used, which were not initially accounted for in the checklist to ensure that these are captured for any future study.

18.7.6.6 Grade of Treating Physiotherapist

The grade of the treating physiotherapists will not be controlled as part of this pragmatic study. However, the seniority or grade of treating physiotherapist will be recorded (Appendix 61). This will determine that if limited variability within the grades of treating physiotherapists was demonstrated, consideration may be paid when designing a future definitive trial, on whether this should be addressed. This could be important to improve engagement with other grades thus increasing study external validity.

18.7.6.7 Duration of Treatment and Discharge Criteria

The frequency and duration a participant attends physiotherapy will be dependent on their progress. This will be determined by the treating physiotherapist in accordance with the pragmatic nature of this study's design (Hotopf, 2002; Hotopf et al, 1999). For the same reason, the treating physiotherapist will decide when their participant is discharged from their care, reflecting normal clinical processes.

18.7.6.8 Assessment of Intervention Acceptability and Feasibility

Intervention acceptability and feasibility will be assessed through a variety of methods. The impact of compliance to the interventions will be assessed though the participant's exercise diary (Appendix 62) and the intervention checklist completed by the treating physiotherapist (Appendix 61). As Hagen et al (2011) acknowledges in their instructional paper on feasibility study design, an assessment of co-interventions and contamination should be assessed through an intervention checklist to ascertain whether similarities or differences occur between treatment arms. This will be important given that the pragmatic nature of the trial presents little restriction on the prescription of co-interventions.

18.7.7 Outcome Measurements

A feasibility study provides researchers with an opportunity to evaluate which outcome measurements should be adopted. Whilst the findings of the pre-study focus groups may suggest other outcome measurements, the following tools have been selected based on the current literature and the national survey results (Chapter 8, Section 8.7). These outcomes may be modified according to the findings of the initial focus group.

The following section will identify each of the planned outcome measurements. The rationale for their adoption will be presented related to the literature. Areas for further exploration to assess the appropriateness of these measurements will be highlighted.

18.7.7.1 Primary Outcome Measure

- **The Lysholm Knee Score** (Appendix 39; Lysholm and Gillquist, 1982).

The Lysholm Knee Score has demonstrated validity (construct validity (convergent and discriminant validity) and internal consistency) and reliability in the FTPD population (Paxton et al, 2003; Kiely et al, 2006). As a knee-specific score, it has been shown to better differentiate individuals with recurrent dislocations and subluxation compared to other scores such as the Kujala Patellofemoral Disorder Score (Kujala et al, 1993; Paxton et al, 2003).

18.7.7.2 Secondary Outcomes

- **The Short Form-12 Health Survey (SF-12)** (Appendix 40; QualityMetric Incorporated, Lincoln, USA).

The SF-12 has also demonstrated validity (construct validity (convergent and discriminant validity) and internal consistency) and reliability in this study's population (Paxton et al, 2003). The inclusion of a general health assessment tool was based on Paxton et al's (2003) recommendation that this area be investigated to fully assess an individual's outcomes following FTPD.

- **The Tegner Activity Score** (Appendix 41; Tegner and Lysholm, 1985).

The Tegner Activity Score has also demonstrated validity (construct validity (convergent and discriminant validity) and internal consistency) and reliability in the FTPD population (Paxton et al, 2003). Similarly the inclusions of an activity level tool such as this was recommended by Paxton et al (2003) to accurately assessment an individual's outcomes.

- **Isometric knee extensor muscle strength**

Isometric extension knee strength measured using a hand-held dynamometer has previously shown to be a reliable and valid method to assess muscle strength (Bohannon, 2001; Hayes and Falconer, 1992; Surburg et al, 1992; Bohannon, 1990). However, this has yet to be determined in the FTPD population. Whilst the thesis's RCT indicated moderate to good inter-rater reliability, this has not been formally assessed. Accordingly, an assessment of this instrument's reliability will be conducted with this cohort. This will be discussed in Section 18.7.7.3.

Isometric extension strength will be assessed at 0º, 30º, 60º and 90º knee flexion to indicate quadriceps strength throughout knee range of motion. Furthermore, assessing a difference between the groups at 60º knee flexion was deemed important as Tang et al (2001) and Basmajian et al (1971) reported that the VMO has its greatest activity at this knee flexion angulation, compared to the other vastii muscles. The 30º measurement also has considerable importance as this position has been cited as when the patella is most likely to dislocate during sporting activities as it disengages from the trochlear groove during knee extension (Colvin et al, 2008). Therefore, by testing this position, it will be possible to examine patellar stability at a functionally important position. The procedure for this assessment is presented in Appendix 63.

- **Knee Joint Position Sense**

Numerous outcome measurements have been recommended for the assessment of knee proprioception. These have included the star excursion balance test (Kinzey and Armstrong, 1998; Munro and Herrington, 2010), stabiliometry (Pereira et al, 2008) and single-leg standing (Harrison et al, 1994). However these all assess a composite of hip, knee and ankle proprioception and postural sway (Crotts et al, 1996). Accordingly, a knee specific measurement of

proprioception, which is principally evaluated through joint position sense testing, was considered valuable in this study.

Seventeen studies have assessed the reliability of different measurements of knee joint position sense (Fischer-Rasmussen et al, 2001; Ghiasi and Akbari, 2007; Kiefer et al, 1998; Kramer et al, 1997; Mir et al, 2008; Nobori et al, 2009; Olsson et al, 2004; Petrella et al, 1997; Pincivero et al, 2001; Piriyaprasarth et al, 2008; Selfe et al, 2006; Stillman and McMeeken, 2001; Stillman et al, 2002; Stillman et al, 1998; Fatoye et al, 2008; Marks, 1995; Marks et al, 1993). The methods and results of these studies are summarised in Appendix 64. These have evaluated joint position sense using three distinct methods: image recorded angulation, electrogoniometry and dynamometry/angular motion chairs, of either active reproduction of target angle where the participant actively moves their limb into a 'target' position and, once returned to the starting position, is then asked to actively move their limb back into this position to replicate the movement; or passive reproduction where the participant's limb is moved by an assessor into the 'target' position and, once returned to the starting position, is then moved by the assessor again and stopped when the participant reports the 'target' angle is reached.

Of the 17 studies, two performed these tests with participants who presented with patellofemoral pathologies. Kramer et al (1997) assessed the active angle reproduction method using an electrogoniometer with 24 people diagnosed with PFPS and 24 asymptomatic healthy controls. Target positions of 15°, 30°, 45° and 60° knee flexion angles were assessed in sitting and standing. Intra-rater reliability was assessed with a duration of three to 14 days between assessments. The intra-rater reliability values assessed using intra-class correlation coefficients ranged from 0.58 to 0.79 in sitting and 0.42 to 0.63 in standing for the PFPS cohort (Kramer et al, 1997).

Selfe et al (2006) assessed the mean difference in target reproduction error of 32 participants diagnosed with PFPS using a passive limb position reproduction method using a seated isokinetic dynamometer with 20° and 60° knee flexion target angles. In addition an active method of assessment was made where participants were instructed to actively positioning their limb in the same target positions but were passively moved by an assessor to the replication of the target angle. They reported that less target reproduction error was recorded using the passive method (passive assessment=4.5°; active assessment=7.2°). No data assessing intra-class correlation coefficients were provided, limiting the analysis of the intra-rater reliability of these methods.

For the other 15 papers which examined healthy participants (Fischer-Rasmussen et al, 2001; Ghiasi and Akbari, 2007; Kiefer et al, 1998; Mir et al, 2008; Nobori et al, 2009; Olsson et al, 2004; Petrella et al, 1997; Pincivero et al, 2001; Piriyaprasarth et al, 2008; Stillman and McMeeken, 2001; Stillman et al, 2002; Stillman et al, 1998), those with hypermobility syndrome (Fatoye et al, 2008), and those with tibiofemoral osteoarthritis (Marks, 1995; Marks et al, 1993), intra-rater reliability was reported as 'good' for the assessment of joint position sense using photographs and digital images, 'good' but variable for electrogoniometry, and 'moderate' but variable when assessed using dynamometry/angle motion chair methods (Landis and Koch, 1977). There was no substantial difference in intra-rater reliability values for active or passive target position reproduction using image-capture methods or electrogoniometry (Appendix 64). Although the evidence-base was limited in size, the assessment of joint position sense by image-recorded angulation, electrogoniometry and dynamometry/angular motion chair demonstrated good inter-rater reliability. Therefore based on these findings, and the results of Kramer et al's (1997) study specifically, which assessed the reliability of joint position sense with a patellofemoral dysfunction population, this feasibility study will assess knee proprioception using an active positioning-active repositioning method in

sitting using an electrogoniometer (Biometrics, Model SG150, Biometrics, Gwent, UK). However, to reflect this weak evidence-base, the reliability of this outcome will be examined as part of this study (Section 18.7.7.3).

The procedure for this test is presented in Appendix 65. The data from the sixth repetition will be collected. Whilst this may be time-consuming this will be trialled in this feasibility study following the recommendations of Selfe et al, (2006), Bennell et al (2005) and Baker et al (2002) who reported that a "one-off" assessment of knee joint position sense may provide erroneous data. To minimise the risks of this, authors have recommended that participants should provide between five and seven trials before proprioceptive data is 'stabilised' and less influenced by measurement error (Selfe et al, 2006; Bennell et al, 2005; Baker et al, 2002). Therefore recording data from the sixth repetition is justified. The inaccuracy of joint position sense will be recorded as the difference between the perceived angle and target angle of flexion to determine the Actual Angular Error (AAE).

All angle reproduction measurements will be performed by the individual site's researchers using the injured knee. The angles tested will be at 10°, 30°, 60° and 80° knee flexion. These angles were defined to ensure that knee joint position sense was assessed in inner-, mid- and outer-range. Furthermore, an assessment of 30° knee flexion was chosen as this is regarded as the angle in which the patella typically engages in the trochlear and is frequently associated as an 'at risk' position for patellar instability, as reported in the biomechanical literature (Sevanongse et al, 2003). The order of the pre-defined angles assessed will be randomised using a concealed allocation method of sealed envelopes to prevent an order effect from occurring (Bland, 2006).

- **Participant subjective response to their knee feeling better** (Appendix 66) - **Assessment of Minimally Important Clinical Difference**

The MICD has been defined as the smallest difference in a score that an individual perceives as important, either beneficial or harmful, to inform researchers and clinicians when meaningful change has occurred (Guyatt et al, 2002; Eton et al, 2004). The MICD has yet to be determined for any outcome measurement used for people following FTPD. Determination of the MICD for each outcome is therefore important as it permits the accurate interpretation of findings based on the perception of clinical change. Furthermore it can inform the expected observed clinical difference required to perform a power calculation for a larger-scale future study (Jones et al, 2003).

No agreed optimal method exists to determine an appropriate sample size for studies investigating MICD (Terwee et al, 2007). However previous authors have suggested a minimum of 50 participants is required for such studies (Kearney et al, 2012; Naal et al, 2010). Therefore the sample of 84 recruited for this study is adequate to perform this type of analysis.

Minimally important clinical difference will be derived in this feasibility study through an anchor-based approach. In this the change in outcome is compared to an external measure such as participant perception of change (Lemieux et al, 2007). This will be determined by asking participants to report whether their knee feels different to pre-intervention status using the response opinions “A lot better” “A little better,” “About the same,” “A little worse,” and “A lot worse” (Appendix 66). This is also included in this feasibility study since patient reported outcome was the most commonly adopted outcome measure, used by 99% of physiotherapist in the national survey (Chapter 8, Section 8.7). Thus

this outcome reflects normal clinical processes, enhancing the generalisability of study findings.

- **Exercise compliance using an exercise diary** (Appendix 62)

Exercise compliance will be recorded by each participant using the exercise diary (Appendix 62). This will provide an indication on adherence to the exercises provided, as well as recording whether there was a difference in the level of progression and subsequent loading between exercise regimes.

- **Frequency of self-reported of patellar dislocations**

Given that recurrent dislocation was acknowledged as an important and frequently used outcome measure within the literature (Chapter 5, Section 5.4.6), this has been included in this study. This data will be collected by directly asking participants.

- **The duration of out-patient physiotherapy treatment**

The duration of treatment as an outcome will determine whether there is a difference in the physiotherapy contacts between the groups. This will be collected from the intervention checklist (Appendix 61).

- **The number of adverse events**

Similar to the assessment of recurrent dislocation events, the assessment of complications has been included. This is important given that this is the first study to assess these interventions in this population. This may better inform what adverse events may be expected when planning a larger-scale trial. This data will be collected by directly asking participants.

18.7.7.3 Reliability Measurements

Whilst providing information on the suitability of the outcome measures selected, the feasibility study can provide an indication on the reliability of the proposed assessment battery. This is particularly important when multiple assessors are employed, providing potential inter-rater variability (Lancaster et al, 2004). Accordingly the inter-rater and intra-rater reliability of the joint position sense and hand-held dynamometry assessments will be evaluated for each site. These were selected since, being collected manually, they have the greatest risk of measurement error. To assess intra-rater reliability, the assessments will be performed at the start of each follow-up appointment, and then a second time with a one hour gap in-between. This duration is aimed to prevent the participant experiencing a learnt effect, whilst also not inconveniencing them. To assess inter-rater reliability, the results from one assessor will be compared to a second assessor to determine the degree of agreement. All data will be finally recorded onto the trial data sheets (Appendix 67).

18.7.7.4 Data Collection Periods

The groups will be evaluated at baseline (pre-rehabilitation), six weeks and six months. The primary end-point will be six months. These time-points have been chosen so not to unnecessarily inconvenience participants with too frequent re-assessment. The final follow-up also supports the findings from a previous hospital survey (Appendix 5) where patients were discharged from physiotherapy after an average of eight weeks. This reiterated the findings from the national survey where patients were most frequently discharged between seven weeks to three months after commencing physiotherapy (Chapter 8, Section 8.9). Therefore by reviewing participants at these two periods, clinical outcomes will be collected near the end of a participant's physiotherapy

treatment, and a period after their discharge. An assessment of six month data (primary end-point) is appropriate to consider longer-term outcomes following physiotherapy discharge. The data collected at each time-point is tabulated in Table 18.2. The data will be recorded on individual data sheets (Appendix 67). Data will be collected by one assessors in each site blinded to the participant's group allocation. The use of a single assessor per site will minimise inter-rater measurement error for individual participants.

Table 18.2. Outcome measurements collected at each data collection period

Time-point	Data Collected
Baseline	- Gender - Age - Duration of knee instability - Other joint disability of the symptomatic leg - Contralateral patellar instability - Disability of the contralateral leg - Family history of patellar dislocation - Beighton Hypermobility score (**Appendix 43**) - Lysholm Knee Score - SF-12 quality of life questionnaire - Tegner Activity questionnaire - Isometric extensor muscle strength at 0º, 30º, 60º and 90º knee flexion measured using a hand-held dynamometer - Active reproduction joint position sense measured using an electrogoniometer at 10º, 30º, 60º and 80º knee flexion
6 weeks	- Lysholm Knee Score - SF-12 quality of life questionnaire - Tegner Activity questionnaire - Isometric extensor muscle strength at 0º, 30º, 60º and 90º knee flexion measured using a hand-held dynamometer - Active reproduction joint position sense measured using an electrogoniometer at 10º, 30º, 60º and 80º knee flexion - Exercise compliance based on the diary results - Frequency of recurrent patellar dislocation - Duration between the primary and second dislocation - Adverse event monitoring
6 months	- Lysholm Knee Score - SF-12 quality of life questionnaire - Tegner Activity questionnaire - Isometric extensor muscle strength at 0º, 30º, 60º and 90º knee flexion measured using a hand-held dynamometer

	- Active reproduction joint position sense measured using an electrogoniometer at 10º, 30º, 60º and 80º knee flexion - Exercise compliance based on the diary results - Frequency of recurrent patellar dislocation - Adverse event monitoring - Duration between the primary and second dislocation - Duration and frequency of physiotherapy appointments - Number of 'did not attend' appointments

Assessments will be performed after the participant's physiotherapy appointment within their hospital department. Specific appointments will be made for the six month assessment by the participating department, as it would be assumed that the participant would be discharged by this time-point. A telephone reminder will be administered if a participant does not attend a follow-up appointment. If the participant fails to attend a second appointment, the questionnaires used within the outcome measurement battery will be sent to the participant in an attempt to gain some information from this follow-up appointment. This was considered important following the high attrition experienced in the thesis's RCT (Chapter 15, Section 15.2). Once each participant has completed the final six month assessment, all data sheets and the participant exercise diaries will be return to the Chief Investigator for analysis.

18.7.8 Ethical Considerations

Leon et al (2011) argue that the conduct of a feasibility study provides an opportunity to enhance a study's 'Good Clinical Practice' principles. The inclusion of a feasibility phase allows the assessment and potential refinement of participant information leaflets, consent procedures, data collection tools, the formatting and use of site delegation logs, data storage and handling practices, as well as monitoring and management of adverse event reporting. Leon et al (2011) acknowledge that this may be particularly important in multi-centre/multi-investigator trials where the logistical management of these

practicalities can be more challenging to ensure consistency than single-centre trials. Through this, this feasibility study can facilitate that all research staff are familiar with the study protocol, are trained and sufficiently experienced to undertake all tasks and are competent to ensure that the trial adheres to the protocol (Leon et al, 2011). These areas will therefore be assessed using screening tools to capture protocol deviations, frequency of missing or incorrect data collection methods, site visits to assess data storage methods and data handling practices. Specific ethical issues regarded this feasibility study are presented below:

- **Data Collection**

All data will be collected on a pre-defined data sheet (Appendix 67). Using these, participants will only be identifiable using a code to protect anonymity. The Chief Investigator will assign the coded number to each participant on randomisation. A de-coding form for the identification of individuals will then be kept in a locked cupboard in the Chief Investigator's department. Data collection sheets will be completed by the physiotherapy assessors from each site. This will be stored in a separate locked box in each participating physiotherapy department. This was stipulated to ensure that all data sheets are stored together thereby reducing the potential for these to be misplaced, whilst also limiting the risk of breaking the assessor's blinding to participant allocation if they happened to review the participant's physiotherapy notes. Once the participant has completed the trial, the physiotherapist will return the data sheets and exercise diaries by recorded delivery to the Chief Investigator. These will then be stored in a separate locked cupboard in the Chief Investigator's department. Once all data has been processed and the findings disseminated, all original data sheets and coding forms will be destroyed.

- **Ethical Approvals**

Ethical approval will be sought through the NHS's National Research Ethics Committee and each site's Research Governance Committee before potential participants are identified. This is in accordance with the Declaration of Helsinki (World Medical Association, 2000).

- **Management of Adverse Events**

All adverse events, defined as an untoward medical occurrence experienced by a participant were there it not necessarily a causal relationship to the intervention, will be recorded. All adverse events will be reported on an Adverse Event Report Form and returned to the Chief Investigator in a timely fashion following Good Clinical Guideline principles (Medical Research Council, 1998). Although unlikely to occur, serious adverse events will also be monitored and entered onto a Serious Adverse Event Report Form. Respecting Good Clinical Practice guidance, the Chief Investigator will be made aware of any such incidents within 24 hour, and if considered to be unexpected and related to the trial, the approving Research Ethics Committee will be notified within 15 days of the event (Medical Research Council, 1998). All participants who experience an adverse or serious adverse event will continue to be followed-up to the cessation of the trial.

- **Inappropriateness for Non-Treatment Control**

The design of this study ensures that participants receive one of three interventions (Chapter 8, Section 8.5). It would be unethical to incorporate a non-treatment control arm since it is currently best practice that people following FTPD should received some form of rehabilitation (Chapter 5, Section 5.3). As a result, it would not have been possible to determine the

natural history of recovery against the treatment arms to determine the clinical importance of physiotherapy interventions *per se* over no-treatment.

- **Participant withdrawal**

Participant withdrawal can be instigated by the participant or Chief Investigator at any time. It will be stated that declining participation shall not affect a participant's current or future treatment.

18.7.9 Plan for Data Analyses

As acknowledged in Section 18.2, the purpose of a feasibility study is to determine whether a larger-scale trial should be conducted, and if indicated, what design features from the feasibility study should be incorporated into its final design (Hagen et al, 2011; Thabane et al, 2010). A feasibility study should not therefore attempt to interpret between- or with-group statistical differences (van Teijlingen and Hundley, 2001; Thabane et al, 2010). Inferential statistical tests will therefore not be included. However, a variety of analyses are required. These will be discussed below.

Descriptive statistical analyses of population characteristics will be conducted. Therefore mean and standard deviations of: age, duration of knee instability, hypermobility score, Tegner activity score, Lysholm Knee Score, SF-12, isometric extensor muscle strength and joint position sense measurements will be calculated. Frequencies will be determined for the occurrence of: other joint disability of the treatment leg, contralateral knee instability, disability of the contralateral leg and multi-joint problems. These will be calculated for the whole cohort and specific exercise groups at each of the data collection periods. These analyses will determine whether the eligibility criteria have been sufficiently sensitive to identify participants who are representative of the

FTPD population (Fithian et al, 2004a; Atkin et al, 2000; Sillanpää et al, 2008a; Hsioa et al, 2010). Finally 95% confidence intervals (CIs) will be calculated for each between-group comparison to provide an estimate of the probable distribution around which the true population values lies for each continuous outcome such as the Lysholm Knee Score, muscle strength and joint position sense measurements (Jones et al, 2003).

With regards to assessing recruitment, screening logs will be examined from each site to provide an estimate of participant identification and subsequent enrolment from each of the 10 sites. Furthermore the frequency to which specific exclusion criterion restricted participant enrolment will be examined.

The intervention checklist and exercise diaries will be reviewed to determine the frequency with which exercises were prescribed and performed. The duration and frequency of different exercises which were completed and continued during the six month follow-up period and the number of physiotherapy appointments made and attended will also be analysed and the mean and standard deviation values for each group determined.

The inter- and intra-rater reliability of the isometric knee extension strength measurements and the joint position sense measurements will be calculated. Both outcomes will be assessed using the intra-class correlation coefficient values of force measured in Newtons and AAE measured in degrees. Ninety-five percent confidence interval values will be estimated for these analyses.

The effect size, measured using the Cohen's D statistic, will be determined for continuous data outcome measurements (Tegner activity score; Lysholm score; SF-12; isometric extensor muscle strength; and joint position sense measurement). These will be calculated from baseline to six weeks and six months with 95% CIs. The calculation of effect size is important in feasibility

studies since it provides an indication of the magnitude of the effect or clinical importance of the findings (Berben et al, 2012). This measures the extent of a treatment effect, to indicate whether the outcomes are responsive to change in this population (Kalinowski and Fidler, 2010). This also indicates whether there is merit in investigating the interventions further as a larger-scale trial if the effect size is substantially important, when interpreted with the MICD. Finally the assessment of effect size is of merit in feasibility studies since it is independent of sample size (Berben et al, 2012). Therefore the typically smaller sample sizes recruited in this study design does not detract from the statistical findings generated by this calculation.

The MICD analysis of each outcome will be conducted by analysing the mean value for each response opinion ("A lot better" "A little better," "About the same," "A little worse," and "A lot worse"). The MICD will be calculated as the mean change of score for each outcome in participants who reported "a little" i.e. "a little better" or "a little worse" change compared to the baseline to the six week and six month follow-up periods. The assessment of multiple patient-based anchors has been advocated as a more clinically relevant means of assessing MICD compared to single point estimates (Hayes et al, 2005b; Revicki et al, 2008) or distribution-based approaches (De Vet et al, 2006; Hayes et al, 2005b; Revicki et al, 2008).

All data extraction forms will be reviewed in order to assess the completeness of the data. The frequency of missing data for each exercise intervention will be identified to determine whether there was a greater likelihood of missing data from one specific exercise group. This may be an important determinant of the acceptability of an intervention, reflecting participant attrition or may indicate how successful the data collection protocol was.

Finally, whilst feasibility and pilot studies have previously used to informed definitive trial sample sizes (Lancaster et al, 2004), the calculation of a power calculation on small sample sizes has recently been considered inappropriate (Leon et al, 2011). This is based on the principle that small sample feasibility trials evaluating between-group effect sizes are inherently imprecise, with a small sample subject to random error because of a high chance of baseline imbalance in important characteristics (Leon et al, 2011; Sim and Lewis, 2012; Lancaster et al, 2004). To address this, as stated in Section 18.7.2, this feasibility study will recruit 84 participants, a larger cohort than the previously recommended 24 to 30 participants (Browne, 1995; Shanyinde et al, 2011; Julious, 2005). Thus in order to calculate the standardised difference for a definitive trial, data from the MICD findings will inform the "clinically important difference" estimate, whilst the standard deviation values for the outcomes will be ascertained. It will thus be possible to more reliably inform the sample size for future trials and limit the threat of incurring a type II statistical error (Jones et al, 2003). This is a key benefit of this feasibility study as it should prevent a definitive trial recruiting insufficient participants based on a poor sample size calculation.

18.8 Phase 3: Post-Study Focus Groups

A post-study series of focus groups will be undertaken to explore how stakeholders viewed the research processes at each site.

18.8.1 Participants

Two focus groups will be conducted at each site. The first focus group will consist of participants (n=4) and, if appropriate, their families and partners. A letter will be sent to those participants who were eligible but declined to participate in the feasibility trial inviting them to be a part of this focus group.

By including an additional two such people, the aim is to determine what aspects of the trial were not attractive in order to enhance recruitment processes in future studies.

The second focus group will consist of clinicians involved in the identification and recruitment of potential participants (n=2), clinicians who delivered the intervention (n=2), assessors and site researchers (n=1 or 2 dependent on site), a physiotherapy service manager (n=1) and a commissioner (n=1). The separation of these groups will ensure that patients and their families are allowed to freely express their views anonymously of the healthcare professionals they refer to in discussion. By gauging the attitudes of participant's first, these findings will be further explored iteratively during the second focus group.

18.8.2 Sampling

As in the pre-study focus group, identification of participants will be conducted using a maximal variation sampling of individuals according to key variations in characteristics that relate to the issues to be explored (Vitcu et al, 2007). Therefore the samples will variety in age, gender and treatment group allocation to ensure representation of these important variables. A purposive sampling strategy will be adopted to identify the clinical/researcher and participants for each focus group, based on their experience with the trial.

18.8.3 Data Collection

Each focus group will be led by an experienced qualitative researcher using a topic list. This will pose questions regarding all aspects of the feasibility study's design and procedures, including issues regarding the implementation of the trial, the engagement with the process, perceptions of its ability to answer the research question and usefulness to clinical practice. It will also examine factors

which may impede or facilitate the study delivery prior to a larger-scale study when modifications may be more difficult to implement. The key areas to be raised are presented in Table 18.3. All focus groups will be digitally recorded and transcribed.

Table 18.3. Topic guide for the participant and researcher/clinician focus groups.

Participant Focus Groups	Researcher/Clinician/Commissioner Focus Group
Recruitment	
- What are the barriers to initial participation? - How timely was initial contact to join the trial? - Was this appropriate in relation to diagnosis/management during a hospital appointment? - Was the format, content and delivery of the Participant Information Leaflet appropriate? - What was the role of friends/family/carers in the consideration on enrolment? - How informed did participants feel towards the trial and its processes? - Was there sufficient time to consider a decision on trial participation?	- How acceptable were the eligibility criteria and how was screening best performed i.e. through medical notes, a screening questionnaire or face-to-face with physical examination? - Was the screening tool sensitivity to detect and record the eligibility of participants? - Was the source of participants appropriate or sufficient to provide the numbers expected?
Randomisation	
- Did participants clearly understand that they would be allocated to one of three groups by chance? - Did the researchers clearly explain how randomisation occurs and why? - Would this have been useful? - Were participants happy with their allocation? - Did participants understand that they could refuse participation if they were not happy with their group allocation?	- How successful was the randomisation process based on logistics i.e. was concealed allocation maintained concealed? - Was randomisation undertaken in a timely manner? - Was randomisation available at all possible times such as weekends and Bank Holidays?
Intervention	
- How easy was it to adhere to treatment guidelines?	- Were the exercises sufficiently clear to teach and progress?

- Was there any discomfort associated with the exercises? - Did participants perceive benefit from any of the exercises? - Was exercise progression appropriate? - What was the burden which these exercises provided? - What was the relationship between the study exercises and the co-interventions? - Was there sufficiently clear instruction regarding the exercise programmes?	- Did the clinicians feel adequately trained to the prescription of interventions? - Was the documentation of prescribed treatments sufficiently clear? - Would physiotherapists recommend any modification to the interventions or co-interventions? - What were physiotherapists attitudes towards the exercises assessed?
Outcome Measurements	
- How burdensome were the outcomes measured? - Could any of the data have been collected in a more efficient manner e.g. postal/telephone-based/electronic? - How clear were the questionnaires and outcome measures presented and understandable?	- Were the data forms formatted and collate most effectively? - Were there any technical problems in performing the assessments? - Was there sufficient training provided regarding the collection of data and undertaking of manual data collection methods i.e. dynamometry and joint position sense testing? - Was blinding of assessors maintained throughout the trial?
Follow-Up	
- What are the barriers to continued participation for follow-up? - Were the follow-up period convenient in the gap between them? - Was the location and timing of follow-up appointments appropriate? - Were participants sufficiently informed when they would be expected to attend the follow-up period? - Would participants have required an incentive to attend this appointment if they had missed one? - If participants did miss an appointment, did the team prompt them appropriately to attend a second appointment?	- Were methods in-place to determine emergency 'unblinding'? - How were missing participants identified and prompted to attend a second appointment? - Was this successful? - Why do physiotherapists think the participants did not attend their follow-up appointment? - Could anything have been done to improve this? - Was their sufficient facilitates and staffing to perform the follow-up review appointments?
Analysis/Dissemination	
- Would participants like to be able to see the results of the study? - How would it be best to present these	- Was the a priori analysis plan followed or deviated? - Was there any difficulty in preparing the

results? - Do participants think other people would be interested in seeing these results? - What would be the best place to present these results to that all who wish to see them, can?	final report across the different study sites and researchers? - Where best do the focus group think these results could be disseminated? - How should be informed of these results to specifically maximise the impact of these findings? - When should these authorities be informed of the results of the study? - Could the present study design have sufficient impact to change national/international policy? - If not to the above, how could this be facilitated?
Study Management	
- Were the site researchers contactable when required? - Did the participants feel supported throughout the study by the clinicians and the trial study group if required? - Were there any problems regarding reimbursement of follow-up appointments?	- Did all members of the clinical and research teams feel adequately trained about the study protocol? - Were there any problems will communication within the trial site between the researchers and clinicians? - Did any communication problems arise between the trial team and the individual site? - Did any problems arise regarding the storage of equipment or data? - Did any issues regarding reimbursement of follow-up appointments or study costs arise? - Was there sufficient staff within the study sites or expertise within the research team to conduct the trial?

A Trial Management Group meeting will be set aside to examine the workability of different members within the research team. This may be particularly important as collaborators will originate from different parts of the country, and will be reliant on electronic means of communication such as email, telephone and teleconference. Therefore an assessment of the logistics and potential technological obstacles such scenarios provide may be a key factor to the success of the research team.

18.8.5 Data Analyses

An inductive qualitative analysis approach will be used to identify themes emerging from the data. Potential themes, which may arise, are recruitment, randomisation, outcome measures, interventions and follow-up study procedures. However, this will remain unknown until data is analysed.

18.9 Summary

This chapter has described and justified a proposed feasibility study based on the results of the three studies previously presented in this thesis. It particularly addresses the weaknesses identified within the RCT. Whilst this feasibility study is designed to address the major uncertainties of a definitive trial, particularly with respect to recruitment and eligibility, outcome measures, sample size, randomisation and follow-up periods, further work to determine the efficacy of the interventions would be required. This would take the form of specific Phase II dose-response trials prior to commencing this feasibility study. Nonetheless, this final chapter provides a clear direction towards further work which is warranted to continue to develop the evidence-base on FTPD.

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Appendices

Content Page

Appendix 1. Search terms adopted for the MEDLINE databases for each of the literature review chapters

MEDLINE Search Strategy – Chapter 3

1. Patellar Dislocation/
2. Patella/ and Dislocations/
3. (patell$ adj3 (dislocat$ or sublux$ or instability)).tw.
4. or/1-3
5. terminology/
6. nomenculature.tw.
7. epidemiology/
8. frequency/
9. incidence/
10. occurrence/
11. prevalence/
12. surveillance/
13. aetiology.tw.
14. etiology/
15. pathogenesis/
16. cause/
17. causality/
18. genu valgum.tw.
19. hypermobility.tw
20. biomechanics.tw.
21. pes planus.tw.
22. patellar alta.tw.
23. patellar baja.tw.
24. core stability.tw.
25. muscle control.tw.
26. trochlear dysplasia.tw.
27. femoral rotation.tw.
28. medial patellofemoral ligament.tw.
29. EMG.tw.
30. Electromyography/
31. onset timing.tw.
32. or/5-31
33. and/4,32
34. exp animals/ not humans/
35. 33 not 34

MEDLINE Search Strategy – Chapter 4

1. Patellar Dislocation/
2. Patella/ and Dislocations/
3. (patell$ adj3 (dislocat$ or sublux$ or instability)).tw.
4. or/1-3
5. assess$.tw.
6. assessment, patient outcome/
7. Diagnoses and Examinations/
8. Physical Examination.tw.
9. Diagnostic Tests, Routine/
10. test$.tw.
11. outcome measure$.tw.
12. Apprehension test.tw.
13. quadriceps-angle, q-angle.tw.
14. tracking.tw.
15. J-sign.tw.
16. Bassetts.tw.
17. Sensitivity and Specificity/
18. diagnostic test accuracy.tw.
19. or/5-16
20. or/17-18
21. and/4,19,20
22. exp animals/ not humans/
23. 21 not 22

MEDLINE Search Strategy – Chapter 5

1. Patellar Dislocation/
2. Patella/ and Dislocations/
3. (patell$ adj3 (dislocat$ or sublux$ or instability)).tw.
4. or/1-3
5. exp Rehabilitation/
6. exp Physical Therapy Modalities/
7. "Physical Therapy (Specialty)"/
8. Braces/
9. Immobilization/
10. rh.fs.
11. rehabilitat$.tw.
12. physiotherapy.tw.
13. physical therapy.tw.
14. (non-surg$ or nonsurg$ or non-operat$ or nonoperat$ or conserv$).tw.
15. (immobilis$ or immobiliz$ or therap$ or exercis$ or taping or tape$ or brace or bracing or manual therapy or electrotherap$).tw.
16. or/5-15
17. 4 AND 16
18. exp animals/ not humans/
19. 17 not 18

MEDLINE Search Strategy – Chapter 6

1. Patellar Dislocation/
2. Patella/ and Dislocations/
3. (patell$ adj3 (dislocat$ or sublux$ or instability)).tw.
4. or/1-3
5. EMG.tw.
6. Electromyography/
7. onset timing.tw.
8. activity.tw.
9. preferential.tw.
10. recruitment.tw.
11. isolate$.tw.
12. exercise/
13. or/5-12
14. exp animals/ not humans/
23. 13 not 14

Appendix 2. Supportive Chapter providing Background Information on the Patellofemoral Joint

A2.1 Introduction

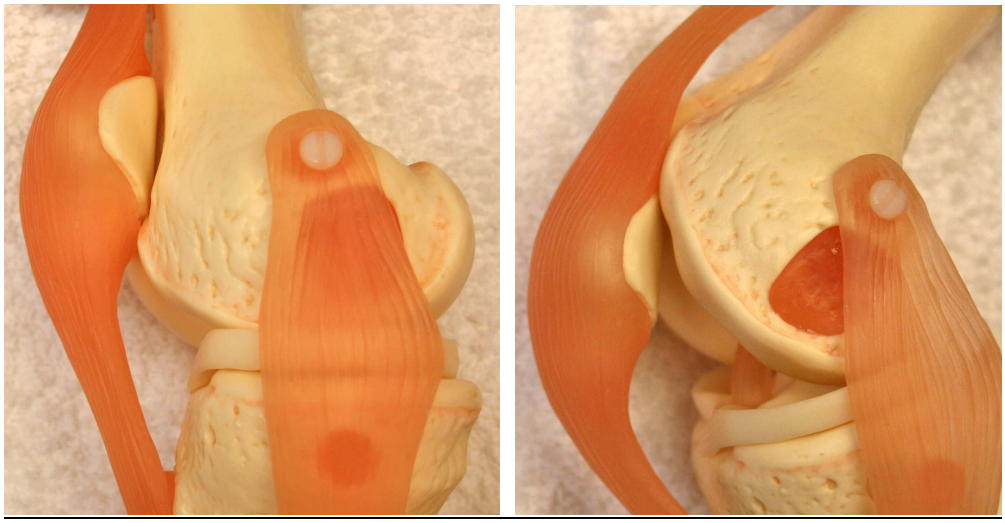
The complexity of the patellofemoral joint's anatomy is a principal factor for the development of its musculoskeletal pathologies (Amis et al, 2008). Only by understanding the anatomical structures and biomechanics of this joint, is it possible to appreciate the difference between the 'normal' and 'pathological' patellofemoral joint.

This supportive chapter introduces the patellofemoral joint. By outlining the key anatomical features of the patellofemoral joint in relation to its structure and function, it will be possible to better understand how mechanical instability arises through dislocation. This chapter has been divided to discuss and analyse the anatomy of the patellofemoral joint (**Section A2.2**), embryology (**Section A2.3**), the function (**Section A2.4**) and finally the biomechanics of the patellofemoral joint (**Section A2.5**).

A2.2 Anatomy

The patellofemoral joint consists of two osseous structures: the patella and the femur (Drake et al, 2009; Tria and Alicea, 1995; **Figure A2.1**).

Figure A2.1. A photograph of a model lateral view of the tibiofemoral joint and the patellofemoral joint at zero and forty-five degrees knee flexion.



A2.2.1 The patella

The patella is a small triangular-shaped bone, located within the quadriceps tendon, anterior to the knee joint (Dath et al, 2006; Drake et al, 2009; **Figure A2.1**). It is the largest sesamoid bone in the body (Sarin et al, 1999; Dath et al, 2006).

The articulating surface of the patella consists of three facets, the medial, the lateral, and the odd or extreme medial facet which is situated on the most medial aspect (**Figure A2.2**; Drake et al, 2009; Griffin et al, 2008). Textbooks have suggested that these facets are divided by two faint transverse ridges which separate the three facets (Dath et al, 2006; Palastanga et al, 2006; Tecklenburg et al, 2006). Although some surgeons have suggested that these ridges are rarely exhibited (Simon Donell, personal communication, 2010), dissection and stereophotogrammetry studies have supported their existence (Kwak et al, 1997). Kwak et al (1997) in their study assessing the articular cartilage surfaces of forty-nine human patellae and twenty-four distal femora, suggested that this difference in opinion may reflect the difference seen in patella morphology with each patella matching the femoral trochlear's tomography.

The patella possesses a thick articular cartilage. It has the largest thickness of articular cartilage in the body being up to seven millimetres in depth (Dath et al, 2006). This reflects the high contact pressures which are produced through the patella within the femoral trochlear during functional activities (Grelsamer, 2000).

Figure A2.2 A photograph of superior and retropatellar aspects of a human patella and its facets.

Anterior View **Retropatellar View**

Wisberg (1941) acknowledged that the shape of the patella can differ between individuals. He classified patella shape into three different configurations based on patellar facet size and shape (**Figure A2.3**). The pathological relevance of the different patellar shapes remains unclear in patellar instability. Whilst structurally, it has been hypothesised that individuals with a Type I patellar shape should have a reduced risk of patellofemoral dysfunction and instability through a more congruent shape, there is insufficient evidence to support this statement. Whilst previous authors have indicated that people with Type II or III patellae may have a greater risk of PFPS, this association has only been demonstrated in computer modelling studies of patellar instability (Amirouche et al, 2009). Furthermore, this association was reported as incorrect in Fucentese et al's (2006) study. They compared twenty-two patellae with underlying trochlear dysplasia with twenty-two age and sex-matched knees with normal trochlear shape through magnetic resonance imaging (Fucentese et al, 2006). The authors reported that there was no significant association between patellar shape and patellar instability (Fucentese et al, 2006).

Figure A2.3 A schematic view of the three Wisberg's patellar shape.

Type I

Type II

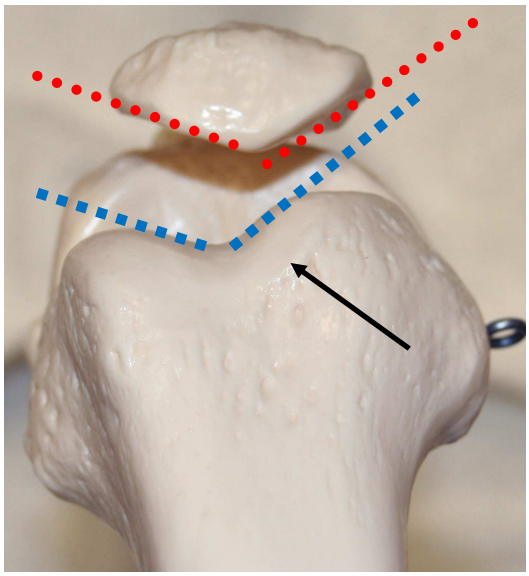
Type III

A2.2.2 The trochlear groove

The patella moves within the distal femur's trochlear groove (Abadie et al, 2009). The groove is formed by the medial and lateral condyles of the femur (Abadie et al, 2009; **Figure A2.4**). The femoral condyles themselves are unequal in size and asymmetrical (Dath et al, 2006). The lateral femoral condyle is larger and extends more anterior in the saggital place (Drake et al, 2009; Agur and Dalley, 2008; Glard et al, 2005). The normal angle of the trochlear groove is 137 degrees with eight degrees of variability (Scuderi, 1995). The groove is flatter at the proximal portion compared to the distal aspect, and is deeper distally to optimise the conformity of the patella (Tria and Alicea, 1995; Drake et al, 2009). Through these features, the femoral trochlear has evolved to provide osseous support for the patella as it engages within the confines of the medial and lateral femoral condyles (Glard et al, 2005).

The asymmetry in the femoral trochlear has been attributed to the development of femoral obliquity as a consequence of bipedal locomotion. Published series comparing apes to humans have reported that apes demonstrate a wide and symmetrical trochlear groove without a protrusion of the lateral femoral lip which is seen in humans (Heiple and Lovejoy, 1971; Tardieu and Trinkaus, 1994; Tardieu, 2000; Tardieu and Dupont, 2001). Through hominid evolution, Gland et al (2005) suggested this morphological feature has selectively developed, becoming genetically assimilated to minimise patellar lateralisation and dislocation during bipedal gait.

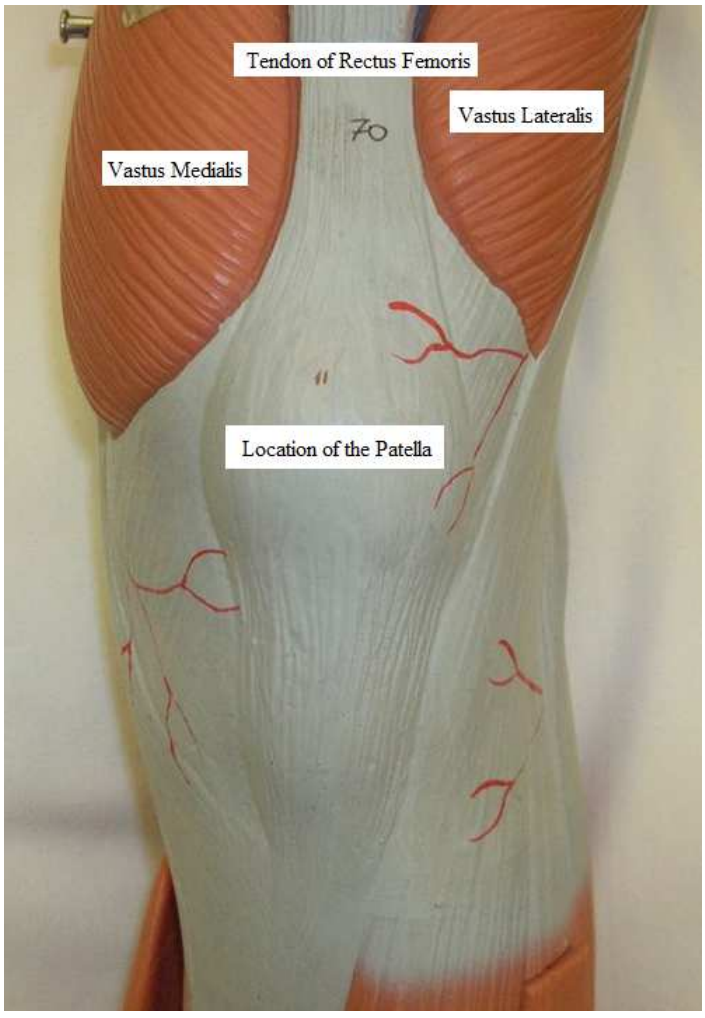
Figure A2.4 A photograph of a model knee depicting the typical trans-epicondylar axis of the trochlear groove, and its congruence with the patella.



A2.2.3 Soft tissues surrounding the patella

The patella is 'enveloped' within the quadriceps complex (Drake et al, 2009). The quadriceps femoris muscle or quadriceps complex is composed of four distinct parts: the vastus intermediius, vastus medialis, vastus lateralis and rectus femoris (Taşkiran et al, 1998; Drake et al, 2009). The quadriceps complex arises from the individual muscle attachments and extends either side of the patella via the patella retinaculum, passing backwards to the collateral ligaments and downwards through the patellar tendon to the tibial condyles (Dath et al, 2006; **Figure A2.5**). The patellar tendon then attaches to the tibial tuberosity (Tortora and Grabowski, 2000).

Figure A2.5. A photograph of a model of the quadriceps muscle complex.



A2.2.3.1 Non-contractile medial soft tissues

The medial retinaculum is situated medial to the patella (Drake et al, 2009). Its fibres originate from the crural fascia and the distal aspects of the vastus medialis, and merge to attach to the patellar tendon at an angle of ten to forty-five degrees (Panagiotopoulos et al, 2006; Drake et al, 2009). Anatomical studies have described the medial retinaculum as a three-layered structure (Warren and Marshall, 1979). These consist of: the knee joint capsule (layer one) which is deepest, the medial retinaculum, medial patellofemoral ligament and the superficial band of the medial collateral ligament in layer two, whilst the deep fascia and distal vastus medialis are most superficial comprising of layer three (Warren and Marshall, 1979; Boden et al, 1997; Fellar et al, 1993).

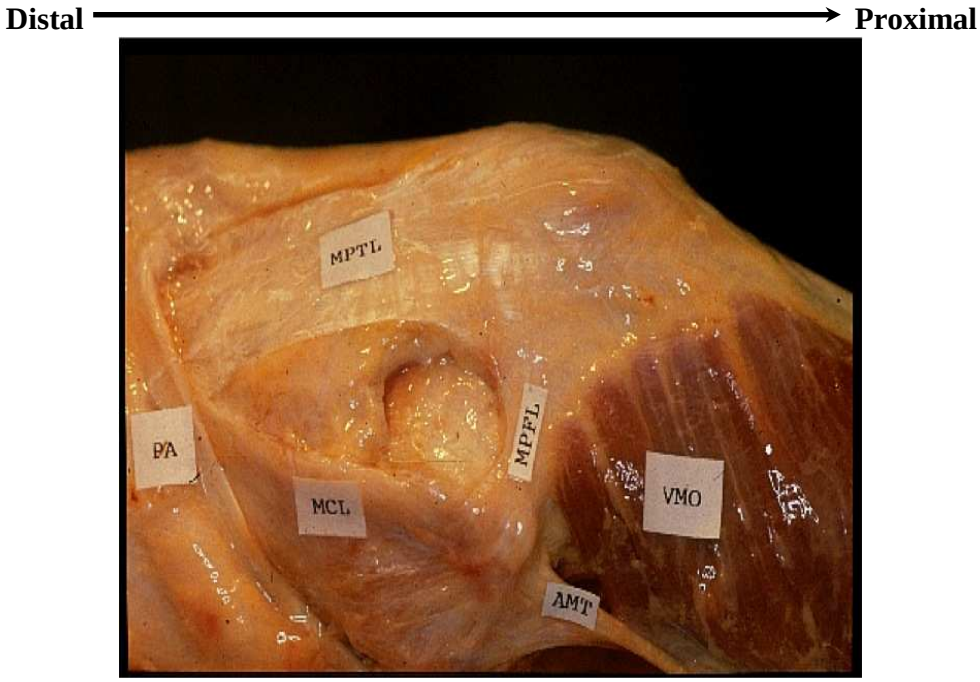
Three ligaments attach to the medial aspect of the patella. The medial patellotibial ligament originates from the medial aspect of the tibia, approximately fifteen to twenty millimetres below the joint line, and fifteen to twenty millimetres medial to the patellar tendon, and inserts on the lower pole of the patella (Panagiotopoulos et al, 2006; **Figure A2.6**). The medial patellomeniscal ligament originates from the medial capsulomeniscal region, and attaches on the lower pole of the patella (Panagiotopoulos et al, 2006). The medial patellofemoral ligament (MPFL) originates from the adductor tubercle of the medial femoral epicondyle, passes along the under surface of the distal vastus medialis, and attaches to the proximal two thirds of the patella (Baldwin, 2009; Hautamaa et al, 1998; Fithian et al, 2004a; Amis et al, 2003; Farahmand et al, 2004; **Figure A2.6**). The MPFL's fibres mesh with the medial retinaculum (Panagiotopoulos et al, 2006). All three ligaments provide restraint to lateral translation of the patella (Amis et al, 2003). However, the evidence-base indicates that the MPFL provides the most restraint, contributing up to fifty percent of all resistance to lateral patellar translation in cadaveric studies (Hautamaa et al, 1998; Nomura et al, 2000; Conlan et al, 1993; Desio et al, 1998).

A2.2.3.2 Contractile medial soft tissues

The contractile or active medial tissue of the patellofemoral joint is the distal vastus medialis or VMO (**Figure A2.6**). The VMO arises from the adductor magnus muscle and, to a lesser degree, from the tendon of the adductor longus muscle. It inserts into the medial border of the patella, between one-third to one-half from the proximal pole (Grelsamer, 2000; Herrington, 1998; Koskinen and Kujala, 1992; Phornphutkul et al, 2007). The vastus medialis longus (VML) originates from the medial lip of the linea aspera and the medial intramuscular septum, and inserts into the medial margin and anterior surface of an aponeurosis, which merges with the quadriceps tendon (Javadpour et al, 1991; Travnik et al, 1995).

Some authors have argued that the distinction of the VMO and VML to two separate anatomical structures is incorrect, suggesting that these muscles are a single entity (Glenn and Samojla, 2002; Jojima et al, 2004). Anatomists and surgeons have cited a number of factors to distinguish whether the vastus medialis is one or two independent muscles (Hubbard et al, 1997; Salmons, 1995). These factors have included the identification of different muscle fibre alignment in two distinct lines of action (Weinstabl et al, 1989), the presence of a fibrofascial plane to indicate a structural boundary between two discrete components (Javadpour et al 1991; Travnik et al, 1995), and separate innervations to allow the VML and VMO to exhibit different contraction onset timings (Glenn and Samojla, 2002; Jojima et al, 2004; Lieb and Perry, 1971; Terry, 1989).

Figure A2.6 A picture of a dissection-prepared knee, demonstrating the oblique fibres of the vastus medialis, and proximity of the MPFL to the distal vastus medialis and patella.



Permission requested for the use of this image from Dr Yrjänä Nietosvaara, the Hospital for Children and Adolescents, Helsinki University Central Hospital, Finland

Eighteen studies have investigated the difference in morphology between the VMO, VML and vastus medialis complex. The results of these studies are presented in **Table A2.1**. Eleven studies have investigated whether there was a difference in fibre alignment within the length of the vastus medialis. All but

one study reported greater obliquity in fibre alignment of the VMO to the VML. There was no clear methodological reason to account for the difference between Glen and Somojla's (2002) findings and the other ten studies. Overall VMO fibre orientations ranged from forty to seventy-seven degrees, with a mean fibre angle of fifty degrees. In comparison the fibre orientation of VML ranged from twelve to thirty-five degrees, with a mean fibre orientation of twenty-two degrees.

Eleven studies investigated the presence of a fibrofascial plane. Of these, six reported the presence of this anatomical structure, although not consistently seen in all cadavers in these series. Finally, eleven studies have examined the vastus medialis' innervation. These indicated that there was no consistency in the existence of a separate innervation to the VMO and VML when magnetic resonance imaging (MRI) or cadaveric studies were assessed. Accordingly, with the exception of a definite change in fibre alignment which itself may alter the force applied to the patella from the VML, there is limited evidence to support the VMO being described as a separate anatomical entity. However only Bose et al's (1980) study assessed vastus medialis morphology in ten knees which had experienced patellar dislocation. It is therefore unclear whether there is a difference in anatomical features between the VML and VMO in this population.

3.2.3.2 The lateral soft tissues

The lateral retinaculum is composed of various layers of fibrous tissue which form the superficial and deep lateral retinaculum (Boden et al, 1997; Palastanga et al, 2006). The anterior portion of the superficial layers consist of a fibrous expansion of the vastus lateralis which passes longitudinally along the lateral border of the patella and inserts into the patellar tendon (Reider et al, 1981). Fibres from the iliotibial band interdigitate with fibres from the vastus lateralis and the patellar tendon to form the superficial oblique retinaculum (Fulkerson and Hungerford, 1990).

The principal contractile structure of the lateral soft tissues is the vastus lateralis. This originates from a broad aponeurosis which attaches to the upper part of the intertrochanteric line, to the anterior and inferior borders of the greater trochanter, to the lateral lip of the gluteal tuberosity, and to the upper half of the lateral lip of the linea aspera (Drake et al, 2009). It attaches on the lateral border of the patella, blending with the quadriceps tendon, and giving an expansion to the capsule of the knee joint (Palastanga et al, 2006). Sixteen studies have investigated the morphology of the vastus lateralis. As with the vastus medialis, some anatomists have subdivided the vastus lateralis into portions based on individual innervations, fibre pennation angle and the presence of anatomical partitions through fascial planes (Becker et al, 2009; Willan et al, 1990). These portions have been termed as: the central partition,

the superficial proximal partition, the deep proximal partition, and the deep distal partition (Becker et al, 2010). Others have divided the vastus lateralis into two, the vastus lateralis longus (VLL) and the vastus lateralis oblique (VLO) (Hallisey et al, 1987; Bennett et al, 1993; Bevilaqua-Grossi et al, 2004). As with the distal vastus medialis, the distal vastus lateralis fibre alignment is more oblique, with an average of thirty-one degrees compared to eleven degrees at the proximal portions (Becker et al, 2010; Becker et al, 2009). Through this angulation, the vastus lateralis and vastus medialis are able to exert a greater translational force on the patella compared to a more acute, horizontal force. Through this morphological difference to the more proximal portions of the muscles, there is greater mechanical advantage on patellar translation (Hall, 2007). However, the literature disputes the presence of a fascial plane and individual innervations between the purported different portions of the vastus lateralis (Becker et al, 2010; Becker et al, 2009).

A2.2.4 Vascular supply

The knee's blood supply orientates around a vascular ring of five geniculate arteries (Drake et al, 2009). These are the superomedial geniculate, superolateral geniculate, middle geniculate, inferomedial and inferolateral geniculate (Dath et al, 2006). Anatomical studies have indicated that the specific vascular supply to the patella is derived from these five arteries to form the "arterial circle" (Kirschner et al, 1997). The patella's principal blood supply enters through the inferior pole.

A2.2.5 Innervation

The knee is innervated from contributions of the sciatic nerve (medial popliteal nerve) and the posterior division of the femoral nerve (saphenous nerve) (Drake et al, 2009). The patella has a multiple sensory efferent supply from the terminal branches of the lateral, intermediate and medial cutaneous nerves, and from the infrapatellar branch of the saphenous nerve (Dath et al, 2006; Drake et al, 2009). Both the vastus medialis and the vastus lateralis are innervated by the femoral nerve, the vastus medialis innervated from a medial and posterior branch, whilst the vastus lateralis is supplied by a lateral and deeper branch (Linss et al, 1990; Engstrom et al, 1991; Wang et al, 1999; Patil et al, 2007). Whilst there appeared no inter-connecting nerve branches from the vastus lateralis and vastus medialis or intermediate in three of the four studies which have investigated this area (Linss et al, 1990; Engstrom et al, 1991; Wang et al, 1999; Patil et al, 2007), Patil et al (2007) demonstrated the presence of an inter-connecting nerve branch was present between the vastus lateralis and vastus intermediate in eight percent of their cadaver specimens. The literature has been unable to account for this difference in findings (Becker et al, 2009).

A2.3 Embryology

The knee joint and patella arises from blastemal cells at approximate the seventh week of intra-uterine life (Gardner and O'Rahilly, 1968; Tria and Alicea, 1995). These cells develop deep to the patellar tendon as an uncalcified cartilaginous structure. The patella can exhibit as many as six ossification centres which typically aggregate to form a single nucleus. The structure grows but does not ossify until the child is approximately four to six years old, forming the patella (Morrison and Menico, 2001; Gardner and O'Rahilly, 1968; Beasley and Vidal, 2004; Sarin et al, 1999). The femoral trochlea is well formed and congruent in the neonate (Beasley and Vidal, 2004: Nietosvaara, 1994). As the child grows, the thick cartilage which covers the patella and trochlear gradually thins deepening the trochlear (Hinton and Sharma, 2003; Nietosvaara and Aalto, 1993). Potential consequence of mal-development during embryological stages can be: patellar alta, where the patella is positioned abnormally high in relation to the femur; patella hypoplasia where the patella under-develops and is abnormally small; and the congenital absence of the VMO itself (Dath et al, 2006).

A2.4 Function of the Patella

The function of the patella is: to increase the leverage of the tendon of the quadriceps femoris muscle, to maintain the position of the tendon when the knee is flexed to achieve optimal knee extensor strength, and to protect the knee joint (Bahr and Maehlum, 2004; Dath et al, 2006).

A2.5 Patellofemoral Joint Biomechanics

The path the patella makes during knee motion is a combined movement through multiple planes of motion. As the patella moves within the femoral trochlea it assumes a toroidal path as it tilts, translates and rotates (Beasley and Vidal, 2004; Stanitski, 2003). At any given time, only a portion of the patella articulates with the femoral sulcus.

In full extension the patella is naturally in its most proximal and lateral displaced position, assuming a superolateral position to the femoral sulcus (Beaslsey and Vidal, 1998; Senavongse et al, 2003). The patella normally engages in the femoral sulcus between ten to thirty degrees knee flexion (Beasley and Vidal, 2004; Senavongse et al, 2003). As the knee flexes from ten to ninety degrees flexion, the patella's contact shifts from the distal to proximal poles (Goodfellow et al, 1976). From ninety to 120 degrees flexion, articular contact pressure remains unchanged as the inferior aspect, odd facet, and ultimately when the quadriceps tendon comes into contact with the trochlear effectively increasing contract area (Grelsamer, 2000). At knee angulations greater than 120 degrees, there is no contact between the patella and the medial

Table A2.1 Table representing a summary of the literature's findings on the assessment of anatomical differences between VMO and VML.

Study	Distinct difference in fibre alignment between VMO and VML		Presence of a fibrofascial plane between VMO and VML		Separate innervations to VMO and VML	
	YES	NO	YES	NO	YES	NO
Bennett et al (1993)						
Farahmand et al (1998)						
Galtier et al (1995)						
Glen and Samojla (2002)						
Hubbard et al (1998)						
Javadpour et al (1991)						
Jojima et al (2004)						
Lefebvre et al (2006)						
Lieb and Perry (1968)						
Nozic et al (1997)						
Ono et al (2005)						
Özer et al (2004)						
Peeler et al (2005)						
Raimondo et al (1998)						
Reider et al (1981)						
Thiranagama (1990)						
Toumi et al (2007)						
Weinstabl et al (1989)						

femoral condyle, with the exception of the lateral facet and the small, nearly vertical odd facet (Grelsamer and McConell, 1998; Kwak et al, 1997; Dath et al, 2004; Goodfellow et al, 1976).

The force and contact pressures which pass through the patellofemoral joint are activity dependent. For instance, during level walking the highest force across the patellofemoral joint is approximately half body weight (Reilly and Martens, 1972), stair climbing and descending increases this to three times body weight (Hehne, 1990), whilst forces are even greater during squatting activities (Dath et al, 2006). Biomechanical studies have suggested that the patellofemoral joint contact pressures are at their lowest from zero to thirty degrees of knee flexion where the patella has not engaged within the femoral trochlear (Quintelier et al, 2008; Melegari et al, 2008).

A2.6 Summary

The patellofemoral joint is complex in relation to its anatomical features and biomechanical activity. If the 'balance' between the anatomical structures is lost a change in biomechanical behaviour can ensue.

Appendix 3. List of physical examination test for people with suspected patellar instability pathology

Assessment	Test Description
Prone quadriceps angle	Patient prone. Knee flexed with one hand while stabilising the pelvis with the other hand. The heel is then brought as close as possible to the buttock. Record the distance from the heel to the buttock and any side-to-side asymmetry.
Popliteal angle	Patient supine, non-test limb fully extended and flat to the plinth. The test limb is passively flexed to 90 degrees hip flexion with the knee flexed. The knee is then passively extended as far as possible and the degree of knee extension is measured with goniometer with one arm of the goniometer on the long axis of the thigh, and the other along then long axis of the lower limb.
Patellar tilt	Patient spine, knee relaxed in full extension. Examiner holds the patella between their thumb and forefinger, and pushes the patella down in an attempt to flip the lateral edge of the patella upwards. Elevation of the lateral patella to less than neutral suggests an abnormal result, where 0 to 20° elevation is normal.
Patellar glide	Patient spine, knee in full extension. Patella manually glided medially and laterally. The patella is divided into 4 quadrants. A glide greater than or equal to 3 quadrants (or more than half the patellar width) represents reduced patella restraint.
Medial and lateral Apprehension tests	Patient supine, knee relaxed in 30° flexion. Examiner uses one hand to push the patella laterally. A positive sign is when it reproduces the patient's pain or causes fear that the patella will dislocate. Apprehension can either be from verbal expression of anxiety, and/or involuntary quadriceps muscle contraction.
ITB flexibility (modified Thomas test)	The patient lies on the uninvolved side with the lower knee flexed to help reduce lumbar lordosis. The examiner lifts the upper flexed or extended leg at the ankle while stabilizing the pelvis with the other hand, then abducts and extends the hip allowing the iliotibial band (ITB) to move posteriorly over the greater trochanter. The examiner then slowly lowers the upper leg. If the leg drops to the table, the test is negative; if it remains abducted, the test is positive. It is extremely important in performing this test to hold the patient's pelvis and keep it at a right angle to the table while moving the involved side.
Graded Thomas Test	Subject supine. Pelvis positioned near the end of the plinth. Non-test limb hip and knee held in maximal flexion by the subject. Test limb is taken passively from the fully flexed position to an extended position off the table. The ipsilateral anterior superior iliac spine (ASIS) is palpated during full range of motion. The test is positive of the ipislateral ASIS begin to nutate before the thigh reached an angel of 20 degrees to the table.
Hypermobility criteria (Beighton-Horan)	Beighton-Horan Assessment [14].
Q angle	Patient supine or standing. A line is drawn from the anterior superior iliac spine, to the centre of the patella. A second line is then drawn from the centre of the patella to the tibial tubercle. The angle this makes is the Q-angle. Normal value is 10 to 15º for men and 15 to 20º for women [6].
Foot arch position	The navicular bone is palpated in sitting and standing. If the navicular bone drops from sitting to standing, the subject is determined to have a pes planus type. If there is no drop, and the arch appears high, then the foot type if cavus.
Tibial torsion (prone goniometric malleolar angle)	Patient supine. Examiner aligns the patient’s legs to that the knees are extended and the patella face ahead. A goniometer is then placed with the one arm aligned with the hallux, and the second arm vertical and the fulcrum to the calcaneous. The angle between the vertical to hallux represented the degree of tibial torsion.
Hip version (prone Staheli method)	Patient lies prone, non-test leg remains straight and flat. Test limb flexed to 90 degrees knee flexion. Subject instructed to keep their pelvis flat on the table while internally or externally rotating the femur. Angle of the tibia from vertical is measured using a

	goniometer.
Standing posture – lower limb	With the patient in relaxed, normal, standing, an observation of overall lower limb femoral and tibial posture is made in respect to being either valgus or varus in orientation.
Pain on palpation of the patellar retinaculum	Careful palpation of the medial aspect of the patellar and medial retinaculum investigating for pain or a palpable defect the medial retinaculum.
Crepitus	Patient's knee is taken through full range of motion, whilst the examiners hand is placed over the patellofemoral joint. A positive recording of creptius is made if crepitus is heard or felt by the examiners during this range of motion.
Patellar TrackingTest (J-sign)	Patient sits on the edge of the plinth, knee in full extension. Patient then actively moves the knee into full flexion. Examiner observes for an exaggerated lateral to medial translation of the patella into the trochlear groove in early flexion.
Bassett's sign	Palpation of the adductor tubercle and medial epicondyle.
VMO Capability test	Patient sits on edge of bed. Examiner observes for atrophy on the medial aspect of the distal thigh when the leg is activity extended against gravity at 15 to 45º.

Appendix 4. A summary table presenting the study characteristics of papers reviewed which had investigated whether altering lower limb joint positioning could preferentially affect VMO EMG activity.

Study	Sample size and Diagnosis	Population Characteristics Gender; mean and SD Age (years) and Height (cm)	Test Procedures	Electrode type; sampling rate; signal processing	Period of EMG Analysis	Contraction type for EMG Analysis
Bos and Blosser (1970)	16 asymptomatic	M/F: 16/0 Age: 19-38 (range) Height: N/D	Isometric knee extension in 0º hip and knee flexion in standing; with ankle dorsiflexion and femoral and tibial 60º external rotation; or in ankle neutral and hip abduction.	Surface electrode, indwelling electrodes also used on 5 participants; SR not stated; no signal processing.	Not stated	Isometric
Cerny (1995)	10 PFPS 10 asymptomatic	PFPS M/F: 1/9 Age: 26.9±80 Height: N/D Asymptomatic M/F: 0/10 Age: 26.5±4.5 Height: N/D	Isometric knee extension in 0º knee flexion and isokinetic knee extension from 30º to 0º knee flexion with hip in neutral, maximal internal rotation, maximal external rotation; or in hip neutral with maximal isometric hip adduction, maximum ankle dorsiflexion, maximal plantarflexion, or ankle neutral. Isometric knee extension holds at 45º flexion with tibial neutral, maximum internal, maximum external rotation. WS-SD exercises to 45º knee flexion with subtalar unconstraint, in maximum supination, maximum pronation; SS to 45º knee flexion with and without maximal isometric hip adduction	Indwelling electrode; SR 2000Hz; FWR and integrated over 0.02 sec intervals; normalised to MVIC	Data integrated if exceeded noise threshold (95% resting EMG during 2 sec baseline period)	Isometric and Isokinetic
Coqueiro et al (2005)	10 PFPS 10 asymptomatic	PFPS M/F: 0/10 Age: 23.2±2.7 Height: 158.0±0.1 Asymptomatic M/F: 0/10 Age: 21.8±2.5 Height: 165.0±0.04	SS at 45º knee flexion, 30º hip abduction, with or without maximal isometric hip adduction	Surface electrode; SR 2000 Hz; processed by RMS, window size not stated; normalised to MVIC	2^{nd}-6^{th} sec into the SS position, average EMG calculated	Isometric

Earl et al (2001)	20 asymptomatic	M/F: 10/10 Age: 28.1±5.9 Height: 170.9 ±11.0	SS to 30º knee flexion with and without maximal isometric hip adduction.	Surface electrode; SR 1000Hz; processed by RMS, window size not stated; normalised to MVIC.	Average EMG calculated for entire 4 sec contraction	Isokinetic
Gregersen et al (2006)	14 asymptomatic	M/F: N/D Age: 28.0 (range 18-30) Height: 182.0 (range 173-191)	Cycling with foot attached to pedal at 10º, 5º, 0º of ankle supination or pronation.	Surface electrode; SR 1200 Hz; FWR & LPF 10Hz; normalised to maximum value during pedalling.	4, 5 sec trials recorded over 5 min period for each foot position. Unclear when 5 sec trials taken. Peak and average EMG used.	Isokinetic
Herrington et al (2006)	43 asymptomatic	M/F:20/23 Age: 22.8±2.3 Height: N/D	Isokinetic knee extension and SS to 90º knee flexion, with hip in either neutral; 30º internal; or 30º external rotation. All exercises performed against a load equivalent to 10% subject's body weight	Surface electrode; SR 2000Hz; processed by RMS window 20ms intervals; normalised to MVIC.	"a standardised period (4 sec from onset)".	Isokinetic
Hertel et al (2004)	8 asymptomatic	M/F: 5/3 Age: 24.0±2.5 Height: 169.5±4.7	SS on 30º slope at 60º knee flexion with and without maximal isometric hip abduction and adduction.	Surface electrode; SR 1000Hz; HPF 75 Hz; processed by RMS; normalisation not used	Maximum RMS value over a 0.5 sec window calculated, from 5 sec contraction	Isometric
Hodges and Richardson (1993)	20 asymptomatic	M/F: 0/20 Age: 19.5±0.8 Height: 166.7±5.2	OKC knee extension from 60º to 0º knee flexion; and SS from 60º to 0º knee flexion, both with and without isometric hip adduction at 15%, 50% and 100% MVIC	Surface electrode; SR, not stated; processed by RMS, window not stated; normalisation not used	Not stated	Isometric
Hung and Gross (1999)	20 asymptomatic	M/F: 10/10 Age: 29.4±5.7 Height: 168.9±8.0	Isometric knee extension in 0º knee flexion or a SS at 50º knee flexion with: forefoot neutral; 10º supination; or 10º pronation, by standing on a lateral or medial wedges.	Surface electrode; SR 500 Hz; processed by RMS 20 ms window; normalised to MVIC	The maximum mean amplitude for the 2^{nd}-4^{th} sec of a 4 sec contraction	Isometric and Isotonic
Karst and Jewitt (1993)	12 asymptomatic	M/F: 6/6 Age: 24.8±5.8 Height: 178.0±10.1	Isometric knee extension at 0º knee flexion. SLR to 25cm in 0º knee flexion, with and without 45º external hip rotation. SLR to 25cm in 0º knee flexion, with isometric hip adduction.	Surface electrode; SR 500 Hz; FWR & LPF 15Hz; normalised to maximum EMG obtained from any of	5 sec isometric phase of each exercise	Isometric

				the exercises		
Lam and Ng (2001)	16 PFPS	M/F: 5/11 Age: 33.9±5.4 Height: N/D	Submaximal (60% MVC) SS at 20º or 40º knee flexion, with hip neutral; 45º hip external rotation; or 30º internal rotation	Surface electrode; SR 500 Hz; integrated but details not stated; normalisation not used	2nd sec of 3 sec contraction	Isometric
Laprade et al (1998)	9 PFPS 20 asymptomatic	PFPS M/F: 0/9 Age: 24.0±N/D Height: 165.8±N/D Asymptomatic M/F: 0/20 Age: 24.0±N/D Height: 165.6±N/D	Isometric knee extension with knee at 60º flexion. Maximal isometric hip adduction with knee flexed at 50º with and without isometric knee extension. Isometric tibial medial rotation performed with tibia at 30º external rotation, knee at 70º flexion, with and without isometric knee extension.	Surface electrode; SR 6 kHz; FWR but level of smoothing unclear; normalised to levels during isometric knee extension at 50%MVC.	Middle 1.5 sec of a 6 sec contraction	Isometric
Livecchi et al (2002)	13 asymptomatic	M/F:13/0 Age: 24.6±3.7 Height: 178.3±4.8	SLR to 40º hip flexion, and isotonic knee extension from 30º to 0º knee flexion in hip neutral; or maximum lateral rotation. All exercises performed with an ankle weight 5% subject's body weight.	Surface electrode; SR 500 Hz; FWR & LPF 50Hz; av EMG normalised to peak EMG from same trial.	Entire contraction (2 sec)	Isotonic
Miller et al (1997a)	6 PFPS 9 asymptomatic	PFPS M/F: 0/6 Age: 20.8±2.3 Height: 165.6±5.8 Asymptomatic M/F: 0/9 Age: 20.4±2.2 Height: 160.0±6.8	SU-SD using a 6 inches high step, and SS to 75º knee flexion with hips in femoral and tibial neutral; 45º internal; and 45º external rotation	Surface electrode; SR 1020 Hz; processed by RMS, window size not stated; normalised to MVIC	For 4 sec on 3rd, 8th and 13th repetition of each exercise. Unclear when in contraction collected	Isotonic
Mirzabeigi et al (1999)	8 asymptomatic	M/F: N/D Age: 26.5±4.2 Height: N/D	Isometric knee extension in 15º knee flexion in neutral; hip in 30º internal; or 30º external rotation. Full extension to full flexion knee isokinetic extension with and without valgus and varus knee force. Full flexion to flexion extension squat. Full flexion to full extension squat with jump.	Indwelling electrode; SR 2500 Hz; FWR and integration over 0.02 sec intervals; normalised to MVIC.	Not documented	Isometric, Isokinetic and Isotonic
Serrão et al (2005)	15 asymptomatic	M/F: 10/5 Age: 21.9±1.6 Height: N/D	Submaximal isometric knee extension (at 10 rep max force level) with 90º knee flexion against a horizontal leg press and tibia in maximum internal, maximal external, or	Surface electrode; SR 1000Hz; processed by RMS, window size unclear; normalised to	2nd-4th sec of 4 sec contraction	Isometric

			neutral rotation.	MVIC.		
Tepperman et al (1986)	20 asymptomatic	M/F: 11/9 Age: 22.8±2.7 Height: N/D	Isometric knee extension at 0º hip and knee flexion with maximum ankle dorsiflexion, maximal plantarflexion, or with the ankle in neutral.	Surface electrode; SR 100Hz post-processing; HPF 40Hz; processed by RMS 33 ms window; normalisation not used.	Plateau of 7 sec contraction	Isometric
Wild et al (1982)	18 PFPS	M/F: 4/14 Age: 11-42 (range) Height: N/D	Isometric knee extension with 0º knee flexion and SLR with 0º knee flexion at 8 to 12 inches, with and without 5 pound ankle weights in hip neutral; internal; or external rotation.	Surface electrode; SR not stated; no signal processing; integration carried out manually by planimetry.	Unclear	Isometric Isotonic
Willis et al (2005)	18 PFPS 22 asymptomatic	<u>PFPS</u> M/F: 9/9 Age: 31.4±5.4 Height: N/D <u>Asymptomatic</u> M/F:13/9 Age:26.6±10.4 Height: N/D	Cycling on static bike with foot in tibial external rotation or neutral.	Surface electrode; SR not stated. Peak EMG values used, but whether raw or processed EMG is unclear; normalised to peak EMG during cycling at maximal resistance.	Mean of peak EMG extracted from 4.5 sec periods at intervals of 5, 10, 15, and 20 min during cycling	Isokinetic
Zakaria et al (1997)	20 asymptomatic	M/F: 0/20 Age: 24.0±2.0 Height: 166.0±7.0	Isometric knee extension with knee at 0º flexion with and without maximal active dorsiflexion; isometric bilateral hip adduction (all with hip at 0º flexion/extension/rotation and 10º abduction).	Surface electrode; SR 2500Hz: FWR & LPF 6Hz; normalised to the control IKE condition	2^{nd}-4^{th} sec of 5-6 sec contraction	Isometric

EMG – Electromyography
F – Female
FWR – Full Wave Rectification
Hz – Hertz
HPF – High Pass Filter
kHz - kiloHertz
LPF – Low Pass Filter
M – male
min – minutes
MIC – Maximal Isometric Contraction
msec – milliseconds
mV – millivolts
MVC – Maximal Voluntary Contraction
MVIC – Maximum voluntary isometric contraction
N/D – Not Documented
PFPS – Patellofemoral Pain Syndrome
RMS – Root Mean Square
sec – seconds
SLR – Straight Leg Raise
SR – Sampling Rate
SS – Semi-squat
SU-SD - step-up step-down
SD – Standard Deviation
WS-SD - walk stance-step down

Appendix 5. Three month audit results of patellar dislocation referral rate at five hospitals in the East of England.

Centre 1

Diagnosis on Referral Form			**December 2007**	**January 2008**	**February 2008**
Patellar Dislocation	**Primary**	Paed/Ortho	2	3	2
		GP	1	2	2
		Physio	0	1	0
		A&E	1	1	1

Centre 2

Diagnosis on Referral Form			**December 2007**	**January 2008**	**February 2008**
Patellar Dislocation	**Primary**	Paed/Ortho	5	4	4
		GP	0	0	0
		Physio	0	0	0
		A&E	2	1	3

Centre 3

Diagnosis on Referral Form			December 2007	January 2008	February 2008
Patellar Dislocation	Primary	Paed/Ortho	4	6	5
		GP	1	3	2
		Physio	0	1	0
		A&E	4	4	4

Centre 4

Diagnosis on Referral Form			December 2007	January 2008	February 2008
Patellar Dislocation	Primary	Paed/Ortho	1	0	1
		GP	1	1	0
		Physio	0	0	0
		A&E	0	1	0

Centre 5

Diagnosis on Referral Form			December 2007	January 2008	February 2008
Patellar Dislocation	**Primary**	Paed/Ortho	0	0	0
		GP	0	0	0
		Physio	0	0	0
		A&E	0	0	0

Appendix 6. National survey study self-administered questionnaire

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Code No. ____

Patellar Dislocation Questionnaire
(version 1.0 - 25.08.09)

Patellar dislocation is a musculoskeletal complaint managed by physiotherapists world-wide. Nonetheless, the evidence-base on this topic remains rather limited, particularly with regards to the physiotherapy rehabilitation of this patient group.

The purpose of this study is to assess how Senior Musculoskeletal Physiotherapists in United Kingdom NHS hospitals assess, treat and conservatively manage patients following primary patellar dislocation. By undertaking this piece of work, we will be better informed when designing future studies, to reflect the practices of current physiotherapists in this country.

Your department has been identified using the NHS websites, and has been included in this study, since you are part of an acute NHS hospital trust in the United Kingdom. All questions in this questionnaire relate to patients following **primary** or **'first time' patellar dislocation**, and not for those with recurrent dislocation problems.

This questionnaire has been assigned to you by your team leader as you are either a Senior member of your department with experience of managing patients with knee disorders. We ask you to answer all the questions as fully and as accurately as possible, and to return it in the stamped address envelope provided. This questionnaire should take approximately **25 minutes** to complete.

Please answer all the questions, ticking the boxes where applicable. Please add further comments in the spaces provided, or on the back of the questionnaire if you require additional space.

Initial Question

Q1. Do you manage patients following primary patellar dislocation?

Yes		If YES, please go to Q2
No		If NO, please return questionnaire in envelope provided

Patient Assessment

The following questions relate to the physiotherapy assessment of patients following primary patellar dislocation

Q2. Approximately for what percentage of your patients do you use the following methods for assessing primary patellar dislocation?

Item	**Assessment method**		**100%**	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of test**
A	Convincing report of a patellar dislocation by patient.								
B	Convincing report of a patellar dislocation by referral.								
C	Observation of:	Gait pattern							
D		Genu valgum							
E		Pronation of the foot /pes planus							
F		Patellar malposition (baja, alta, squinting; tilt)							
G		Patellar tracking							
H		VMO atrophy/hypertrophy							
I	Assessment of:	Patellofemoral crepitations							
J		Effusion							
K		Femoral anteversion							
L		Tibial torsion							
M		Multi-joint ligamentus laxity							
N		Quadriceps Strength							
O		Glutei strength							
P		Hamstring Strength							
Q	Special tests:	Q-angle							
R		Apprehension test							
S		Basett's Sign							
T		J-sign							
U		Patellar compression test							
V		Lateral or medial patellar glide							
W	Other…								
X	Other…								
Y	Other…								

Q3. Using the **Item** Letter Code, please rank the order in which you would typically use the above assessment methods most often for your patients following primary patellar dislocation.

	Item
Most frequently used	
Second most frequently used	
Third most frequently used	

Fourth most frequently used	
Fifth most frequently used	

Treatment Strategies

The following questions relate to the physiotherapy treatment strategies which may be used for patients following primary patellar dislocation.

Q4. Approximately, for what percentage of your patients who have sustained a primary patellar dislocation, do you use the following treatment modalities?

Item	**Type**		**100 %**	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of treatment**
A	Exercises (Range of motion)	Active knee exercises							
B	Exercises (strengthening/ recruitment)	General quadriceps							
C		Specific VMO							
D		Hamstring							
E		Glutei muscle							
F		Transversus abdominus							
G	Exercises (stretches)	Quadriceps							
H		Hamstrings							
I		Calf muscles							
J		ITB/tensor fascia lata							
K	Exercises (others)	Proprioception lower limb exercises							
L	Manual therapy	Patellar accessory mobilisations							
M	Advice	Rest and/or behaviour/sporting modification							
N		Reassurance							
O		Elevation							
P	Taping	VMO stimulating taping techniques							
Q		VL inhibiting taping techniques							
R		ITB inhibiting taping techniques							
S	Appliances	Knee braces							
T		Footwear adaptation/ over-the-counter orthotics							
U	Electrotherapy	Ultrasound							
V		Electronic stimulation							
W	Biofeedback	Electronic biofeedback techniques							
X		Manual biofeedback techniques							
Y	Miscellaneous	Ice							
Z		Postural correction							
AA		Acupuncture							
AB		Cognitive Behavioural Therapy							

AC	Others…								
AD	Others…								

Q5. Using the **Item** Letter Code, as before, please rank the order in which you would typically use the above treatments most often for these patients.

	Item
Most frequently used	
Second most frequently used	
Third most frequently used	
Fourth most frequently used	
Fifth most frequently used	

We now wish to further explore the types of strengthening or recruitment exercises which you prescribe to your patients following primary patellar dislocation.

Q6. The following exercises have been described as being able to strengthen the quadriceps and/or the VMO. Approximately for what percentage of your patients do you use these exercises? *For example*, if you teach half of your patients an isometric knee extension exercise IN hip adduction, you would tick the **74-50%** box on the row titled **Isometric knee extension with…hip adduction**

		100 %	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of exercise**
Semi-Squat with…	Lower Limb Neutral							
	Hip Adduction							
	Hip Abduction							
	Hip Internal Rotation							
	Hip External Rotation							
	Tibial Internal Rotation							
	Tibial External Rotation							
	Femoral and Tibial Internal Rotation							
	Femoral and Tibial External Rotation							
	Foot Supination							
	Foot Pronation							
	Ankle Dorsiflexion							
	Ankle Plantarflexion							
Isometric Knee Extension with…	Lower Limb Neutral							
	Hip Adduction							
	Hip Abduction							
	Hip Internal Rotation							
	Hip External Rotation							
	Tibial Internal Rotation							
	Tibial External Rotation							

	Foot Supination							
	Foot Pronation							
	Ankle Dorsiflexion							
	Ankle Plantarflexion							
		100 %	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of exercise**
Straight Leg Raise with…	Lower Limb Neutral							
	Hip Adduction							
	Hip Abduction							
	Hip Internal Rotation							
	Hip External Rotation							
	Ankle Dorsiflexion							
	Ankle Plantarflexion							
Isotonic Knee Extension with…	Lower Limb Neutral							
	Hip Adduction							
	Hip Abduction							
	Hip Internal Rotation							
	Hip External Rotation							
	Tibial Internal Rotation							
	Tibial External Rotation							
	Ankle Dorsiflexion							
	Ankle Plantarflexion							
Static Bike/Cycling with…	Lower Limb Neutral							
	Tibial Internal Rotation							
	Tibial External Rotation							
	Foot Supination							
	Foot Pronation							
Step-Up Step-Down Exercises with…	Femoral and Tibial Internal Rotation							
	Femoral and Tibial External Rotation							
	Foot Supination							
	Foot Pronation							
Other…								
Other…								
Other…								

Q7. Do you mainly treat your patients following primary patellar dislocation ‘one-to-one’, ‘as a group with other patients’ or are these patients treated both as a group and individually?

	Tick
In groups	
One-to-One	
Both	

Outcome Measures

The following questions relate to some outcome measures which the literature has suggested may be used by physiotherapists for patients following patellar dislocation.

Q8. Approximately for what percentage of this patient group do you use the following self-reported measures?

Item		**100 %**	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of tool**
A	Patient Reported Satisfaction							
B	Cincinnati							
C	Fulkerson Patellofemoral Rating Scale							
D	Hughston VAS knee score							
E	International Knee Documentation Committee (IKDC) form							
F	Short-Form 12 or 36							
G	Lysholm							
H	Kujula							
I	Tegner							
J	Musculoskeletal Function Assessment Injury and Arthritis Survey							
K	Other…							
L	Other…							
M	Other…							

Q9. Using the **Item** Letter Code, please rank the order in which you would typically use the above outcome measures most often for your patients.

	Item
Most frequently used	
Second most frequently used	
Third most frequently used	
Fourth most frequently used	
Fifth most frequently used	

Access to the Multi-Disciplinary Team

Q10. Approximately, for what percentage of your patients do you involve other professionals **whilst** a patient following a primary patellar dislocation is under your care?

	100 %	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**
Senior Physiotherapy Colleague						
Appliance Department for knee brace						
Biomechanics Department for Orthotics						
General Practitioner						
Orthopaedic Surgeon						
Radiology for further imaging						
Other…						
Other…						
Other…						

Patient Discharge

Q11. As an approximate percentage, where do you most commonly discharge these patients to?

	100 %	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**
Home/No further treatment						
Senior physiotherapy colleague						
General Practitioner						
Orthopaedic Surgeon						
Biomechanics						
Other…						
Other…						
Other…						

Q12. In your experience, what is the average total duration of rehabilitation from initial assessment to physiotherapy discharge, which patients require after a primary patellar dislocation?

Duration	**Tick**
0 - 2 weeks	
3 - 6 weeks	
7 weeks - 3 months	
4 - 6 months	
Longer than 6 months	

Physiotherapist Information

The final questions relate to you and how often you manage patients following primary patellar dislocation.

Q13. Please indicate your present physiotherapy position.

Band 5	
Band 6	
Band 7	
Band 8a	
Band 8b	
Band 8c	

Q14. Estimate how many primary patellar dislocation patients you treat per month, and what percentage is this of your monthly case load?

	Numbers per Month	**Percentage of monthly case load**
Primary (initial) patellar dislocation	**cases**	**%**

Thank you for completing this questionnaire.

Please now, using the stamped addressed envelope supplied with this questionnaire, return this completed questionnaire to:

Toby Smith
Research Physiotherapist in Orthopaedics
Institute of Orthopaedics
Norfolk and Norwich University Hospital
Colney Lane
Norwich NR4 7UY

The deadline for returning this questionnaire is **30TH November 2009**. A reminder will be sent to all non-respondents 3 weeks after this questionnaire was sent out. Repeat reminders will be made until either all questionnaires have been returned, or after three separate mailings have been made.

It will be assumed that by completing and returning the questionnaire you have provided your consent for the results of this questionnaire to be used for publication. At no point will your identity be revealed, as your results will remain anonymous throughout.

Appendix 7. Justification and referencing behind each question posed in the national survey study's questionnaire.

Q1. Do you manage patients following primary patellar dislocation?
(This question was asked to determine whether the questionnaire is applicable to the respondent)

Yes
No
If no go to end.

Q2. Approximately for what percentage of your patients do you use the following methods for assessing primary patellar dislocation?
(This was included to determine which tests are used most frequently to assess this group of patients)

Apprehension test
(Scuderi and McCann, 2005; Hawkins et al, 1986; Boden et al, 1997; Dath et al, 2006; Cosgarea et al, 2002; Woo and Busch, 1998)

Bassett's Sign
(Sallay et al, 1996; Beaseley and Vidal, 2004; Hawkins et al, 1986; Boden et al, 1997; Woo and Busch, 1998)

Q-angle
(Scuderi and McCann, 2005; Brukner and Karim, 2001; Buchner et al, 2005; Beaseley and Vidal, 2004; Hawkins et al, 1986; Boden et al, 1997; Kujala et al, 1989; Nikku et al, 2005; Cosgarea et al, 2002; Woo and Busch, 1998)

Patella tracking and J-sign
(Aglietti et al, 2001; Boden et al, 1997; Woo and Busch, 1998; Cosgarea et al, 2002; Dath et al, 2006;

Assessment of femoral anteversion
(Brukner and Karim, 2001; Buchner et al, 2005; Hawkins et al, 1986; Boden et al, 1997; Nikku et al, 2005; Cosgarea et al, 2002)

Assessment of genu valgum
(Brukner and Karim, 2001; Buchner et al, 2005; Hawkins et al, 1986; Boden et al, 1997; Cosgarea et al, 2002; Woo and Busch, 1998)

Observation for pronation of the foot / pes planus

(Brukner and Karim, 2001; Boden et al, 1997; Cosgarea et al, 2002; Woo and Busch, 1998)

Assessment for tibial torsion
(Buchner et al, 2005; Boden et al, 1997; Nikku et al, 2005; Cosgarea et al, 2002; Woo and Busch, 1998)

Lateral or medial patella glide
(Scuderi and McCann, 2005; Brukner and Karim, 2001; Boden et al, 1997; Woo and Busch, 1998

Assessment of multi-joint ligamentus laxity
(Brukner and Karim, 2001; Buchner et al, 2005; Beaseley and Vidal, 2004; Nikku et al, 2005; Cosgarea et al, 2002; Woo and Busch, 1998)

VMO atrophy/hypertrophy
(Brukner and Karim, 2001)

Patella malpostion (baja, alta, squinting)
(Hawkins et al, 1986; Woo and Busch, 1998; Brukner and Karim, 2001; Buchner et al, 2005; Beaseley and Vidal, 2004; Kujala et al, 1989; Fithian et al, 2004; Donell, 2006: Cosgarea et al, 2002)

Patella tilt
(Scuderi and McCann, 2005; Boden et al, 1997; Cosgarea et al, 2002)

Palpable patellofemoral crepitus
(Boden et al, 1997; Woo and Busch, 1998)

Assessment for effusion
(Boden et al, 1997; Woo and Busch, 1998)

Hip muscle strength
(Boden et al, 1997)

Gait
(Cosgarea et al, 2002; Woo and Busch, 1998)

Patella compression test
(Hawkins et al, 1986)

Q3. Using the **Item** Letter Code, please rank the order in which you would typically use the above assessment methods most often for your patients following primary patellar dislocation.
(This was included to determine of the test identified in Q3, which tests are considered the most important to clinicians to assess this group of patients)

Q4. Approximately, for what percentage of your patients who have sustained a primary patellar dislocation, do you use the following treatment modalities?
(This question attempt to determine what treatment modalities are used and how frequently used by physiotherapists to treat patellar instability)

Specific VMO strengthening exercises
(Brukner and Karim, 2001; Buchner et al, 2005; Boden et al, 1997; Garth et al, 1996; Cosgarea et al, 2002)

General quadriceps strengthening exercises
(Scuderi and McCann, 2005; Brukner and Karim, 2001; Beaseley and Vidal, 2004; Boden et al, 1997; Cosgarea et al, 2002; Woo and Busch, 1998; Garth et al, 1996; Mäenpää and Lehto, 1997; Cash and Hughston, 1988; Kiviluoto et al, 1986; Larsen and Lauridsen, 1982)

Hamstring strengthening exercises

Glutei muscle strengthening exercises

Taping
(Scuderi and McCann, 2005; Beaseley and Vidal, 2004; Boden et al, 1997; Woo and Busch, 1998; Callaghan, 1997)

Ice
(Cosgarea et al, 2002; Garth et al, 1996)

Patella accessory mobilisations

Rest and/or behaviour/sporting modification
(Woo and Busch, 1998)

Biofeedback techniques

Elevation

Ultrasound

Hydrotherapy
(Boden et al, 1997)

Electronic stimulation
(Cosgarea et al, 2002; Garth et al, 1996)

Acupuncture

Stretching exercises for quadriceps

Stretching exercises for hamstrings
(Cosgarea et al, 2002)

Knee braces
(Scuderi and McCann, 2005; Buchner et al, 2005; Boden et al, 1997; Cosgarea et al, 2002; Woo and Busch, 1998; Shellock et al, 1994; Garth et al, 1996; Mäenpää and Lehto, 1997 213; Cash and Hughston, 1988; Muhle et al, 1999)

Stretching exercises for calf muscles

Proprioception exercises

Stretching exercises for ITB/tensor fascia lata
(Brukner and Karim, 2001)

Active range of movement exercises
(Buchner et al, 2005; Beaseley and Vidal, 2004; Boden et al, 1997; Cosgarea et al, 2002; Garth et al, 1996)

Q5. Using the **Item** Letter Code, as before, please rank the order in which you would typically use the above treatments most often for these patients.
(*This was asked to given an indication of the treatments which the responding physiotherapist's feel are the most effective treatments used for these patients.)*

Q6. The following exercises have been described as being able to strengthen the quadriceps and/or the VMO. Approximately for what percentage of your patients do you use these exercises? **(*As we are interested in assessing VMO exercises as an experimental intervention, and intend to assess the efficacy of these types of exercises we need to know which specific type of VMO exercises clinicians perform. Accordingly, this question was included.)***

Semi-Squat with… **Lower Limb Neutral** (Hertel et al, 2004; Earl et al, 2001; Coqueiro et al, 2005; Miller et al, 1997; Herrington et al, 2006; Hodges and Richardson, 1993)

	Hip Abduction
	(Coqueiro et al, 2005; Earl et al, 2001; Hertel et al, 2004; Hodges and Richardson, 1993)
	Hip Adduction (Hertel et al, 2004)
	Hip Internal Rotation (Herrington et al, 2006)
	Hip External Rotation (Herrington et al, 2006)
	Tibial Internal Rotation
	Tibial External Rotation
	Femoral and Tibial Internal Rotation (Miller et al, 1997)
	Femoral and Tibial External Rotation (Miller et al, 1997)
	Foot Supination (Hung and Gross, 1999)
	Foot Pronation (Hung and Gross, 1999)
	Ankle Dorsiflexion
	Ankle Plantarflexion
Isometric Knee Extension with…	**Lower Limb Neutral** (Herrington et al, 2006; Hodges and Richardson, 1993)
	Hip Adduction (Cerny, 1995; Coqueiro et al, 2005; Laprade et al, 1998)
	Hip Abduction
	Hip Internal Rotation (Cerny, 1995; Mirzabeigi et al, 1997; Lam and Ng, 2001)
	Hip External Rotation (Cerny, 1995; Mirzabeigi et al, 1997; Lam and Ng, 2001)
	Tibial Internal Rotation (Cerny, 1995; Laprade et al, 1998; Serrão et al, 2005)
	Tibial External Rotation (Cerny, 1995; Serrão et al, 2005)
	Foot Supination (Hung and Gross, 1999)
	Foot Pronation (Hung and Gross, 1999)
	Ankle Dorsiflexion (Cerny, 1995; Zakaria et al, 1997)
	Ankle Plantarflexion (Cerny, 1995)
Straight Leg Raise with…	**Lower Limb Neutral** (Wild et al, 1982; Livecchi et al, 2002; Karst and Jewitt, 1993)
	Hip Adduction (Karst and Jewitt, 1993)
	Hip Abduction
	Hip Internal Rotation (Wild et al, 1982)
	Hip External Rotation (Livecchi et al, 2002; Wild et al, 1982)
	Ankle Dorsiflexion
	Ankle Plantarflexion
Isokinetic Knee Extension with…	**Lower Limb Neutral** (Coqueiro et al, 2005; Hung and Gross, 1999; Cerny, 1995; Zakaria et al, 1997; Serrão et al, 2005; Laprade et al, 1998; Mirzabeigi et al, 1997; Livecchi et al, 2002; Lam and Ng, 2001)
	Hip Adduction (Hodges and Richardson, 1993)
	Hip Abduction
	Hip Internal Rotation (Cerny, 1995; Herrington, 2006)
	Hip External Rotation (Cerny, 1995; Herrington, 2006; Livecchi et al, 2002)
	Tibial Internal Rotation
	Tibial External Rotation
	Ankle Dorsiflexion
	Ankle Plantarflexion
Static Bike/Cycling with…	**Lower Limb Neutral** (Gregerson et al, 2006; Willis et al, 2005)
	Tibial Internal Rotation

	Tibial External Rotation (Willis et al, 2005)
	Foot Supination (Gregersen et al, 2006)
	Foot Pronation (Gregersen et al, 2006)
Step-Up Step-Down Exercises with…	**Lower Limb Neutral** (Cerny, 1995; Miller et al, 1997)
	Femoral and Tibial Internal Rotation (Miller et al, 1997)
	Femoral and Tibial External Rotation (Miller et al, 1997)
	Foot Supination (Cerny, 1995)
	Foot Pronation (Cerny, 1995)

Q7. Do you mainly treat your patients following primary patellar dislocation 'one-to-one', 'as a group with other patients' or are these patients treated both as a group and individually? **(*This question was set to indicate where and how patients are treated, in either individual or group setting).***

Q8. Approximately for what percentage of this patient group do you use the following self-reported measures?
(***This question was included to attempt to determine approximately how long patients are seen by their physiotherapists, to compare whether future study patient's treatment reflects that of current practice in respect to duration of total treatment)***

Cincinnati

Lysholm
(Buchner et al, 2005; Sallay et al, 1996; Nikku et al, 1997 419; Paxton et al, 2003)

Tegner
(Buchner et al, 2005; Nikku et al, 1997 419; Nikku et al, 2005; Paxton et al, 2003)

Modified International Knee Documentation Committee (IKDC) form
(Paxton et al, 2003)

Fulkerson Patellofemoral Rating Scale
(Fulkerson et al, 1990)

Kujula
(Mäenpää and Lehto, 1997; Mäenpää et al, 1997 424; Nikku et al, 2005; Paxton et al, 2003; Kujala et al, 1993)

Hughston VAS Knee Score
(Nikku et al, 1997 419; Nikku et al, 2005)

Subjective Patient Satisfaction

(Identified as a frequently used measure for discharge in a notes audit of 20 consecutive NNUH patellar dislocation patient records).

Q9. Using the **Item** Letter Code, please rank the order in which you would typically use the above outcome measures most often for your patients.
(***This was included to determine which of the measures identified in Q11, are considered the most useful outcome measures used to evaluate this patient group)***

Q10. Approximately, for what percentage of your patients do you involve other professionals **whilst** a patient following a primary patellar dislocation is under your care?
(This was designed to determine which specialities are most frequently accessed to assist in the management of this group of patients)

Biomechanics Department for orthotics

Appliance Department for knee brace

Orthopaedic Surgeon
(Scuderi and McCann, 2005; Brukner and Karim, 2001; Beaseley and Vidal, 2004)

General Practitioner

Radiology for further imaging
(Scuderi and McCann, 2005; Brukner and Karim, 2001; Beaseley and Vidal, 2004; Hawkins et al, 1986; Boden et al, 1997; Dath et al, 2006; Nikku et al, 2005; Donell, 2006; Cosgarea et al, 2002; Woo and Busch, 1998)

Q11. As an approximate percentage, where do you most commonly discharge these patients to?
(This was finally asked to suggest where treatment ends and the management concludes for this patient group).

Q12. In your experience, what is the average total duration of rehabilitation from initial assessment to physiotherapy discharge, which patients require after a primary patellar dislocation?

Q13. Please indicate your present physiotherapy position.
(This was included to provide an indication of the respondent's experience and clinical position).

Q14. Estimate how may patellar dislocation patients you treat per month, and what percentage is this of your monthly case load?
(This was included to provide an indication of the experience the respondent has with patients who suffer patellar dislocations.)

Appendix 8. National survey study covering letter.

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Dear Colleague,

Re: How do senior musculoskeletal physiotherapists manage patients following primary patellar dislocation? A survey of NHS musculoskeletal physiotherapy departments in the United Kingdom

Patients following primary or 'first time' patellar dislocation can be managed conservatively with physiotherapy. However, the evidence-base on this topic remains rather limited, particularly with regards to the physiotherapy rehabilitation of this patient group.

The purpose of this study is to assess how senior musculoskeletal physiotherapists in United Kingdom NHS hospitals assess, treat and manage this group of patients. By undertaking this piece of work, we will be better informed when designing future studies, to reflect the practices of current physiotherapists in this country. Your department has been identified using the NHS websites, and has been included in this study, since you are part of an acute NHS hospital trust in the United Kingdom.

We invite you to participate in this nationwide survey. Please find attached a questionnaire. We would be most grateful if this questionnaire could be completed either by yourself, or a Senior member of your musculoskeletal out-patient physiotherapy team who has the most experience, or a particular interest, in managing patients with knee disorders.

The questionnaire has been designed to be completed within **twenty five** minutes. If no one in your department feels able to complete the questionnaire, please return the questionnaire and this covering letter in the post. For our records, if you are able, could you please indicate at the bottom of this letter why the questionnaire could not be completed.

All data will be kept anonymous. We will not be able to identify who specifically completed the questionnaire. The coded number at the top of each questionnaire shall be used by the Principle Investigator (**Toby Smith**) as a means of identifying which departments have not returned the questionnaire. This is because at approximately three weeks after receiving this questionnaire, all non-respondents shall be sent a letter to remind them that the questionnaire has not been completed and returned. We want to include the views and experiences of as many physiotherapists as possible to optimise the

strength of this study. Therefore, a further three weeks after sending the reminder letter, all non-respondents will be sent a second copy of the questionnaire and stamped addressed envelope to all non-respondents to provide a further opportunity to participate in this project. We will not send another reminder after this.

All data will also be kept confidential. Through this, the coded numbers on each sheet will not be used to identify how individual hospitals responded. To maintain anonymity, rather that obtaining written informed consent, it is assumed that by returning the questionnaire, you have provided informed consent to participate in this study. Nonetheless, this study has been approved by the East Norfolk and Waveney Research Governance Committee and the Norfolk Research Ethics Committee. There are no known risks in participating in this study, and participation in this project is voluntary. This study will form the basis for a paper to be published in a peer-review journal. The results from this study will also form part of a PhD thesis for the Principle Investigator, at the University of East Anglia. Accordingly, all data collected will be kept for a period of four years, in a locked cupboard in the Orthopaedic Department at the Norfolk and Norwich University Hospital, whilst the data is being disseminated through these means.

We want to disseminate the findings of this study widely. To do this, we will send you a copy of the final paper either by e-mail or by post. If you would like to receive this report electronically, please write a departmental email address in the space provided at the foot of this letter. Alternatively, we will post a copy of this paper once it is made available.

Please return the questionnaires in the stamped address envelop by **30th November 2009**.

If you have any further questions, or if any problems arise during the completion of this questionnaire, please feel free to contact me by email on toby.smith@nnuh.nhs.uk or at the Norfolk and Norwich University Hospital by telephone at 01603 286990, and I will be happy to answer your questions.

Many thanks for all your help, and we look forward to collating the results.

Yours faithfully

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Norfolk and Norwich University Hospital, UK

Dr **XXXX**
XXXX
University of East Anglia, UK

Ms **XXXX**
XXXX
University of East Anglia, UK

Prof **XXXX**
XXXX
University of East Anglia, UK.

I am unable to complete this questionnaire because:
……
……
……
Email address to receive an electronic version of the final report:_____

Appendix 9. National survey study pilot study feedback form

1. Did you understand why you had received this questionnaire?

2. Did you receive sufficient information on the covering sheet to be able to complete the questionnaire?

3. How long did it take you to complete it?

4. Was the format clear in respect to understanding how to respond to the questions?

5. Did you understand that this was assessing *primary* and not *secondary* dislocation cases?

6. Do you think the questionnaire assesses all the factors important in the assessment and treatment of patients following patellofemoral dislocation?

7. Were there any questions which you felt needed further explanation in order to answer the questions?

8. Were there enough "Other" options for the questions where applicable?

9. Was the number of ranked responses appropriate for questions 3,5 and 7? Would fewer options have been better?

10. Do you think the personal questions about yourself should be at the start of the questionnaire, rather than at the end as they presently are?

11. Did you understand what you needed to do with the questionnaire once it had been completed?

12. Is there anything you would improve in this questionnaire to make its completion easier?

Appendix 10. Results of the national survey study pilot

1. Did you understand why you had received this questionnaire?

Yes – 10

2. Did you receive sufficient information on the covering sheet to be able to complete the questionnaire?

Yes – 10

3. How long did it take you to complete it?

Minutes – 30, 30, 25, 25,20-30, 15, 20, 25, 25, 20 (mean – 24.5 minutes)

4. Was the format clear in respect to understanding how to respond to the questions?

Yes - 10

5. Did you understand that this was assessing *primary* and not *secondary* dislocation cases?

Yes – 10

6. Do you think the questionnaire assesses all the factors important in the assessment and treatment of patients following patellofemoral dislocation?

Yes – 10
Comment: "could add radiology investigations in assessment (1)"

7. Were there any questions which you felt needed further explanation in order to answer the questions?

Yes –

No – 8

Comment – "Question 5 – no space (1)" "Q7 – just done in neutral (1)" "how about biofeedback such as balance biodex, objective tests – kinCom etc (1)"

8. Were there enough "Other" options for the questions where applicable?

Yes – 10

9. Was the number of ranked responses appropriate for questions 3,5 and 7? Would fewer options have been better?

Yes – 9
No – 0
Comment – “most frequently used item difficult to rank if assessment/Rx method used in 100% (1)” “options o.k. but difficult to answer with treatments as it would depend on a specific pt’s presentation (1)”

10. Do you think the personal questions about yourself should be at the start of the questionnaire, rather than at the end as they presently are?

Yes – 1
No – 3
Comment – “Either way (5)” “no difference(1)” “would years experience be more significant than grade? (1)””End better. Good to focus on point an questionnaire at start (1)”

11. Did you understand what you needed to do with the questionnaire once it had been completed?

Yes – 10

12. Is there anything you would improve in this questionnaire to make its completion easier?

Yes – 0
No – 7
Comment – “most frequently used item difficult to rank if assessment/Rx method used in 100% (1)” “it’s just quite long! (1)” “difficult to accurately rate assessment and treatment as a percentage! (1)”

Appendix 11. National survey study non-respondent reminder letter.

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Appendix 9. 1st Reminder Letter
(Version 1.0 - 25.08.09)

Dear Colleague,

Re: How do senior musculoskeletal physiotherapists manage patients following primary patellar dislocation? A survey of NHS musculoskeletal physiotherapy departments in the United Kingdom

Approximately **three** weeks ago, we invited you and your department to participate in a national survey examining the management of patients following primary patellar dislocation. As stated in this previous letter, if a department was unable or had not returned the questionnaire, a letter would be sent to all non-respondents to remind them of the questionnaire and to complete it.

It is important that if you can, please complete this questionnaire. In order to be able to make the greatest conclusions from this study, it is essential that as many physiotherapists as possible complete and return this questionnaire.

If no one in your department feels able to complete the questionnaire, possibly because your team do not manage patients following patellar dislocation, then please indicate this in Question One and return the questionnaire for our records. Similarly, if you are not able to complete the questionnaire, either because your department, as standard practice, are unable to assist in such projects, or due to time/cost reasons, please indicate this on the questionnaire, and return it in the post, for our records.

If you have any further questions, or require a second copy of the questionnaire and stamped addressed envelope, please feel free to contact me by email on toby.smith@nnuh.nhs.uk or at the Norfolk and Norwich University Hospital by telephone at 01603 286990.

Yours faithfully

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Norfolk and Norwich University Hospital, UK

Dr **XXXX**
XXXX
University of East Anglia, UK

Ms **XXXX**
University of East Anglia, UK

Prof **XXXX**
University of East Anglia, UK.

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Appendix 11. National survey study non-respondent reminder letter
2nd Reminder Letter (version 1.0 - 25.08.09)

Dear Colleague,

Re: How do senior musculoskeletal physiotherapists manage patients following primary patellar dislocation? A survey of NHS musculoskeletal physiotherapy departments in the United Kingdom

Approximately **six** weeks ago, we invited you and your department to participate in a national survey, examining the management of patients following primary or 'first time' patellar dislocation. As stated in this previous letter, if a department had not returned the questionnaire, a second letter and questionnaire would be sent giving all non-respondents a further opportunity to participate in the study. Since your department has not respondent to the last reminder sent, we have now sent you a second copy of the questionnaire and stamped addressed envelope to provide you with a further opportunity to participate in this project. We will not send you another reminder after this letter.

It is important that if you can, please complete this questionnaire. In order to be able to make the greatest conclusions from this study, it is essential that as many physiotherapists as possible complete and return this questionnaire.

If no one in your department feels able to complete the questionnaire, possibly because your team do not manage patients following patellar dislocation, then please indicate this in Question One and return the questionnaire for our records. Similarly, if you are not able to complete the questionnaire, either because your department, as standard practice, are unable to assist in such projects, or due to time/cost reasons, please indicate this on the questionnaire, and return it in the post, for our records.

Please find attached the initial letter detailing the study, and providing guidance in completing the questionnaire. If you have any further questions, please feel free to contact me by email on toby.smith@nnuh.nhs.uk or at the Norfolk and Norwich University Hospital by telephone at 01603 286990, and I will be happy to answer your questions.

Yours faithfully

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Norfolk and Norwich University Hospital, UK

Dr **XXXX**
XXXX
University of East Anglia, UK

Ms **XXXX**

Prof **XXXX**

XXXX
University of East Anglia, UK

XXXX
University of East Anglia, UK.

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Dear Colleague,

Re: How do senior musculoskeletal physiotherapists manage patients following primary patellar dislocation? A survey of NHS musculoskeletal physiotherapy departments in the United Kingdom

Patients following primary or 'first time' patellar dislocation can be managed conservatively with physiotherapy. However, the evidence-base on this topic remains rather limited, particularly with regards to the physiotherapy rehabilitation of this patient group.

The purpose of this study is to assess how senior physiotherapists in United Kingdom NHS hospitals assess, treat and manage this group of patients. By undertaking this piece of work, we will be better informed when designing future studies, to reflect the practices of current physiotherapists in this country. Your department has been identified using NHS websites, and has been included in this study, since you are part of an acute NHS hospital trust in the United Kingdom.

We invite you to participate in this nationwide survey. Please find attached a questionnaire. We would be most grateful if this questionnaire could be completed either by yourself, or a Senior member of your musculoskeletal out-patient physiotherapy team who has the most experience, or a particular interest, in managing patients with knee disorders.

The questionnaire has been designed to be completed within **twenty five** minutes. If no one in your department feels able to complete the questionnaire, please return the questionnaire and this covering letter in the post. For our recorded, if you are able, could you please indicate at the bottom of this letter why the questionnaire could not be completed.

All data will be kept anonymous. We will not be able to identify who specifically completed the questionnaire. The coded number at the top of each questionnaire shall be used by the Principle Investigator (**Toby Smith**) as a means of identifying which departments have not returned the questionnaire earlier. This is the last reminder to complete this questionnaire, and we will now not send another reminder.

All data will also be kept confidential. Through this, the coded numbers on each sheet will not be used to identify how individual hospitals responded. To maintain anonymity, rather that obtaining written informed consent, it is assumed that by returning the questionnaire, you have provided informed consent to participate in this study.

Nonetheless, this study has been approved by the Norfolk and Norwich Orthopaedic Peer-Review panel, the East Norfolk and Waveney Research Governance Committee and the Norwich Research Ethics Committee. There are no known risks in participating in this study, and participation in this project is voluntary. This study will form the basis for a paper to be published in a peer-review journal. The results from this study will also form part of a PhD thesis for the Principle Investigator, at the University of East Anglia. Accordingly, all data collected will be kept for a period of four years, in a locked cupboard in the Orthopaedic Department at the Norfolk and Norwich University Hospital, whilst the data is being disseminated through these means.

We want to disseminate the findings of this study widely. To do this, we will send you a copy of the final paper either by e-mail or by post. If you would like to receive this report electronically, please write a departmental email address in the space provided at the foot of this letter. Alternatively, we will post a copy of this paper once it is made available.

Please return the questionnaires in the stamped address envelop by **29th January 2010**.

If you have any further questions, or if any problems arise during the completion of this questionnaire, please feel free to contact me by email on toby.smith@nnuh.nhs.uk or at the Norfolk and Norwich University Hospital by telephone at 01603 286990, and I will be happy to answer your questions.

Many thanks for all your help, and we look forward to collating the results.

Yours faithfully

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Norfolk and Norwich University Hospital, UK

Dr **XXXX**
XXXX
University of East Anglia, UK

Ms **XXXX**
XXXX
University of East Anglia, UK

Prof **XXXX**
XXXX
University of East Anglia, UK.

I am unable to complete this questionnaire because:
……
……
……
……
Email address to receive an electronic version of the final report:_____

Appendix 12. National survey study Research Ethics Committee and Research Governance Committee approval letters

NHS National Research Ethics Committee Approval

22 October 2009

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Institute of Orthopaedics
The Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane, Norwich
NR4 7UY

Dear Mr Smith

Study Title:	**How do senior musculoskeletal physiotherapists manage patients following primary patellar dislocation? A survey of acute National Health Service musculoskeletal physiotherapy departments in the United Kingdom.**
REC reference number:	**09/H0310/84**
Protocol number:	**1.0**

The Research Ethics Committee reviewed the above application at the meeting held on 12 October 2009. Thank you for attending to discuss the study.

The Committee welcomed the opportunity to ask you for clarification on the following points:

- With reference to the pilot study, you explained that Senior Outpatient Physiotherapists at spent an afternoon completing the questionnaires. This gave the opportunity to test whether the questions were clear with a view to improving text prior to administering as part of the research study so as to ensure useful responses and not to waste research participants' time. This also allowed you to gauge the amount of time it will take for respondents to complete the survey.

- Regarding the intention to send reminders to non-responders, you clarified that you will only be able to identify which Trusts have not fully responded rather than individual Physiotherapists. This means that the Senior Physiotherapists will be asked to remind their staff to respond. You recognise that this could potentially cause conflict, but generally Heads of Physiotherapy Departments are not directly linked to staff. It is hoped that it will not be necessary to send out reminders, but other studies show that reminders do achieve results.

- In the context of your PhD studies, you confirmed that this application is one of three linked studies: this study is seeking to discover how Physiotherapists currently treat this condition, another study will be a randomised controlled trial comparing different exercise regimes, and a third will be a clinical survey of what patients find difficult to do when they have this condition. Each study will be put forward for NHS REC review.

- In response to questions of funding and costs, you advised that you expect to only obtain a grant to cover stationery / support costs but not your time. If you do receive additional funding you would use this to request time out of your clinical duties.

- Members noted that the financial breakdown included payment for registration as a randomised controlled trial, and advised you this would not be necessary for this study.

Ethical opinion

Members concluded that the "pilot" had been a sensible exercise to carry out, and were happy that this had involved willing supportive colleagues. With reference to funding, the Committee recognised that Action Arthritis will scrutinise the costings, but the Committee would wish to be advised as to how the money will be spent if you are awarded a grant.

Regarding the potential for senior staff to pressurise their staff into participation, it was decided that as participants will be responding directly to you anonymously the potential participant would not feel obliged to their NHS Trust to make a return.

With reference to trial registration, although the Committee has advised you that the cost of registration with the ISRCTN Register is an unnecessary expense, the Declaration of Helsinki guides that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject. Clinical research may be registered free of charge at http://clinicaltrials.gov, and you are advised to explore this option.

The Members of the Committee present gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

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).

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, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

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

Other conditions specified by the REC:

Informed Consent Process

Revision is required to Appendix 3 Covering Letter, and a final version (with updated version number and date) submitted to the Committee for information:

- Paragraph 4, sentence 3: "For our record~~ed~~s";
- Paragraph 5, sentence 4: "..... all non-respondents shall be sent a ~~reminder~~ letter to remind~~er~~ them ....";
- Paragraph 6, sentence 4: ".... this sudy has been approved by the ..... ~~NREC Central Allocation System~~ Norfolk Research Ethics Committee".

Community Consideration

On receipt of funding for this study, you are requested to provide the REC with a clear breakdown as to how the money will be spent.

It is 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 documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter	Mr Toby O Smith	27 August 2009
REC application	IRAS 2.3	01 September 2009
Protocol	1.0	25 August 2009
*Letter of invitation to participant**	*1.0 (Protocol Appendix 3)*	*25 August 2009*
Letter from Sponsor	, Research Contracts Manager, UEA	07 August 2009
Letter from Statistician	, UEA (e-mail)	13 August 2009
Questionnaire: Non-validated: Patellar Dislocation Questionnaire (Protocol Appendix 2)	1.0	25 August 2009
Application Checklist	IRAS 2.3	01 September 2009
Chief Investigator CV	Toby Oliver Smith	26 August 2009
Participant Information Sheet: Pages 28 and 29 of protocol		
Academic Supervisor CV		
Study Flow Diagram (Protocol Appendix 8)	1.0	25 August 2009
1st Reminder Letter (Protocol Appendix 9)	1.0	25 August 2009
2nd Reminder Letter (Protocol Appendix 9)	1.0	25 August 2009

** to be revised*

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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

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.

09/H0310/84	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerelv

Chair

Email: @ .nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" [SL-AR2 for other studies]

Copy to: *Sponsor Contact: , UEA*
R&D office for NHS care organisation at lead site:

Research Governance (Site-Specific) Approval

Mr Toby Oliver Smith
Physiotherapy Department,
Out-Patients East,
Norfolk and Norwich University Hospital
Colney Lane, Norwich
NR4 7UY

29/10/2009

Dear Mr Smith

Re: 2009ORTH10(190-11-09) · How do senior musculoskeletal physiotherapists manage patients follwoing primary patellare dislocation? a survey of actue NHS musculoskeletal psysiotherapy departments in the United Kingdom.

Following confirmation of a favourable Ethical opinion I am pleased to confirm that your project has been given full approval from the
Governance Committee and Research Management Team and you may start your research.

Please note that this approval applies to the following sites:

- Hospital

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign and return one copy to the Research Governance Committee office. Failure to return the standard terms and conditions may affect the conditions of approval.

Please note, under the agreed standard terms and conditions of approval you must inform this Committee of any proposed changes to this study and to keep the Committee updated on progress.

If you have any queries regarding this or any other study please contact , at the above address. Please note, your reference number is **2009ORTH10(190-11-09)** and this should be quoted on all correspondence.

The Committee would like to take this opportunity to wish you every success with this project.

Yours sincerely

Dr
Chair

Encs – Standard terms and conditions
Guidance for screening of patient notes

Appendix 13. Raw data for national survey study

Assessment Dataset

Assessment method		Frequency (%) to which respondents used assessment methods for % of their patients													
		100%		99-75%		74-50%		49-25%		24-1%		0%		Not aware of test	
Convincing report of a patellar dislocation by patient.		82	(51.3)	40	(25.0)	13	(8.1)	4	(2.5)	7	(4.4)	14	(8.8)	0	
Convincing report of a patellar dislocation by referral.		71	(44.4)	53	(33.1)	21	(13.1)	10	(6.3)	2	(1.3)	3	(1.9)	0	
Observation of:	Gait pattern	109	(68.1)	19	(11.9)	11	(6.9)	12	(7.5)	4	(2.5)	15	(9.4)	0	
	Genu valgum	83	(51.9)	20	(12.5)	12	(7.5)	17	(10.6)	10	(6.3)	18	(11.3)	0	
	Pronation of the foot /pes planus	85	(53.1)	24	(15.0)	15	(9.4)	16	(10.0)	4	(2.5)	16	(10.0)	0	
	Patellar malposition (baja, alta, squinting; tilt)	81	(50.6)	39	(24.4)	21	(13.1)	6	(3.8)	5	(3.1)	8	(5.0)	0	
	Patellar tracking	106	(66.3)	29	(18.1)	11	(6.9)	4	(2.5)	7	(4.4)	13	(8.1)	0	
	VMO atrophy/hypertrophy	105	(65.5)	28	(17.5)	9	(5.6)	9	(5.6)	3	(1.9)	46	(28.8)	0	
Assessment of:	Patellofemoral crepitations	68	(42.5)	23	(14.4)	14	(8.8)	18	(11.3)	11	(6.9)	26	(16.3)	0	
	Effusion	101	(63.1)	31	(19.4)	10	(6.3)	5	(3.1)	7	(4.4)	6	(3.8)	0	
	Femoral anteversion	54	(33.8)	21	(13.1)	29	(18.1)	19	(11.9)	12	(7.5)	25	(15.6)	0	
	Tibial torsion	52	(32.5)	23	(14.4)	32	(20.0)	17	(10.6)	18	(11.3)	19	(11.9)	0	
	Multi-joint ligamentous laxity	63	(39.4)	41	(25.6)	28	(17.5)	11	(6.9)	10	(6.3)	7	(4.4)	0	
	Quadriceps Strength	107	(66.9)	31	(19.4)	11	(6.9)	6	(3.8)	3	(1.9)	2	(1.3)	0	
	Glutei strength	72	(45)	28	(17.5)	23	(14.4)	9	(5.6)	8	(5.0)	20	(12.5)	0	
	Hamstring Strength	83	(45.9)	30	(18.8)	22	(13.8)	12	(7.5)	12	(7.5)	1	(0.6)	0	
Special tests:	Q-angle	32	(20.0)	29	(18.1)	23	(14.4)	21	(13.1)	17	(10.6)	38	(23.8)	0	
	Apprehension test	75	(46.9)	33	(20.6)	19	(11.9)	9	(5.6)	7	(4.4)	16	(10.0)	1	(0.6)
	Bassett's Sign	5	(3.1)	5	(3.1)	9	(5.6)	8	(5.0)	3	(1.9)	14	(8.8)	116	(72.5)
	J-sign	25	(15.6)	14	(8.8)	16	(10.0)	9	(5.6)	19	(11.9)	19	(11.9)	58	(36.3)
	Patellar compression test	36	(22.5)	39	(24.4)	29	(18.1)	9	(5.6)	13	(8.1)	25	(15.6)	9	(5.6)
	Lateral or medial patellar glide	100	(62.5)	36	(22.5)	9	(5.6)	7	(4.4)	5	(3.1)	4	(2.5)	0	
Other…	X-ray	1	(1)	0		0		0		1	(1)	0		0	
	Length of ITB	4	(3)	4	(3)	0		0		0		0		0	
	Lat retinaculum tightness	1	(1)	0		0		0		0		0		0	
	Sag sign	0		1	(1)	0		0		0		0		0	
	Medial retinaculum tightness	0		0		1	(1)	0		0		0		0	
	Lateral patellar swelling	0		1	(1)	0		0		0		0		0	
	Range of motion	4	(3)	0		0		0		0		0		0	
	Proprioception	4	(3)	2	(1)	0		0		0		0		0	
	Core stability	1	(1)	0		0		0		0		0		0	
	Single leg squat	3	(2)	0		2	(1)	0		0		0		0	
	Knee ligament test	1	(1)	0		0		0		0		0		0	
	Retropatellar palpation	1	(1)	0		0		0		0		0		0	
	Clark test	1	(1)	0		0		0		0		0		0	
	Muscle length (Quad/Ham/Calf)	6	(4)	0		0		0		0		0		0	
	Lunge	0		0		1	(1)	0		0		0		0	
	Squat	1	(1)	0		0		0		0		0		0	
	VMO firing-timing	1	(1)	0		0		0		0		0		0	
	Step down test	1	(1)	0		0		0		0		0		0	
	Gastrocnemius strength	1	(1)	0		0		0		0		0		0	
	Hop test	0		1	(1)	0		0		0		0		0	
	Genu recurvatum assessment	1	(1)	0		0		0		0		0		0	
	Neuro pattern movement	1	(1)	0		0		0		0		0		0	

ITB – Iliotibial Band
Ham - Hamstring
Quad - Quadriceps
VMO – Vastus Medialis Obliquus

Appendix 13. Raw data for national survey study

Treatment Dataset

Treatment		Frequency (%) to which respondents used treatment methods for % of their patients						
		100%	99-75%	74-50%	49-25%	24-1%	0%	Not aware of treatment
Exercises (in general)		722 (42)	379 (22)	224 (13)	150 (9)	95 (5)	161 (9)	0
Exercises (Range of motion)	Active knee exercises	117 (73)	34 (21)	4 (3)	1 (1)	2 (1)	2 (1)	0
Exercises (strengthening/ recruitment)	General quadriceps	118 (74)	26 (16)	3 (2)	4 (3)	2 (1)	7 (4)	0
	Specific VMO	103 (64)	27 (17)	10 (6)	7 (4)	4 (3)	9 (6)	0
	Hamstring	46 (29)	43 (27)	27 (17)	15 (9)	14 (9)	15 (9)	0
	Glutei muscle	48 (30)	47 (29)	20 (13)	14 (9)	5 (3)	6 (4)	0
	Transversus abdominus	8 (5)	25 (16)	36 (23)	21 (13)	22 (14)	48 (30)	0
Exercises (stretches)	Quadriceps	40 (25)	31 (19)	33 (21)	17 (14)	14 (9)	16 (10)	0
	Hamstrings	45 (28)	38 (24)	29 (18)	21 (16)	7 (4)	20 (13)	0
	Calf muscles	42 (26)	35 (22)	31 (19)	23 (11)	12 (8)	17 (11)	0
	ITB/tensor fascia lata	33 (21)	43 (27)	27 (17)	26 (13)	12 (8)	19 (12)	0
Exercises (others)	Proprioception lower limb exercises	122 (76)	30 (19)	4 (3)	1 (1)	1 (1)	2 (1)	0
Manual therapy	Patellar accessory mobilisations	12 (8)	31 (19)	32 (20)	25 (16)	31 (19)	22 (14)	0
Advice	Advice (in general)	288 (60)	76 (16)	38 (8)	22 (5)	29 (6)	24 (5)	
	Rest and/or behaviour/sporting modification	102 (64)	31 (19)	8 (5)	5 (3)	7 (4)	3 (2)	0
	Reassurance	146 (91)	15 (9)	0	0	0	0	0
	Elevation	40 (25)	30 (19)	30 (19)	17 (11)	22 (14)	21 (13)	0
Taping	Taping (in general)	9 (2)	37 (8)	63 (13)	64 (13)	118 (25)	169 (35)	21 (4)
	VMO stimulating taping techniques	6 (4)	26 (16)	38 (24)	26 (16)	38 (24)	26 (16)	0
	VL inhibiting taping techniques	3 (2)	5 (3)	10 (6)	23 (14)	42 (26)	68 (43)	9 (6)
	ITB inhibiting taping techniques	0	5 (3)	15 (9)	15 (9)	38 (24)	75 (47)	12 (8)
Appliances	Appliances (in general)	12 (4)	23 (7)	46 (14)	67 (21)	87 (27)	84 (26)	1 (1)
	Knee braces	7 (4)	10 (6)	19 (12)	27 (17)	43 (27)	53 (33)	1 (1)
	Footwear adaptation/ over-the-counter orthotics	5 (3)	13 (8)	27 (17)	40 (25)	44 (28)	31 (19)	0
Electrotherapy	Electrotherapy (in general)	2 (1)	9 (3)	15 (5)	27 (8)	72 (23)	195 (61)	0
	Ultrasound	2 (1)	4 (3)	6 (4)	9 (6)	44 (28)	95 (59)	0
	Electronic stimulation	0	5 (3)	9 (6)	18 (11)	28 (18)	100 (63)	0
Biofeedback	Biofeedback (in general)	12 (4)	20 (6)	25 (8)	27 (8)	70 (22)	162 (51)	4 (1)
	Electronic biofeedback techniques	0	5 (3)	6 (4)	10 (6)	38 (23)	98 (61)	3 (2)
	Manual biofeedback techniques	12 (8)	15 (9)	19 (12)	17 (11)	32 (20)	64 (40)	1 (1)
Miscellaneous	Ice	42 (26)	29 (18)	41 (26)	19 (12)	16 (10)	13 (8)	0
	Postural correction	26 (16)	34 (21)	32 (20)	27 (17)	18(11)	22 (14)	1 (1)
	Acupuncture	0	0	6 (4)	17 (11)	37 (23)	99 (62)	1 (1)
	Cognitive Behavioural Therapy	2 (1)	7 (4)	6 (4)	22 (14)	35 (22)	96 (60)	2 (1)
Others	Sport rehabilitation	1 (1)	0	0	0	0	0	0
	Gait re-education with crutches	0	0	1 (1)	0	0	0	0
	Hydrotherapy	0	0	0	1 (1)	1 (1)	0	0
	Movement pattern re-education	3 (2)	0	0	0	0	0	0
	Patella self-mobilisation	0	1 (1)	0	0	0	0	0
	Unloading tape	0	0	0	1 (1)	0	0	0
	Exercises for lower limb	1 (1)	0	0	0	0	0	0
	Functional strength	1 (1)	0	0	0	0	0	0

ITB – Iliotibial Band; VL – Vastus Lateralis; VMO – Vastus Medialis Obliquus

Appendix 13. Raw data for national survey study

Quadriceps-VMO Exercise Technique

Exercise		Frequency (%) to which respondents used treatment methods for % of their patients						
		100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of treatment**
Semi-squat with	Lower Limb Neutral	83 (52)	42 (26)	14 (9)	5 (3)	1 (1)	15 (9)	0
	Non-neutral lower limb orientations	63 (3)	99 (5)	150 (8)	95 (5)	184 (10)	1246 (65)	81 (4)
	Hip Adduction	14 (9)	14 (9)	16 (10)	4 (3)	18 (11)	92 (58)	2 (1)
	Hip Abduction	7 (4)	14 (9)	31 (19)	9 (6)	15 (9)	81 (51)	3 (2)
	Hip Internal Rotation	4 (3)	7 (4)	14 (9)	9 (6)	34 (21)	87 (54)	5 (3)
	Hip External Rotation	16 (10)	17 (11)	20 (13)	10 (6)	14 (9)	80 (50)	3 (2)
	Tibial Internal Rotation	0	0	7 (4)	8 (5)	15 (9)	123 (77)	7 (4)
	Tibial External Rotation	5 (3)	8 (5)	15 (9)	7 (4)	21 (13)	99 (62)	5 (3)
	Femoral and Tibial Internal Rotation	1 (1)	0	9 (6)	7 (4)	11 (7)	124 (78)	8 (5)
	Femoral and Tibial External Rotation	2 (1)	13 (8)	9 (6)	12 (8)	11 (7)	104 (65)	9 (6)
	Foot Supination	7 (4)	10 (6)	13 (8)	10 (6)	16 (10)	96 (60)	8 (6)
	Foot Pronation	1 (1)	4 (3)	5 (3)	5 (3)	14 (9)	123 (77)	8 (6)
	Ankle Dorsiflexion	4 (3)	4 (3)	6 (4)	8 (5)	9 (6)	119 (74)	10 (6)
	Ankle Plantarflexion	2 (1)	8 (5)	5 (3)	6 (4)	9 (6)	118 (74)	12 (8)
Isometric knee extension with…	Lower Limb Neutral	81 (51)	36 (23)	9 (6)	6 (4)	1 (1)	25 (16)	2 (1)
	Non-neutral lower limb orientations	59 (4)	91 (6)	86 (5)	66 (4)	104 (7)	1127 (70)	67 (4)
	Hip Adduction	8 (5)	12 (8)	12 (8)	9 (6)	5 (3)	107 (67)	7 (4)
	Hip Abduction	4 (3)	8 (5)	11 (7)	6 (4)	9 (6)	115 (72)	7 (4)
	Hip Internal Rotation	2 (1)	7 (4)	8 (5)	7 (4)	7 (4)	123 (77)	6 (4)
	Hip External Rotation	18 (11)	24 (15)	19 (12)	8 (5)	11 (7)	80 (50)	0
	Tibial Internal Rotation	2 (1)	4 (3)	6 (4)	12 (8)	21 (13)	109 (68)	6 (4)
	Tibial External Rotation	6 (4)	8 (5)	7 (4)	7 (4)	16 (10)	110 (69)	6 (4)
	Foot Supination	1 (1)	3 (2)	3 (2)	4 (3)	8 (5)	131 (82)	10 (6)
	Foot Pronation	0	2 (1)	5 (3)	5 (3)	9 (6)	127 (79)	12 (8)
	Ankle Dorsiflexion	16 (10)	21 (13)	11 (7)	6 (4)	6 (4)	96 (60)	4 (3)
	Ankle Plantarflexion	2 (1)	2 (1)	4 (3)	2 (1)	12 (8)	129 (81)	9 (6)
Straight leg raise with…	Lower Limb Neutral	72 (45)	36 (23)	14 (9)	8 (5)	4 (3)	25 (16)	1 (1)
	Non-neutral lower limb orientations	67 (7)	101 (11)	58 (6)	37 (4)	69 (7)	612 (64)	17 (2)
	Hip Adduction	4 (2)	9 (6)	9 (6)	7 (4)	11 (7)	115 (72)	5 (3)
	Hip Abduction	7 (4)	7 (4)	7 (4)	7 (4)	9 (6)	119 (74)	4 (3)
	Hip Internal Rotation	2 (1)	8 (5)	9 (6)	6 (4)	15 (9)	116 (73)	4 (3)
	Hip External Rotation	26 (16)	38 (24)	19 (12)	9 (6)	14 (9)	54 (34)	0
	Ankle Dorsiflexion	26 (16)	33 (21)	11 (7)	7 (4)	9 (6)	73 (46)	1 (1)
	Ankle Plantarflexion	2 (1)	6 (4)	3 (2)	1 (1)	11 (7)	135 (84)	2 (1)
Isotonic knee extension with…	Lower Limb Neutral	65 (41)	26 (16)	15 (9)	2 (1)	4 (3)	46 (29)	2 (1)
	Non-neutral lower limb orientations	40 (3)	71 (6)	57 (4)	41 (3)	77 (6)	963 (75)	31 (2)
	Hip Adduction	4 (2)	9 (6)	5 (3)	4 (3)	8 (5)	126 (79)	4 (3)
	Hip Abduction	3 (2)	7 (4)	4 (3)	6 (4)	10 (6)	126 (79)	4 (3)
	Hip Internal Rotation	2 (1)	5 (3)	4 (3)	4 (3)	11 (7)	129 (81)	5 (3)
	Hip External Rotation	12 (8)	17 (11)	13 (8)	5 (3)	13 (8)	96 (60)	4 (3)
	Tibial Internal Rotation	0	7 (4)	5 (3)	7 (4)	7 (4)	131 (82)	3 (2)
	Tibial External Rotation	3 (2)	11 (7)	10 (6)	6 (4)	11 (7)	115 (72)	4 (3)
	Ankle Dorsiflexion	15 (9)	14 (8)	14 (9)	5 (3)	9 (6)	100 (63)	3 (2)
	Ankle Plantarflexion	1 (1)	1 (1)	2 (1)	4 (3)	8 (5)	140 (88)	4 (3)
Static	Lower Limb Neutral	75 (47)	36 (23)	25 (16)	4 (3)	2 (1)	18 (11)	0

Bike/Cycling with…	Non-neutral lower limb orientations	0	13 (2)	11 (2)	12 (2)	66 (10)	550 (82)	21 (3)
	Tibial Internal Rotation	0	5 (3)	2 (1)	2 (1)	10 (6)	135 (84)	6 (4)
	Tibial External Rotation	0	4 (3)	4 (3)	6 (4)	7 (4)	134 (84)	5 (3)
	Foot Supination	0	3 (2)	3 (2)	3 (2)	8 (5)	139 (87)	4 (3)
	Foot Pronation	0	1 (1)	2 (1)	1 (1)	8 (5)	142 (89)	6 (4)
Step-Up Step-Down exercises with…	Femoral and Tibial Internal Rotation	8 (5)	8 (5)	10 (6)	1 (1)	11 (7)	115 (72)	7 (4)
	Femoral and Tibial External Rotation	16 (10)	28 (18)	14 (9)	2 (1)	9 (6)	87 (54)	4 (3)
	Foot Supination	9 (6)	11 (7)	8 (5)	6 (4)	5 (3)	119 (74)	2 (1)
	Foot Pronation	1 (1)	2 (1)	3 (2)	3 (2)	5 (3)	139 (87)	7 (4)

Outcome Measure Dataset

Outcome measure	**Frequency (%) to which respondents used outcome measures for % of their patients**						
	100%	**99-75%**	**74-50%**	**49-25%**	**24-1%**	**0%**	**Not aware of tool**
Self-reported patient satisfaction	103 (66)	25 (16)	8 (5)	2 (1)	2 (1)	16 (10)	0
Cincinnati	0	1 (1)	6 (4)	2 (1)	6 (4)	97 (62)	47 (30)
Fulkerson Patellofemoral Rating Scale	0	0	2 (1)	1 (1)	3 (2)	84 (54)	70 (45)
Hughston VAS knee score	15 (10)	6 (4)	2 (1)	0	2 (1)	75 (48)	60 (39)
IKDC	5 (3)	1 (1)	2 (1)	0	5 (3)	89 (57)	58 (37)
Short-Form 12 or 36	1 (1)	1 (1)	5 (3)	2 (1)	6 (4)	89 (57)	56 (36)
Lysholm	2 (1)	4 (3)	7 (5)	3 (2)	4 (3)	78 (50)	62 (40)
Kujula	0	1 (1)	3 (2)	1 (1)	2 (1)	75 (48)	78 (50)
Tegner	1 (1)	4 (3)	1 (1)	1 (1)	3 (2)	74 (47)	76 (49)
Musculoskeletal Function Assessment Injury and Arthritis Survey	1 (1)	2 (1)	2 (1)	1 (1)	5 (3)	84 (54)	65 (42)
MYMOP	3 (2)	4 (3)	0	0	0	0	0
KOOS	2 (1)	1 (1)	2 (1)	0	2 (1)	0	0
PFPS	2 (1)	0	0	1 (1)	0	0	0
LEFS	11 (7)	1 (1)	3 (2)	1 (1)	2 (1)	0	0
VAS Pain	2 (1)	2 (1)	0	0	0	0	0
Objective functional and clinical measures	5 (3)	1 (1)	0	0	0	0	0
In house knee questionnaire	0	1 (1)	0	0	0	0	0
Achievement of agreed goals	1 (1)	0	0	0	0	0	0
Oxford/MRC muscle strength	1 (1)	0	0	0	0	0	0

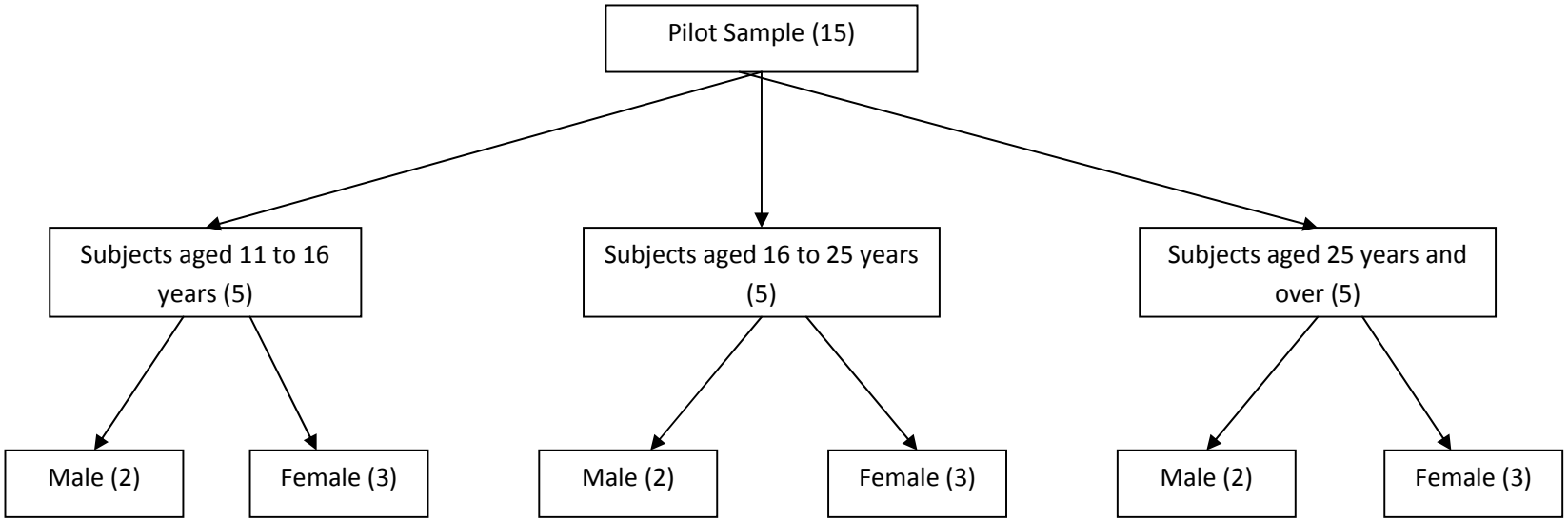
IKDC - International Knee Documentation Committee
KOOS – Knee Injury and Osteoarthritis Outcome Score
LEFS – Lower Extremity Functional Score
MRC – Medical Research Council
MYMOP – Measure Yourself Medical Outcome Profile
PFPS – Patellofemoral Pain Score
VAS – Visual Analogue Scale

Appendix 14. Patellar dislocation recruitment rates to a specialist patellar clinic at a teaching hospital in the East of England.

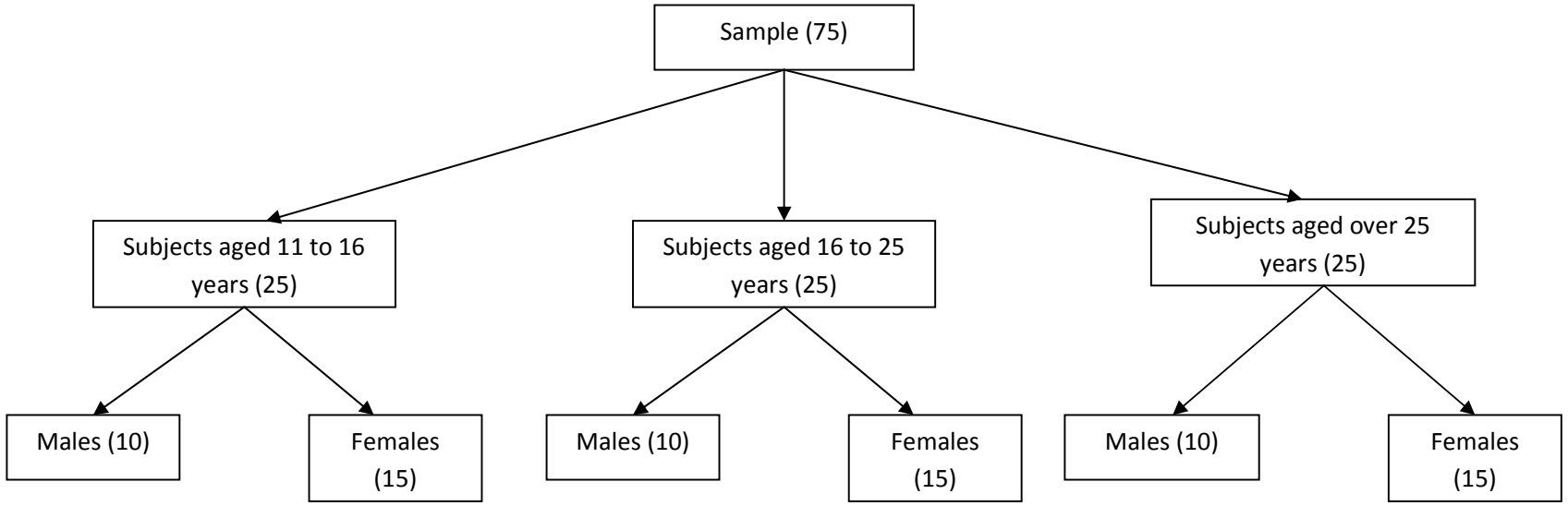
Referral Type	Month 1	Month 2	Month 3
First Contact	9	7	7
Follow-up	15	16	21
Total	24	23	28

Appendix 15. Activity survey quota sampling strategies.

The Sampling Strategy Adopted for the Pilot Survey Study



The Sampling Strategy Adopted for the Principal Survey Study



Appendix 16. The Contompasis Score

1. Passive opposition of the thumb to the flexor aspects of the forearm ("thumb to wrist test"). Points are allocated according to the extent to which the thumb meets or passes the forearm as follows:

Thumb and forearm not touching and separated by between 30° - 75°	2
Thumb touches the forearm	4
Thumb digs into the forearm easily	5
Thumb can be pushed beyond the axis of the forearm	6

2. Passive dorsiflexion of the 5th metacarpophalangeal joint. The angle measured is the long axis of the forearm with the long axis of the 5th digit:

Hyperextension between 30° - 85°	2
Hyperextension of 90° - 100°	4
Hyperextension of 100° - 120°	5
Hyperextension > 120°	6

3. Passive hyperextension of the elbow. The angle measured is the long axis of the forearm with the long axis of the upper arm:

Hyperextension between 0° - 5°	2
Hyperextension between 10° - 15°	4
Hyperextension between 16° - 20°	5
Hyperextension > 20°	6

4. Passive hyperextension of the knee:

Hyperextension of 0° - 5°	2
Hyperextension of 10° - 15°	4
Hyperextension of 16° - 20°	5
Hyperextension > 20°	6

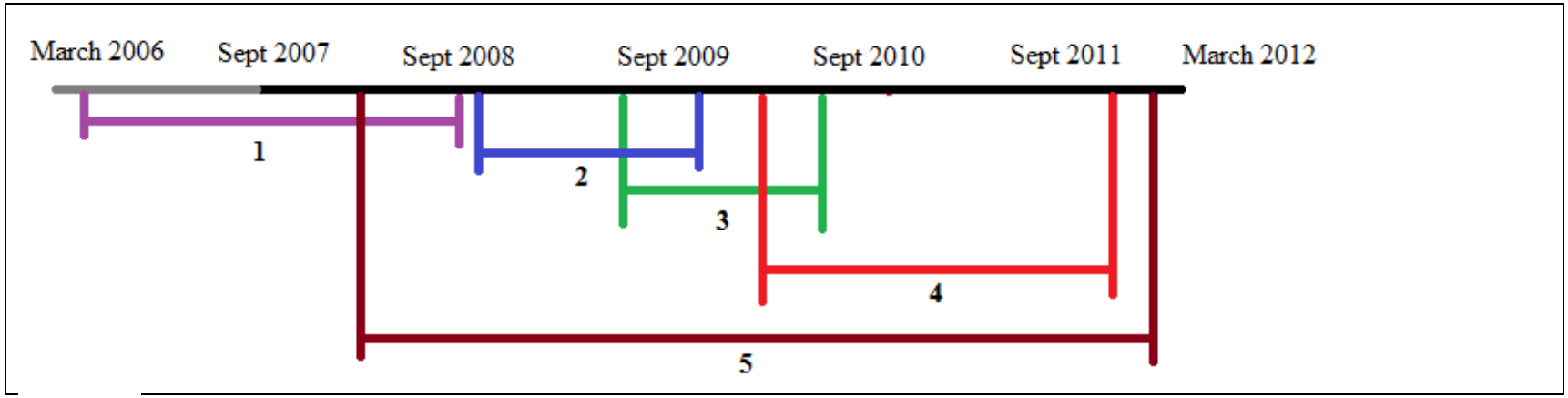
5. Forward flexion of the spine, attempting to place the hands flat on the floor in front of the feet (which are together) without bending the knees:

No contact with the ground	2
Fingertips touching the ground	4
Fingers touching the ground	5
Palms can be placed flat in the ground	6
Wrists can be palced on the ground	7
Forearms reach the ground	8

6. Foot flexibility test (ankle dorsiflexion and calcaneal stance position). The degree of eversion of the calcaneal is recorded:

0° - 2° of eversion	2
3° - 5° of eversion	4
6° - 10° of eversion	5
11° - 15° of eversion	6
> 15° of eversion	7

Appendix 17. PhD Time-time



Denotes planning conducted prior to PhD registration.

1. Planning and Literature Review
2. Activity Survey Study
3. National Survey Study
4. RCT
5. Preparation of thesis and dissemination

Appendix 18. Covering Letter for Activity Survey for under 16 year olds

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Dear Patients,

The doctors and physiotherapists want to see what activities, such as playing games, or school and home tasks, makes you and patients with your knee problem, feel like your knee cap may "pop out" of joint. The purpose of this project is to find this out.

There will be an Information Sheet attached with this letter and a Questionnaire (or list of questions). Please read the information or have someone read it for you. Don't worry if you don't understand it straight away. Your parents have also been told about this, and have been given the Information Sheets, so you can ask them to help you understand.

After reading the information, if you want to answer the questions on the Questionnaire, then please do so, and either send it or ask your parent to post it back to myself, using the envelope given. If you are one of the first people to help with this investigation, you may be asked to complete a second identical Questionnaire one week later, and to post this also back to myself, using the second envelope given. This will be done to see if there was a difference between the two Questionnaire's results.

If you have any questions about this project, please contact me, my details are printed in the Patient Information Leaflet.

Thank you,

Mr Toby O Smith
Chief Investigator
Senior Orthopaedic Physiotherapist
Norfolk and Norwich University Hospital

Appendix 19. Covering Letter for Activity Survey for parents/guardians of respondents under 16 years old

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Dear Sir or Madam,

Your child is being invited to join a study investigating what activities or situations cause patients with knee cap instability to feel that their knee cap may "pop out" of joint or feel unstable. We presently do not clearly know which activities are most problematic for patients such as your child, and accordingly the purpose of this study is to begin to find this out.

Attached with this letter should be a Patient Information Leaflet for yourself and your child, a Questionnaire and a stamped addressed envelope. If you and your child are interested in helping us with this study, please could yourself and your child read through the Patient Information Leaflet. You may discuss this with your friends and relatives as well as your child, before deciding whether to assist with this study. If you do want your child to join the study, they will be asked to complete the Questionnaire, and send it back to myself in the stamped addressed envelope. For those people who participate in the early part of this study, your child may have received two identical questionnaires. Please ask your child to complete the first, and return it in the envelope provided. Exactly one week later, ask your child to complete the second questionnaire and also return that in the other envelope. This will be used to examine the reliability of our results.

If you or your child have any questions regarding the study, please feel free to contact me, my details are printed in the Patient Information Leaflet. Finally, thank you for taking the time to read this letter, and thank you for your child's participation in the study if you and they choose to do so.

Yours faithfully,

Mr Toby O Smith
Chief Investigator
Senior Orthopaedic Physiotherapist
Norfolk and Norwich University Hospital

Appendix 20. Covering Letter for Activity Survey for over 16 year olds

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Dear Sir or Madam,

You are being invited to join a study investigating what activities or situations cause patients with knee cap instability to feel that their knee cap may "pop out" of joint or feel unstable. We presently do not clearly know which activities are most problematic for patients such as yourself, and accordingly the purpose of this study is to begin to find this out.

Attached with this letter should be a Patient Information Leaflet, a Questionnaire and a stamped addressed envelope. If you are interested in helping us with this study, please read through the Patient Information Leaflet. You may discuss this with your friends and relatives before deciding whether to assist with this study. If you do want to join the study, you will be asked to complete the Questionnaire, and send it back to myself in the stamped addressed envelope. For those people who participate in the early part of this study, you may have received two identical questionnaires. Please complete the first, and return it in the envelope provided. Exactly one week later, please complete the second and return that in the other envelope. This will be used to examine the reliability of our results.

If you have any questions regarding the study, please feel free to contact me, my details are printed in the Patient Information Leaflet. Finally, thank you for taking the time to read this letter, and thank you for participating in the study if you choose to do so.

Yours faithfully,

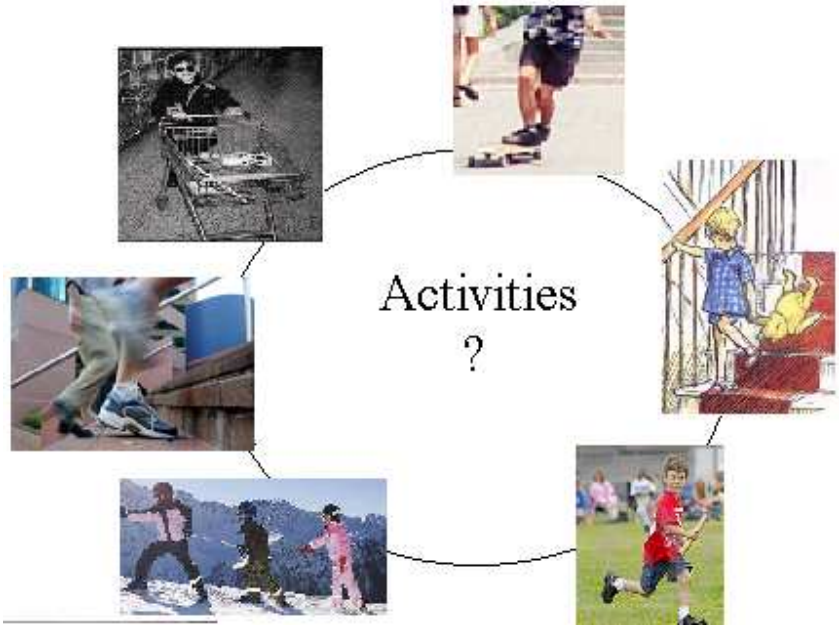
Mr Toby O Smith
Chief Investigator
Senior Orthopaedic Physiotherapist
Norfolk and Norwich University Hospital

Appendix 21. Activity Survey Patient Information Leaflet for under 11 to 14 year olds

Patient Information Sheet (11-14 Years)
(Version 2.0 20.10.2008)

What activities cause patellar instability patients to perceive knee instability? A survey design.

Your doctor and physiotherapist have decided they want to see what activities such as playing games or school and home tasks, makes young people feel that their knee cap may "pop out" of joint. They have made a list of questions to look at this. We would like to invite you to take part in this investigation and answer these questions at home.



Take time to decide if you want to say **YES** or **NO** to this. Please read, or have someone to read to you, this information. Don't worry if you don't understand it straight away. Your parents have also been told about this, and you can talk to them about it as well so that you are sure you understand what you are being asked to do.

1. Why are we doing this?

We want to see what activities such as playing games at home or at school, make young people and adults feel that their knee cap may "pop out" of joint or feel

unsafe. This will give the doctors and physiotherapists at hospitals a better idea of what activities cause this problem in young people and adults who have the same knee problem as yours.

2. What will be different for you?

You and your family will be given a list of questions when you are at the hospital. When you go home, if you would like, you can answer the questions with your family, and then they can post these questions back to the hospital. The questions should take you about 10 minutes to answer. If you are one of the first people to help with this investigation, you may be asked to complete a second identical list of questions exactly 1 week later. Complete this second list of questions, and post this also back to myself, using the second envelope given.

3. Why do we ask you?

We know you have the type of knee problem we are interested in. As part of our investigation we are asking all young people and adults who come to the hospital who have knee problems similar to yours to take part.

4. Do I have to take part?

No. It is up to you and your parents to decide. If you decide you don't want to, that's absolutely fine. The doctors and physiotherapists will look after you in exactly the same way as they would if you do decide to take part.

5. Who will know about me and the answer to my questions?

No one will know about the answers you give to the questions are from you, because your name is not on the question sheet. No one will know who replies to the questionnaire. Your name will not be on your answer sheet and no one will know it is from you.

Once we have your answers and all the other people's answers, we will write a report about our investigation in a medical journal. But, no one will know that the answers you returned are yours. Your name will not be mentioned in the report and so no one will know you took part unless you tell them.

6. Who can I speak to if I have any questions?

You can speak to your parents who have also been given information about this project. You can also speak to the doctors or physiotherapists at the hospital.

One of the physiotherapists involved is **Toby Smith**. You and your parents can always speak to him if you have any more questions. Your parents also have some further contact details of people to speak to if they have any complaints or worries. You can contact **Toby** at the **Physiotherapy Department** at the hospital on **01603 286990.**

Appendix 22. Activity Survey Patient Information Leaflet for 14 to 16 year olds

Patient Information Sheet (Age 14-16)
(Version 2.0 20.10.2008)

What activities cause instability for patients with patellar instability?

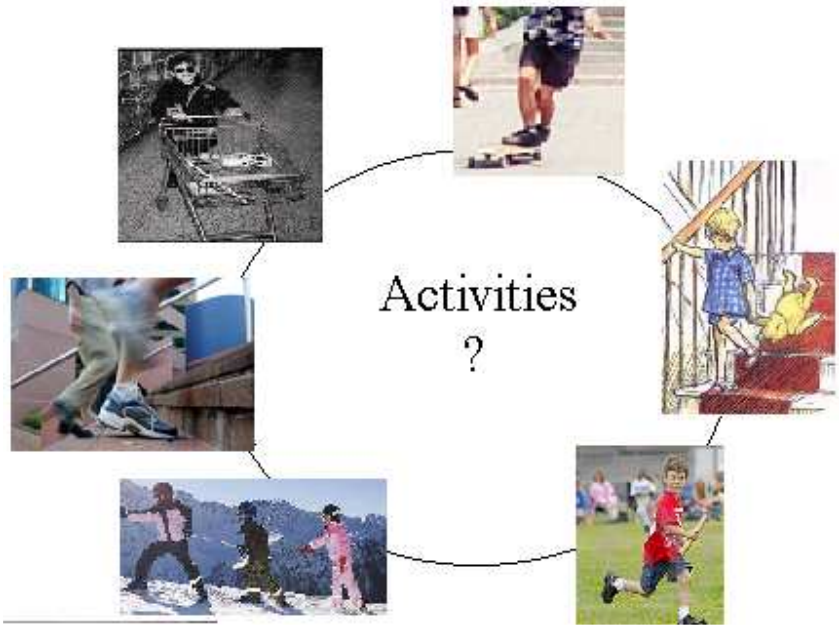
Your doctor and physiotherapist are doing a project to see what activities such as sports, home or school tasks, makes people feel that their knee cap may "pop out" of joint. They have made a list of questions to look at this. We would like to ask you and your parents whether you would like to take part in this project.

What are we hoping to achieve with this project?

The aim of this project is to make a list of activities which people feel may cause their knee cap to "pop out" of joint or feel unstable. This can occur with patients who have had a patellar or knee cap dislocation. This condition is called patellar instability, which occurs in adults as well as young people. We have made a list of questions to find out which activities cause the knee cap to feel unstable, as we do not know exactly what these activities are.

Why is the project being done?

We want to find out what activities cause people to feel knee cap instability. This will help us to recognise the activities which are likely to cause a problem. We want to be able to measure how good or bad a patient's knee cap instability is and to try to establish how effective the treatments for this condition are.



Why have you been chosen?
We are asking children and teenagers as well as adults who have been sent to the hospital about knee cap instability problems to take part in our project.

How will the project be done?
If you agree to take part, you will be asked to answer a list of questions. This is to be completed at home and returned within 3 weeks of receiving the Questionnaire. The questions should take approximately 10 minutes to complete. Once you have sent it back to the hospital in the stamped addressed envelope attached with the questionnaire, then you have completed the study. If you are one of the first people to help with this investigation, you may be asked to complete a second identical list of questions exactly 1 week later. Please complete this second list of questions, and post this also back to myself, using the second envelope given. This will be done to see if there was a difference between the two lists of questions.

What are the risks and discomfort?
There are no risks in taking part in this study. If you feel uncomfortable about answering any of the questions, you can leave them blank.

What are the arrangements for compensation?
This research project has been approved by an independent Research Ethics Committee who believes that it is of minimal risk to you. However, research can carry unexpected risks and we want you and your parents to be informed of your rights in the unlikely event that any harm should occur because of taking part in this project.

If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. If you wish to complain, or have any worries about how you have been approached or treated during this study, you can contact the normal hospital complaints service, details of which are provided below.

What about the results of the Questionnaire?
The Questionnaire will be returned to the Physiotherapist involved with this study. However, since you will not be asked to write your name on the Questionnaire, no one will know that the answers you returned are yours. All your information will be kept confidential.

Who will have access to your Questionnaire answers?
We will keep all your information confidential. Only the Physiotherapist and Doctors involved with this study will have access to the Questionnaire. The Questionnaires will be stored in a locked cupboard in the hospital. However, a representative of the hospital's Research Ethics Committee may also have access to data if requested. However, it will not be possible to identify you from the Questionnaire as your name will not be on the sheets.

The results from our project will be published as papers in medical journals. Your name will not be used when the research results are published, so that you can never be recognised.

Do I have to take part in this project?
No. If you and your parents decide not to take part in this project, this is entirely your right and will not in any way change your present or future treatment.

Who do I speak to if I have further questions or worries?
Please contact **Toby Smith**, the Physiotherapist at the Physiotherapy Department, on **01603 286990**. You can contact him either through the switchboard or via your hospital physiotherapist or doctor who can get in touch with them.

If you or your parents have any complaints about the way in which this project is being or has been conducted, in the first instance please discuss them with Toby Smith. If the problems are not resolved, or you and your parents wish to comment in any other way, please contact your local Patient Advisory Liaison Service (PALS) at the Norfolk and Norwich University Hospital on 01603 289045.

Appendix 23. Activity Survey Patient Information Leaflet for over 16 year olds

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Patient Information Sheet (Over 16s)
(Version 2.0 20.10.2008)

What activities cause instability for patients with patellar instability?

Investigators:- Mr Toby O Smith BSc (Hons) MCSP
Mr **XXXX**

of the Norfolk and Norwich University Hospital

Dr **XXXX**
Ms **XXXX**
Dr **XXXX**
Dr **XXXX**

of the Faculty of Health, University of East Anglia

You are being invited to take part in a medical research study. However, before you make a decision to participate, it is important that you fully understand why the project is being undertaken, and what it will involve. Please read this information sheet carefully, and discuss it with friends and relatives. If there is anything, which you are not sure about, please ask for further information before you decide whether or not you wish to participate.

Thank you for reading this.

What is the purpose of this study?
You have been referred to the Orthopaedic Department or Physiotherapy Department at the **XXXX** Hospital because of the problems you are experiencing with your knee cap (or patella). I understand that your knee cap has either come out of joint, or feels like it may come out of joint. We describe this as instability. Presently, there is no reliable way to grade the severity of patella instability. This project will allow us to develop a questionnaire which assesses this. In order to do this, we need to know what activities cause people to feel that their knee cap is insecure and may pop out. This study will find this out.

Why have I been chosen?
You have been referred to the Orthopaedic Department or Physiotherapy Department at the **XXXX** Hospital because of instability or dislocation of your knee cap. You have also be chosen as you fulfil the study criteria requiring that you are 11 years of age or over; able to read and understand English, have been diagnosed with patellar instability by your orthopaedic surgeon or physiotherapist. You will be one of **90** patients taking part.

Do I have to take part in the study?
It is up to you to decide whether or not to take part. This study is entirely voluntary. If you did decide to participate in the study, you will be asked to complete a questionnaire. By completing and returning this questionnaire in the stamped addressed envelope enclosed, it will be assumed that you have provided consent to enter into this trial. A decision not to take part, will not affect the standard of care you receive in any way.

What will happen to me if I decide to take part?
If you decided to participate, then you will enter the study. The Physiotherapist or Orthopaedic Surgeon who give you this Patient Information Leaflet, will have also given you a 5 sided A4 questionnaire, and an envelope. After reading this Patient Information Leaflet, if you wish to participate in this study, then you can complete the questionnaire. The questionnaire describes a variety of activities which may cause your knee cap to feel like it will "pop out". You will be asked how much each of these activities causes you to feel that your knee cap will pop out of joint or dislocate. There is no right or wrong answer, please tick the box as indicated to describe how each of the activities affect you and your knee. If you feel there are other activities which cause you problem which are not listed in the questionnaire, please write them in the space provided, and mark how much they affect your knee. Once completed, please return the questionnaire in the stamped addressed envelope provided. For those people who participate in the early part of this study, your surgeon or physiotherapist may ask you to complete two questionnaires in total. You may be asked to complete an identical questionnaire exactly one week later, and then to return this in a second envelope. This will be used to examine the reliability of our results. Once you have posted the questionnaire, your participation in the study is finished.

What do I have to do?
All you need to do is answer the questions asked on the questionnaire based on your experiences.

What are the possible disadvantages and risks of taking part?
There are no specific disadvantages in taking part in this study. However, if you feel anxious about any part of the study, you are free not to participate in the study without having to give a reason. Similarly if there are any questions you do not feel comfortable answering on the questionnaire then you are free not to answer them.

What are the possible benefits of taking part in the study?
There are no benefits to you by taking part. It is hoped that the information we get from this study may help the Researcher to devise a questionnaire to assess patient's knee cap instability and to determine how effective the treatments are for this condition.

What if something goes wrong?
If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you. This can be explained to you by your local Patient Advisory Liaison Service (PALS) at the **XXXX** Hospital on **XXXX**. They will be able to assist if you have any concerns about this study.

Will I get paid for participating?
You will not be paid for your participation. Since you will be attending a hospital appointment when you will receive this Patient Information Leaflet, Questionnaire and Stamped Addressed envelope, you will not be reimbursed your mileage costs.

Will my taking part in this study be kept confidential?
The information you provide from the Questionnaire will be analysed. Once the study has been completed all questionnaires will be destroyed in the hospital confidential waste. The questionnaires have a numerical code. This code cannot identify you. The findings from this study may be reported orally at medical meeting and conferencing, and/or published in a scientific journal. However, no one will know that the answers returned are yours, and you will not be able to be identified at any point.

What will happen to the results of the research study?
As noted, it is anticipated that the findings from this study will be published in an orthopaedic medical journal. This will not include any information that directly identifies you. If you wish to obtain a copy of the final report, please contact the Researcher who will be able to help. The results from this study will form part of a Doctorate in Philosophy (PhD) thesis for the Researcher, at the University of East Anglia. In addition, approximately a year after you have finished participating in the study, it is anticipated that the findings will be published in an orthopaedic medical or physiotherapy journal.

Who is organising and funding the research?
The research is being organised by the Researcher (Toby Smith), and being supervised by Consultant Orthopaedic Surgeon Mr **XXXX**, and Dr **XXXX**, Ms **XXXX** and Dr **XXXX**, academic staff of the University of East Anglia. An application to fund this study has been sent to the charity Action Arthritis. The Researcher conducting the research is being paid to undertaking this study though this funding application.

Who has reviewed the study?
This study has been reviewed by the Cambridgeshire 3 Research Ethics Committee and the East Norfolk and Waveney Research Governance Committee.

Who do I contact for further information?
If you wish for more information about the study, please contact **Toby Smith**, the Chief Investigator at the Physiotherapy Department, on **01603 286990** or by e-mail on toby.smith@nnuh.nhs.uk.

If you have any other general questions about participating in this or other research studies, you may also contact your local Patient Advisory Liaison Service (PALS) at the **XXXX** Hospital on **XXXX**.

Thank you for taking the time to read through this information sheet, and thank you for participating in the study if you choose to do so.

Appendix 24. Activity Survey Patient Information Leaflet for parents/guardians of respondents under 16 years old

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Patient Information Sheet (Parents)
(Version 2.0 20.10.2008)

What activities cause instability for patients with patellar instability?

Investigators:- Mr Toby O Smith BSc (Hons) MCSP
Mr **XXXX**

of the Norfolk and Norwich University Hospital

Dr **XXXX**
Ms **XXXX**
Dr **XXXX**
Dr **XXXX**

of the Faculty of Health, University of East Anglia

Your child is being invited to take part in a medical research study. However, before you and your child make a decision to participate, it is important that you fully understand why the project is being undertaken, and what it will involve. Please read this information sheet carefully, and discuss it with your child and your friends and relatives. If there is anything, which you are unsure about, please ask for further information before deciding whether or not you wish to participate.

Thank you for reading this.

What is the purpose of this study?
Your child has been referred to the Orthopaedic Department or Physiotherapy Department at the **XXXX** Hospital because of the problems they are experiencing with their knee cap (or patella). I understand that your child's knee cap has either come out of joint, or feels like it may come out of joint. We describe this as instability. Presently, there is no reliable way to grade the severity of patellar instability. This project will allow us to develop a questionnaire which assesses this. To do this we need to know what activities cause people to feel that their knee cap will "pop out". This study will find this out.

Why has my child been chosen?
Your child has been referred to the Orthopaedic Department or Physiotherapy Department at the **XXXX** Hospital because of instability or dislocation of their knee cap. They have also be chosen as they fulfil the study criteria that is that they are 11 years of age or over; able to read and understand English, have been diagnosed with patellar instability by your orthopaedic surgeon or physiotherapist. Your child will be one of **90** patients taking part.

Does my child have to take part in the study?
It is up to you and your child to decide whether or not to take part. This study is entirely voluntary. If you and your child did decide to participate in the study, your child will be asked to complete a questionnaire. By completing and returning this questionnaire in the stamped addressed envelope enclosed, it will be assumed that you and your child have provided consent to enter into this trial. If your child did not take part it will not affect the standard of care they will receive in any way.

What will happen to my child if I decide to let them take part?
If you and your child decided to participate, then your child will enter the study. You will have been given a 3 sided A4 questionnaire and envelope with this information leaflet. If you and your child decide to participate in the study, your child may complete the questionnaire. The questionnaire describes a variety of activities or situations which may cause their knee cap to feel like it will "pop out". Your child will be asked you how much each of these activities causes them to feel that their knee cap will pop out of joint or dislocate. There is no right or wrong answer, please advise your child to tick the box as indicated to describe how each of the activities affect them and their knee. If your child feels that there are other activities which cause them problems which are not listed in the questionnaire then they can write them in the space provided on the questionnaire, and mark how much they affect their knee. Once completed, please return the questionnaire in the stamped addressed envelope provided. For those people who participate in the early part of this study, your surgeon or physiotherapist may ask your child to complete two questionnaires in total. They may be asked to complete an identical questionnaire exactly one week after the first questionnaire. In this instance, please could your child complete the questionnaire and return it in the second envelope. This will be used to examine the reliability of our results. Once you or your child has posted the questionnaire, your child's participation in the study is finished.

What do I have to do?
All you need to do decide whether you would like your child to participate in the study, and ask them to answer the questions asked on the questionnaire based on their experiences.

What are the possible disadvantages and risks of taking part?
There are no specific disadvantages in taking part in this study. However, if you or your child feels anxious about any part of the study, they are free not to participate in the study without having to give a reason. Similarly if there are any questions your child do not feel

comfortable answering, or you don't want your child to answer on the questionnaire, then they are free not to answer them.

What are the possible benefits of taking part in the study?
There are no benefits to your child from taking part. It is hoped that the information we get from this study may help the Researcher to devise a questionnaire to assess patient's knee cap instability and to determine how effective the treatments are for this condition.

What if something goes wrong?
If your child is harmed by taking part in this research project there are no special compensation arrangements. If your child is harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you and your child have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you and your child. This can be explained to you by your local Patient Advisory Liaison Service (PALS) at the **XXXX** Hospital on **XXXX**. They will be able to assist if you have any concerns about this study.

Will I get paid for my child's participating?
You and your child will not be paid for your participation. Since they will be attending a hospital appointment when you will receive this Patient Information Leaflet, Questionnaire and Stamped Addressed envelope, you will not be reimbursed your mileage costs.

Will my child's taking part in this study be kept confidential?
The information your child provides from the Questionnaire will be analysed. Once the study has been completed all questionnaires will be destroyed in the hospital confidential waste. The questionnaires have a numerical code. This code cannot identify your child. The findings from this study may be reported orally at medical meeting and conferencing, and/or published in a scientific journal. However, since no one will know that the answers returned are your child's, your child will not be able to be identified at any point. The child's notes may be accessed for audit and monitoring purposes by a member of the study team. This is to check that the consent forms have been completed and retained.

The results from this study will form part of a Doctorate in Philosophy (PhD) thesis for the Researcher, at the University of East Anglia. In addition, approximately a year after your child has finished participating in the study, it is anticipated that the findings will be published in an orthopaedic medical or physiotherapy journal.

What will happen to the results of the research study?
As noted, it is anticipated that the findings from this study will be published in an orthopaedic medical journal. This will not include any information that directly identifies your child. If you wish to obtain a copy of the final report, please contact the Researcher who will be able to help.

Who is organising and funding the research?
The research is being organised by the Researcher (Toby Smith), and being supervised by Consultant Orthopaedic Surgeon Mr **XXXX** and Lectures Dr **XXXX**, **XXXX** and Dr **XXXX** of the University of East Anglia. An application to fund this study has been sent to the charity Action Arthritis. The Researcher conducting the research is being paid for undertaking this study through this funding application.

Who has reviewed the study?
This study has been reviewed by the Cambridgeshire 3 Research Ethics Committee and the East Norfolk and Waveney Research Governance Committee.

Who do I contact for further information?
If you wish for more information about the study, please contact **Toby Smith**, the Chief Investigator at the Physiotherapy Department, on **01603 286990** or by e-mail on toby.smith@nnuh.nhs.uk.

If you have any other general questions about participating in this or other research studies, you may also contact your local Patient Advisory Liaison Service (PALS) at the **XXXX** Hospital on **XXXX**.

Thank you for taking the time to read through this information sheet, and thank you for your child's participation in the study if you and they choose to do so.

Appendix 25. Under 16 year old Activity Survey Questionnaire

Questionnaire (Under 16s)

(Version 2.0 24.03.2009)

Below is a list of activities which may make your knee cap to feel like it will "pop out" of joint.

Read each activity, then tick the box which describes how often you feel your knee cap will "pop out" of joint. Please only tick one box for each activity.

Do not tick the "*don't do this activity*" box if you avoid the task as it causes your knee cap to feel like it will "pop out" of joint. Instead, mark how often this activity causes your knee to feel unstable. Only tick this box if you don't do the activity for any other reason apart from knee cap instability.

If there are any activities not listed which cause your knee cap to feel like it will "pop out", please write what these in the 'Others' spaces at the end of the questionnaire. You can then tick the box which describes how often you feel your knee cap will "pop out" of joint for each activity.

For example:

If your knee cap OFTEN feels unstable or will "pop out" when SQUATTING, then tick the OFTEN box

	Always	Often	Some of the time	Rarely	Never	Don't do this activity
Squatting		✓				

Thank you

Office Use (Surgeon/Physio please circle before giving to Participant)

Age (11-16 / 16-25 / 25 -) Male / Female Family History (yes / no) Contompasis Hypermobility Score (/70)

My knee cap feels unstable or will "pop out" when…

	Always	Often	Some of the time	Rarely	Never	Don't do this activity
Walking in a straight line on *even* surfaces						
Walking in a straight line on *uneven* surfaces						
Walking on slippery, wet or icy surfaces						
Kneeling						
Squatting						
Crossing my legs when sitting						
Getting in and out of a car						
Turning to look over my shoulder						
Climbing stairs						
Going down stairs						
Stepping onto or over a high step						
Running in a straight line on *even* surfaces						
Running in a straight line on *uneven* surfaces						
Running sideways						
Changing direction when running, such as cutting or slalom						
Jumping						
Hopping						
Twisting or changing direction during PE or sports						

Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						

Appendix 26. Over 16 year old Activity Survey Questionnaire

Questionnaire (Adult)

(Version 2.0 24.03.2009)

Below is a list of activities which may cause your knee cap to feel like it will "pop out" of joint or feel unstable.

Please read through each statement, ticking the box which best describes how often your knee cap feels like it will "pop out" of joint or feels unstable.

Please only tick one box for each statement.

Do not tick the "*don't do this activity*" box if you avoid the task as it causes your knee cap to feel like it will "pop out" of joint. Instead, mark how often this activity causes your knee to feel unstable. Only tick this box if you don't do the activity for any other reason apart from knee cap instability.

If there are any activities not mentioned which you feel cause your knee cap to feel unstable, please write these down in the 'Others' spaces at the end of the questionnaire. You can then tick the box to indicate how often this occurs.

For example:

If your knee cap OFTEN feels unstable or will "pop out" when SQUATTING, then tick the OFTEN box

	Always	Often	Some of the time	Rarely	Never	Don't do this activity
Squatting		✓				

Thank you for your assistance

Office Use (Surgeon/Physio please circle before giving to Participant)

Age (11-16 / 16-25 / 25 -) Male / Female Family History (yes / no) Contompasis Hypermobility Score (/70)

My knee cap feels unstable or will "pop out" when…

	Always	Often	Some of the time	Rarely	Never	Don't do this activity
Walking in a straight line on *even* surfaces						
Walking in a straight line on *uneven* surfaces						
Walking on slippery, wet or icy surfaces						
Turning a heavy trolley round a supermarket aisle						
Kneeling						
Squatting						
Crossing my legs when sitting						
Getting in and out of a car						
Turning to look over my shoulder						
Climbing stairs						
Going down stairs						
Stepping onto or over a high step						
Running in a straight line on *even* surfaces						
Running in a straight line on *uneven* surfaces						
Running sideways						
Changing direction when running, such as cutting or slalom						
Jumping						
Hopping						
Twisting or changing direction during Sports or PE activities						

Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						
Other (please specify)…….						

Appendix 27. Activity survey pilot study feedback form

Pilot Questionnaire Feedback

Please you answer the following questions about the questionnaire that you have just completed.

Was the questionnaire easy to complete	**Yes / No**
If no, how could it be made clearer?	
Approximately how long did it take you to complete the questionnaire?	**_____ minutes**
Could this have been shorter?	
Were the questions easy to understand?	**Yes / No**
If no, which questions were unclear?	
If you are under 11 years old… **Did your parents find the questions easy to understand?**	
Were the activities described relevant to you and your knee problem?	**Yes / No**
If no, which activities were these and why?	
Are there any activities/tasks you felt should have been on this list which were not?	
What could have been done to make this project easier for you?	
Was the Patient Information Leaflet clear and understandable?	**Yes / No**

Appendix 28. Activity survey study Research Ethics Committee and Research Governance Committee approval letters

NHS National Research Ethics Committee Approval

07 November 2008

Mr Toby Smith
Senior Orthopaedic Physiotherapist
Norfolk and Norwich University Hospital
Out-Patients East
Norfolk and Norwich University Hospital
Colney Lane
NR4 7UY

Dear Mr Smith

Full title of study: **What activities and to what frequency do patients with patellar instability perceive their patella to be unstable?**
REC reference number: **08/H0306/80**

Thank you for your letter of 30 October 2008, 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 Vice-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 Committee has designated this study as exempt from site-specific assessment (SSA). The favourable opinion for the study applies to all sites involved in the research. There is no requirement for other Local Research Ethics Committees to be informed or SSA to be carried out at each site.

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.

Management permission at NHS sites ("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 is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

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

Document	*Version*	*Date*
Patient Information Sheet (Over 16s)	2.0	20 October 2008
Patient Information Sheet (14-16 Years)	2.0	20 October 2008
Patient Information Sheet (11-14 Years)	2.0	20 October 2008
Patient Information Sheet (Parents)	2.0	20 October 2008
Participant Consent Form	2.0	20 October 2008
Copy of email from re consent		
Amended page of Application Form re data storage		
Revised pages 5 & 6 of protocol		
Response to Request for Further Information		30 October 2008
CV - (Lecturer in Medical Statistics)		
CV - (Lecturer in Physiotherapy)		
CV - (Reader in Physiotherapy)		
CV - Consultant Orthopaedic Surgeon and Honorary Reader		07 July 2008
Letter from East Norfolk & Waveney Research Governance Committee		08 August 2008
Compensation Arrangements: UEA Norwich		03 September 2008
Covering Letter: Mr Toby O Smith		04 September 2008
Protocol	1.0	06 July 2008
Investigator CV: Toby Oliver Smith		06 July 2008
Application	5.6	04 September 2008
CV - (Research Associate)		
Study Flow (Appendix 16)	1.0	06 July 2008
The Sampling Strategy Adopted for this Survey Design (Appendix 2)	1.0	06 July 2008
Letter of invitation to participants' parents	1.0	06 July 2008
Letter of invitation to participant	1.0	06 July 2008
Financial Considerations (Appendix 17)	1.0	06 July 2008
Contompasis Semi-Questionnaire Scoring System for Hypermobility (Appendix 3)	1.0	06 July 2008
Questionnaire		
Questionnaire: Pilot Questionnaire Feedback (Appendix 15)	1.0	06 July 2008
Questionnaire: Under 16s (Appendix 14)	1.0	06 July 2008
Questionnaire: Adult (Appendix 13)	Version 1.0	06 July 2008

Statement of compliance

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 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
- 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.

08/H0306/80	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mr
Vice-Chair

Email: @eoe.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to:

R & D Department
University of East Anglia
Norwich
Norfolk NR4 7TJ

R& D Dept
Norfolk and Norwich University Hospital
Colney Lane
NR4 7UY

Research Governance (Site-Specific) Approval

Mr Toby O Smith
Physiotherapy Department
Out-Patients East
Norfolk and Norwich University Hospital
Colney Lane
Norwich
NR4 7UY

08 August 2008

Dear Mr Smith

Re: 2008PHYS02S (106-08-08) What activities and to what frequency do patients with patellar instability perceive their patella to be unstable?

Thank you for submitting the above project to the Research Governance Committee for research management and scientific peer review.

Members agreed that this was a well prepared and clearly referenced application. The Committee would be happy to approve this project **once you have received a favourable Ethical opinion.**

You are asked to inform the R&D office once you have secured external funding for the study.

What to do next
1. You will need to contact the Research Ethics Committee Office where you wish to have your project ethically reviewed. Your nearest Research Ethics Committee is Norfolk (contact). If you wish to use a different Ethics Committee please visit the National Research Ethics Service website (www.nres.npsa.nhs.uk) for details of other committees in the Strategic Health Authority. You should supply the Ethics Committee with a copy of this letter.

2. Once you have received a 'favourable opinion' from the Research Ethics Committee you will need to provide the R&D office with a copy of:
- the 'favourable opinion' letter from the Research Ethics Committee.
- any documents amended as a result of the Ethical review. Please ensure that any changes are tracked by underlining them or using an italic font and giving revised version numbers and dates. The original or approved text should not be deleted from the revised document but should be 'struck out'.

When the Research Governance Committee office is in receipt of this information your project will be reviewed to verify that there are no further research management issues arising from the amended information. You will then be issued with a formal approval letter and you will be able to commence your study. **You must not begin your research before you receive a formal approval letter.**

If you have any queries regarding this or any other project please contact , Research Governance Administrator, at the above address. Please note, the reference number for this study is **2008PHYS02S (106-08-08)** and this should be quoted on all correspondence.

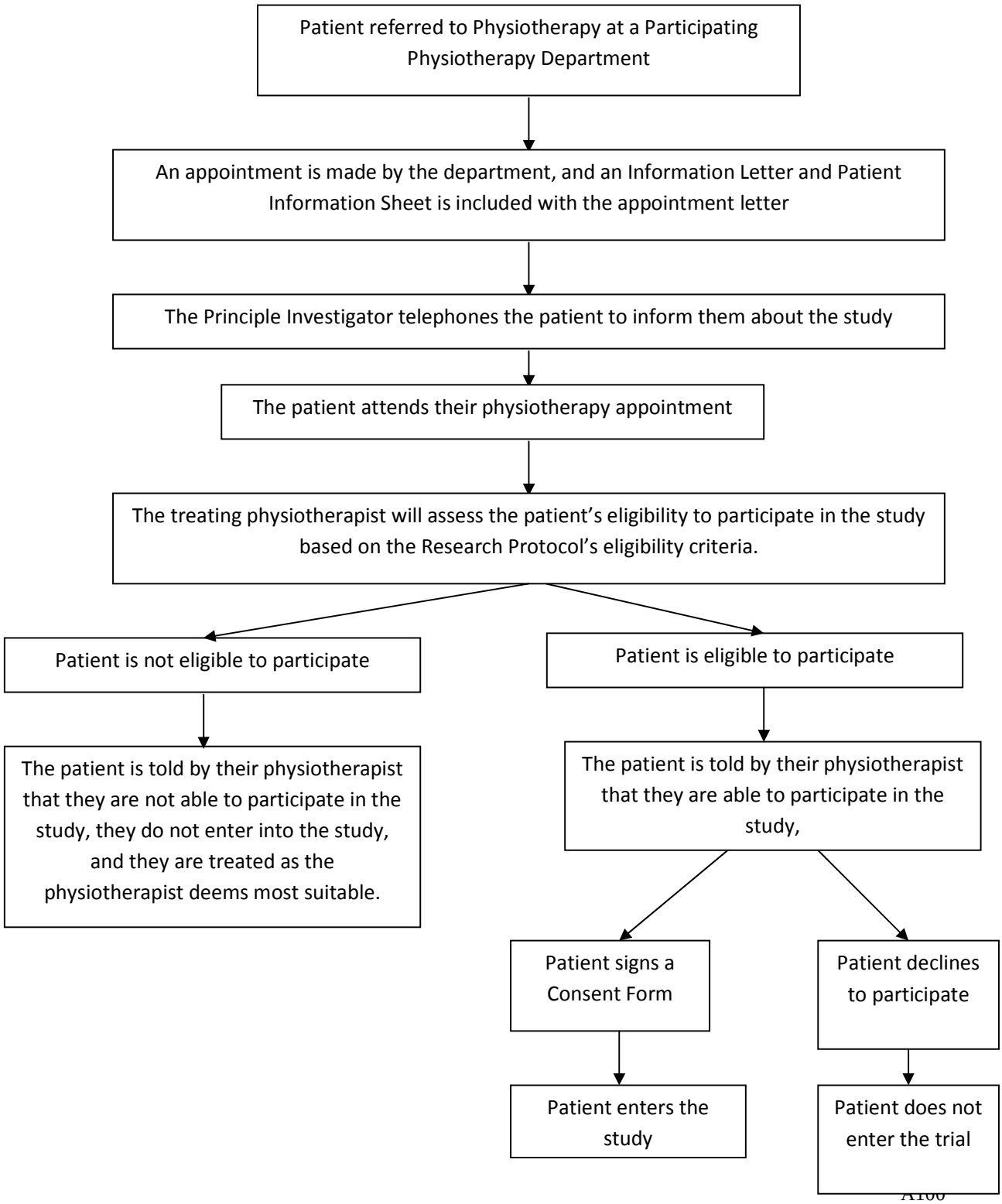
Yours sincerely

Dr
Chair

Appendix 29. The randomised controlled trial timescale

Data	Activity	Outcome
October 2007-December 2009	Develop, submit and revise proposal and ethics documents.	Submit ethics approval
December 2009 – March 2010	Ethical approval from Ethics Committee and Research and Development Governance Approval from each participating site.	Obtain ethics approval
March 2010-April 2010	Prepare stationary. Meet with Physiotherapy Team to discuss standardisation, selection criteria assessment and blinding	Begin recruitment
May 2010 – September 2011	Recruitment. Pre-rehabilitation, 6 week and 6 month assessments	Data collection complete
September 2011- October 2011	Data analysis	Analysis complete
October 2011 – December 2011	Preparation of written report	Submit manuscript to peer-review journal. Completion or RCT chapters into PhD thesis

Appendix 30. A flow chart of the randomised controlled trial recruitment process



Appendix 31. The randomised controlled trial covering letter

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Institute of Orthopaedics
Norfolk and Norwich University Hospital,
Colney Lane
Norwich
NR4 7UY

(DATE)

Dear

A research project is being undertaken at the Physiotherapy Department at the **XXXX** Hospital, the **XXXX** Hospital, or the **XXXX** Hospital in **XXXX**. The aim of this project is to see whether there is a difference in the outcome of two difference types of physiotherapy exercise programmes after knee cap or patellar dislocation. Since you have been referred to one of these departments, I will telephone you in the next 7 days to tell you more about this project as you may be able to help us with this project.

Please find attached an Information Sheet about the study which provides some information on why we are doing this project, what it involves, and how we are going to use the results of this project.

If you have any questions now, before I phone you, please feel free to contact me on toby.smith@nnuh.nhs.uk or 01603 646544.

I look forward to speaking to you,

Yours faithfully

Mr Toby O Smith
Principle Investigator
Research Physiotherapist in Orthopaedics
Norfolk and Norwich University Hospital, UK.

Appendix 32. The randomised controlled trial patient information leaflet

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Patient Information Sheet
(Version 1.0 ~ 17.11.09)

A randomised controlled trial to compare a specific VMO programme, to a general quadriceps regime on functional and quality of life outcomes for primary patellar dislocation patients?

Investigators:-

Mr Toby O Smith BSc (Hons) MSc MCSP
Dr **XXXX**
Ms **XXXX**
Professor **XXXX**

You are being invited to take part in a medical research study. You have been sent this form as you may be suitable to help in this study. However, before you make a decision to participate, it is important that you fully understand why the project is being undertaken, and what it will involve. Please read this information sheet carefully, and discuss it with friends and relatives. If there is anything, which you are not sure about, please ask for further clarification before you decide whether or not you wish to participate.

Thank you for reading this.

What is the purpose of this study?
You are about to begin a programme of physiotherapy treatment for your knee cap, or patella. It has been suggested that patients should receive a specific type of exercises to strength a small muscle (vastus medialis obliquus or VMO) which may help to keeping your knee cap in place. The main purpose of this study is to evaluate whether teaching these specific VMO exercises, in addition to a standard rehabilitation programme, improves outcomes, compared to performing general thigh strengthening exercises and the standard rehabilitation programme.

Why have I been chosen?

You have been referred to your local Physiotherapy Department because your knee cap has dislocated or "popped out". You are 16 years of age, or older. You do not have any other knee ligament injuries and your knee cap has not "popped out" before. You will be one of **50** patients taking part, **25** patients will receive the general thigh strengthening exercises and standard rehabilitation treatment, and **25** will receive the VMO exercises and standard rehabilitation treatment. This research is being carried out at the **XXXX** Hospital in **XXXX**, the **XXXX** Hospital in **XXXX** and the **XXXX** Hospital.

Do I have to take part in the study?
It is up to you to decide whether or not to take part. Your participation in the study is entirely voluntary. If you did decide to participate in the study, you will be asked to sign a consent form when you attend your first physiotherapy appointment. This will be witnessed by your Physiotherapist, who will also sign the form. You will then be given a copy of the signed and dated consent form to keep. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I decide to take part?
If you decided to participate, then you will enter the study. When you attend your first physiotherapy appointment, the physiotherapist will assess your knee. If the physiotherapist feels that you will be suitable to participate in the study, they will say so, and you can tell them if you wish to take part or not. If you say yes then one of the department's Physiotherapists will ask you to fill in 4 questionnaires and an assessment sheet, and ask you some questions about your knee and your other joints. They will also briefly assess your knee strength and movement. The whole assessment should take approximately 20 minutes in total after your physiotherapy appointment.

You will then be randomised to receive your physiotherapy treatment with either the specific VMO exercises or the general thigh strengthening exercises. Which group you will be in, will be determined by picking a sealed envelope out of a bag. Cards will have previously been placed inside envelopes, to indicate whether patients are allocated to one or the other treatment. All the envelopes are then sealed and placed in a bag. By doing this, the Principle Investigator picking the envelope is unaware of which type of card he will get. The group you will be in will be dependent on which type of card the Principle Investigator picks out of the bag. Using this method, you have a 50:50 chance of being in either group. We do this because sometimes we do not know which way of treating patients is best, and so we need to make comparisons between groups to compare treatments. The people are selected into the groups by chance to try and give the researchers more confidence to state that the results of each subject are due to their treatment, rather than how they were selected.

If you are in the general thigh strengthening exercise group, then the physiotherapist will teach you a series of exercises to encourage your knee to regain movement, strength and co-ordination. You may receive treatments such as ultrasound, or hands-on treatments, as well as advice regarding ice. You may also be referred to a Gym Class to progress your

rehabilitation using machines such as bikes, treadmill machines and stepping machines. The physiotherapist will tailor your rehabilitation to meet your specific treatment requirements and targets, getting you better, and allowing you to return to the activities you wish to return to. You would be advised to continue the exercises taught to you by your physiotherapist, for as long as you wish once you have been discharged by the physiotherapist. You will be asked to mark how often you do your exercises using an Exercise Diary provided by your treating physiotherapist.

If you are in the specific VMO muscle exercise group, you will receive the same treatment as the normal treatment programme, but, rather than performed the general thigh strengthening exercises, you will be taught some specific strengthening exercises to strength the VMO muscle, the muscles on the inner part of your knee. The exercises you would be taught include squeezing a ball between your knees as you squat down a little against a wall, a mini-squatting exercise knee dips from a step, and a gentle exercise pushing your foot in an inwards against a table. Each exercise would be taught to you by the physiotherapist when your knee feels comfortable enough to perform these tasks. You would be advised to perform each exercise 10 times, 3 times daily during your rehabilitation at home. You would be advised to continue these exercises for as long as you wished once you have been discharged by the Physiotherapy department. As with the other group, you will be asked to mark how often you do your exercises using an Exercise Diary provided by your treating physiotherapist.

Six weeks after beginning your physiotherapy, the same Physiotherapist who assessed you at the start of the study will again ask you to fill in the same 4 questionnaires and an assessment sheet given to you at the start of your treatment. They will ask you if your knee cap has “popped out” again during the last six weeks. They will also assess your knee strength and movement, the same way as in the earlier assessment. This should take approximately 20 minutes in total.

This same assessment procedure will also be repeated six months after you have begun your physiotherapy, to see if your knee has changed over this period of time. Again, this should take approximately 20 minutes each time. Once this is completed, you have finished the study.

What do I have to do?
All you need to do is follow what your physiotherapist will instruct you to do, and not to do any other exercises or activities which they have not told you to do.

What are the possible disadvantages and risks of taking part?
There are no specific disadvantages in taking part in this study. Patients who are potentially at risk from performing specific VMO exercises or general thigh strengthening exercises for your condition have been excluded from the study purposely. However, if you feel anxious about any part of the study, you are free to withdraw from the study without having to give a reason.

As your physiotherapist will explain during your rehabilitation, there is the potential for pain, discomfort and inconvenience during your rehabilitation following the normal treatment programme, particularly in the first few weeks. However, the addition of the VMO or general thigh strengthening exercises should not increase or decrease this potential for discomfort.

What are the possible benefits of taking part in the study?
There are no benefits to you by taking part. It is hoped that the information we get from this study may help to determine whether patients with patella or knee cap dislocation should receive VMO muscle exercises or general thigh strengthening exercises in the future.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment being studied. If this happens, the Principal Investigator (Toby Smith) will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw the Principal Investigator will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information the Principal Investigator might consider it to be in your best interests to withdraw you from the study. He will explain the reasons and arrange for your care to continue.

What if something goes wrong?
If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

Will I get paid for participating?
You will not be paid for your participation. However, since it is expected that you would have been discharged from your Physiotherapy Department by the time your six month assessments are made, your parking fees and mileage will be compensated, so you will also not incur any expense by participating in the study.

Will my taking part in this study be kept confidential?
If you consent to take part in the research study, any of your medical records may be inspected by responsible individuals from your hospital or from regulatory authorities where it is relevant in this study, for the purposes of analysing the results. They may also be looked at by responsible individuals from your hospital or from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital.

Your General Practitioner and the person who referred you to the Physiotherapy Department, will be notified of your participation in this study.

Once the study has been completed, once all data has been processed, all original data sheets and coding forms will be destroyed.

What will happen to the results of the research study?
The results from this study will form part of a Doctorate in Philosophy (PhD) thesis for the Principal Investigator (Toby Smith) at the University of East Anglia. In addition, approximately a year after you have finished participating in the study, it is anticipated that the findings will be published in an orthopaedic medical or physiotherapy journal. This will not include any information that directly identifies you. If you wish to obtain a copy of the final report, please contact the Principle Investigator (Toby Smith) who will be able to help.

Who is organising and funding the research?
The research is being organised by the Principal Investigator Toby Smith who is a Research Physiotherapist, and is being supervised by the Consultant Orthopaedic Surgeon Professor **XXXX** and Dr **XXXX** and Ms **XXXX** from the University of East Anglia. The study shall be funded by Action Arthritis, to cover the costs of the equipment, expenses and the Physiotherapist's time. The Principal Investigator conducting the research is not being paid for undertaking this study.

Who has reviewed the study?
This study has been reviewed by the Institute of Orthopaedics peer-review panel, the Norfolk Research Ethics Committee, the East Norfolk & Waveney Research Governance Committee, and the **XXXX** Hospital Research Governance Committee.

Who do I contact for further information?
If you wish for more information about the study, please contact the Principle Investigator Toby Smith at the Orthopaedic Department at the Norfolk and Norwich University Hospital on 01603 646544.

Thank you for reading through this information sheet, and thank you for participating in the study if you choose to do so.

Appendix 33. The randomised controlled trial consent form

Centre Number:
Study Number:
Patient Identification Number for this trial:

Consent Form

(Version 1.0 ~ 17.11.09)

A randomised controlled trial to compare a specific VMO programme, to a general quadriceps regime on functional and quality of life outcomes for primary patellar dislocation patients?

Investigators:-

Mr Toby O Smith BSc (Hons) MSc MCSP
Dr **XXXX**
Ms **XXXX**
Professor **XXXX**

Please could you read through, initial the boxes and sign the space provided below.

(1) I confirm that I have read the attached "Patient Information Sheet" dated **17.11.09** (version 1.0) for the above study and that I have had the opportunity to ask questions.

(2) I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical or legal rights being affected.

(3) I understand that sections of my medical notes may be looked at by responsible individuals from the **XXXX** Hospital, **XXXX** Hospital or **XXXX** Hospital, **XXXX** or from regulatory authorities where it is relevant in this study. I give permission for these individuals to have access to my records.

(4) I agree to take part in the above study.

(5) I agree that my GP will be informed of my participation in this study.

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Patient's Parent/Guardian (if applicable)	Date	Signature
_____	_____	_____
Physiotherapist (witness)	Date	Signature

1 for patient; 1 for Principle Investigator; 1 to be kept with hospital notes

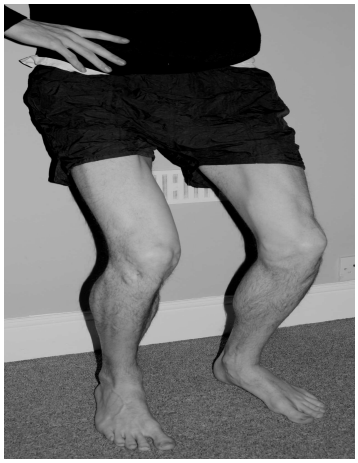
Appendix 34. The randomised controlled trial general quadriceps exercise regime

General Quadriceps Rehabilitation Group
(Version 1.0 ~ 17.11.09)

All exercises should be performed with patient's shoes off, and patients should be instructed to perform them each **7** times, **3** times daily. These will be progressed by your treating physiotherapist.

Wall Slide Exercise

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. From a fully upright standing position, squat down to a half squatting position. Hold this position and tighten your tight muscles to draw your knee caps up. Hold this for **20** seconds, then relax and slowly slide back up until upright again.

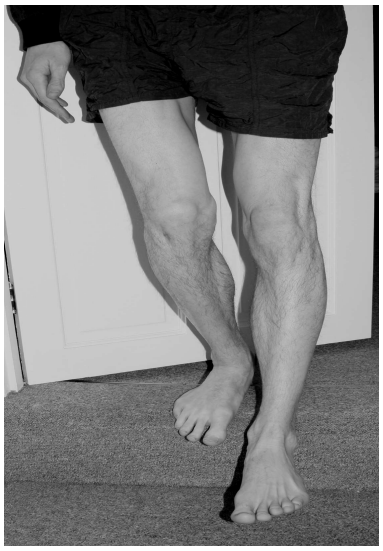


Straight Leg Raise

Lying on your back, with your head supported with a couple of pillows, legs out straight and relaxed. Draw your toes and foot up towards your head, pressure your knee down straight into the bed, and raise you whole leg straight up into the air. Raise your leg so that it is about 10 centimetres off the bed. Hold for 20 seconds, then relax your leg down into the bed.

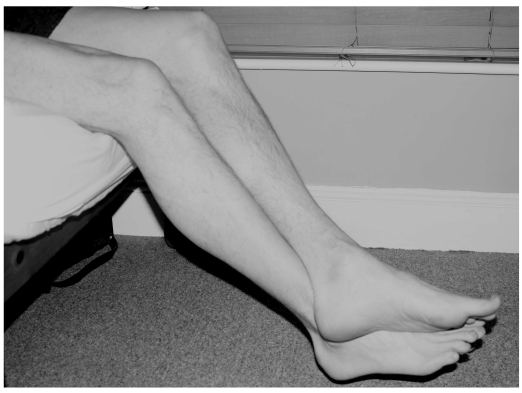
Leg Dips

Standing on a step or wooden box, approximately 4 to 6 inches high. Your "injured" leg should be on the top of the box or step. Then slowly over a **10** second period lower your uninjured leg off the step to touch the floor, making the injured knee work. Once your toes have touched the floor then slowly return to straighten your injured knee over a **10** second period. You may initially need to hold onto a banister or wall during this exercise, but as you get better try to exercise without such a support.



Isometric Quadriceps

Sitting on a chair, with your injured leg's knee slightly bent (40°). Place you unaffected foot over your injured leg's ankle. Push you injured leg forwards against your unaffected leg so that you are resisting this movement. Touch the muscle on the inside part of your knee to feel the contraction during this exercise. Hold this contract for **20** seconds, and then relax.



Appendix 35. The randomised controlled trial specific-VMO exercise regime

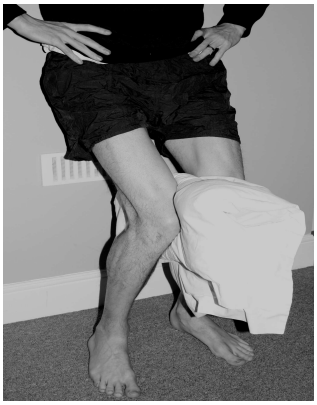
VMO Exercise Rehabilitation Group

(Version 1.0 ~ 17.11.09)

All exercises should be performed with patient's shoes off, and patients should be instructed to perform them each **7** times, **3** times daily. These will be progressed by your treating physiotherapist.

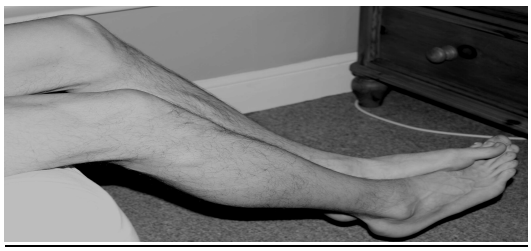
Modified Wall Slide Exercise

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. Place a fat towel between your knees. From a fully upright standing position, squat down to a half squatting position. Then push your knees together, squeezing into the towel. Hold this position and squeeze for **20** seconds, then relax and slowly slide back up until upright again.



Isometric Quadriceps and Tibial/Femoral Internal Rotation

Sitting on a chair or the edge of a bed, with your injured leg turned inward, and knee slightly bent (40°). Place you unaffected foot over the side of your injured leg's foot. Try to turn you injured leg's foot inwards and then, at the same time p your injured leg forwards all against your unaffected foot so that you are resisting this movement. Touch the muscle on the inside part of your knee to feel the contraction during this exercise. Hold this contract for **20** seconds, and then relax.



Isometric Quadriceps with hip rotation in semi-squatting position

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. Point your feet inwards so that your whole leg is turned inwards to about a 2 o'clock and 10 o'clock position. Slide down the wall so that your knees are slightly bent (to about 30 degrees). Tighten your thigh muscles up as tight as you can. Hold for **20** seconds. The relax and slowly slide back up the wall until in an upright position again.

Leg Dips in Internal Tibial/Femoral Rotation

Standing on a step or wooden box, approximately 4 to 6 inches high. Your "injured" leg should be on the top of the box or step so that your foot and toes are pointing at approximately a 2 o'clock or 10 o'clock position so that you leg is rotated inwards. Then slowly over a 5 second period lower your uninjured leg off the step to touch the floor, making the injured knee work. Once your toes have touched the floor then slowly return to straighten your injured knee over a **20** second period. You may initially need to hold onto a banister or wall during this exercise, but as you get better try to exercise without such a support.

Appendix 36. The randomised controlled trial exercise diary

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Patient Exercise Diary (Weeks 1 to 11)

Treatment Day / Date	Exercises Completed (Tick if completed)	Treatment Day / Date	Exercises Completed (Tick if completed)
1 (0 week)		41	
2		42 (6 weeks)	
3		43	
4		44	
5		45	
6		46	
7 (1 week)		47	
8		48	
9		49 (7 weeks)	
10		50	
11		51	
12		52	
13		53	
14 (2 weeks)		54	
15		55	
16		56 (8 weeks)	
17		57	
18		58	
19		59	
20		60	
21 (3 weeks)		61	
22		62	
23		63 (9 weeks)	
24		64	
25		65	
26		66	
27		67	
28 (4 weeks)		68	
29		69	
30		70 (10 weeks)	
31		71	
32		72	
33		73	
34		74	
35 (5 weeks)		75	
36		76	
37		77 (11 weeks)	
38			
39			
40			

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

Patient Exercise Diary (Weeks 11 to 52)

Treatment Week	Exercises Completed (Tick if completed)
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	

Appendix 37. Data collection sheet for specific interventions study participants received

Patient Treatment Checklist

(Version 1.0 ~ 17.11.09)

Please **tick** in the applicable box which treatments you perform for each treatment session.

Patient study number:

Intervention	Treatment 1 Date:	Treatment 2 Date:	Treatment 3 Date:	Treatment 4 Date:	Treatment 5 Date:	Treatment 6 Date:	Treatment 7 Date:	Treatment 8 Date:	Treatment 9 Date:	Treatment 10 Date:
Discomfort from another MSK regions since last Rx										
Modified Wall Slide Exercise										
Isometric Quadriceps with hip rotation in semi-squatting position										
Leg Dips in Internal Femoral and Tibial Rotation										
Isometric Quadriceps and Tibial Internal Rotation										
Wall slide in neutral										
Isometric quadriceps in semi-squat neutral										
Leg dips in neutral										
Isometric quadriceps in neutral										
Knee Rom exercises										
Ice										
Ultrasound of medical retinaculum										
Hamstring stretches										
Calf Stretches										
Glutei exercises										
Proprioception exercises										
Lateral retinaculum frictions										
Medial Patellar Glides										
Tibiofemoral Mobilisations										
Inferential/Ultrasound combined										
Acupuncture										
Gym programme										
Taping Techniques										
Tubigrip and compression bandage										
Other-										
Other-										
Other-										

MSK – Musculoskeletal Rx - Treatment

Appendix 38. Retrospective notes audit results at one of the participating hospitals (n=20).

Age at Initial Hospital Consultation (years)			
Age	**Frequency**	**Age**	**Frequency**
14	1	23	1
15	1	24	1
16	3	27	1
17	1	31	1
18	2	34	1
20	1	38	1
21	2	52	1
22	2		

Age at Initial Dislocation/Onset of Symptoms (years)			
Age	**Frequency**	**Age**	**Frequency**
6	1	16	6
8	1	17	1
11	1	21	1
13	3	22	1
14	3	23	1
15	1		

Gender	
Response	**Frequency**
Male	10
Female	10

Occupation	
Response	**Frequency**
Student	10
Office Worker	3
Waitress	1
Electrician	1
Sales Rep	1
Roller-skating Instructor	1
Care Assistance	1
Not Documented	3

Cause/Mechanism of Primary Dislocation	
Response	**Frequency**
Football (twist on running)	2

Basketball (twist on running)	1
Throwing ball (twisting)	1
Hockey (impact on patella)	1
Dancing	1
Judo Throw	1
Getting into car	1
Getting out of chair	1
Climbing over gait	1
Roller-skating	1
Slipped whilst walking	1
Biomechanical changes from RTA	1
Not documented	7

Cause/Mechanism of Recurrent-Dislocation/Instability	
Response	**Frequency**
Dancing	3
Football (twisting on running)	2
Walking down stairs	2
Hockey (twisting on running)	1
Getting into a chair	1
Not documented	11

Diagnostic tests undertaken for patellar instability – orthopaedic surgeon	
Response	**Frequency**
Apprehension Test	19
Range of Motion	18
Patellar Tracking	16
Hip Alignment (Rotation)	12
Tibia Alignment (Rotation)	12
Quadriceps bulk	11
Quadriceps Strength	10
Hypermobility (Beighton Score)	9
Palpation	7
Ligament Stability Tests	4
Effusion	3
Squat	3
Patellar Crepitus	2
Leg Length	1

Diagnostic tests undertaken for patellar instability – physiotherapist	
Response	**Frequency**
Range of Motion	8

Quadriceps Strength	5
Effusion	4
Apprehension Test	2
Straight leg raise	2
Gait	2
Quadriceps Bulk	2
Lower Limb Soft Tissue Length	1
VMO Strength (not documented how assessed)	1

Osteochondral Fracture	
Response	**Frequency**
Yes	2
No	18

Was patellar dislocation reduced in A&E or spontaneous	
Response	**Frequency**
Spontaneous	15
A & E	2
No documented	2
By a Bystander	1

DNA'd Orthopaedic Appointment	
Response	**Frequency**
Yes	2
No	18
If Yes, How often	One time - 2

Physiotherapy treatment acknowledged in notes	
Response	**Frequency**
Yes	12
No	8

Was physiotherapy and conservative treatment or surgery the initial treatment strategy?	
Response	**Frequency**
Physiotherapy and conservative	16
Surgery	3
Not documented	1

Orthopaedic Surgical Procedure Undertaken	
Response	**Frequency**

Medial Reefing	20
Lateral Release	14
Tibial Tubercle Transfer	13
Trochleoplasty	2

Source of Physiotherapy Referral	
Response	**Frequency**
Consultant Orthopaedic Surgeon	12
GP	3
Not documented	4

Source of Orthopaedic Referral e.g. GP/Physiotherapist.	
Response	**Frequency**
GP	11
Other Orthopaedic Consultant	8
A&E	3
Not Documented	1

Was this a Norwich patient?	
Response	**Frequency**
Yes	11
No	9

Was the physiotherapy receive by patients pre- or post-operative?	
Response	**Frequency**
Pre-operative	0
Post-operative	11

If Physiotherapy notes available – were they given exercises?	
Response	**Frequency**
Yes	8
Not clearly documented	3

If yes, what type	
Response	**Frequency**
Inner Range Quadriceps	5
Quadriceps (unspecified)	5
Step Up Step Down	4
Static Quadriceps	4
Straight Leg Raise	3
Semi-squats	2

Lunges	2
Semi-squat with adduction	2
Semi-squat with hip rotation (int. or ext. not specified)	2
PNF with foot positions	2
Hip Adduction	1
Static VMO	1
VMO exercise (unspecified)	1
Isotonic knee extension	1

How frequently	
Response	**Frequency**
10 repetitions	1
4 times daily	1
Not documented	9

Any other physiotherapy treatments?	
Response	**Frequency**
Range of movement exercises	6
Ice	5
Bracing	4
Static bike	3
Gait Re-education	3
Wobble Board	2
Hamstring stretch	1
Hamstring strengthening	1
Taping	1
Elevation	1
Calf Stretch	1
Hydrotherapy	1
Not Documented	1

Frequency of Physiotherapy	
Response	**Frequency**
Fortnightly	6
Weekly	4
Varied	1

Number of Physiotherapy Sessions	
Response	**Frequency of Response**
1 session	2
3 sessions	1

4 sessions	3
5 sessions	2
10 sessions	1
12 sessions	1
15 sessions	1

Duration of Physiotherapy (weeks or months)	
Response	**Frequency of Response**
1 week	2
4 weeks	1
6 weeks	1
7 weeks	1
8 weeks	4
16 weeks	1
28 weeks	1

What final criteria/outcomes assessed to permit discharge?	
Response	**Frequency**
Subjective confidence in knee	10
Restoration of Range of Movement	2
Reduction in Symptoms	1
Not Documented	1

DNA'd Physiotherapy	
Response	**Frequency**
Yes	0
No	11

Duration from discharge from physiotherapy to re-dislocated (months)	
Response	**Frequency**
Not clearly documented	11

Was the physiotherapy intervention successfully i.e. recurrent dislocation resolved/return to requested activities?	
Response	**Frequency**
Yes	2
Evidence	Return to sports and work noted - 2
Not clearly documented	9

Is there any indication that the patient was compliant or not with their physiotherapy?	
Response	**Frequency**
Yes	1

Evidence	Patient reported home exercise programme repetition
No	10

What was the duration between primary and second dislocation (months)?	
Response	**Frequency of Response**
1 month	1
2 months	1
6 months	2
7 months	1
9 months	2
12 months	1
24 months	2
Not Documented	10

Frequency of recurrent dislocation in a given period of time	
Response	**Frequency of Response**
1 in 1 month	2
2 in every month	1
1 in 6 weeks	1
4 in 6 months	1
1 in 7 months	1
1 in 9 months	1
1 in 10 months	1
5 in 12 months	1
11 in 11 years	1
Not Documented	10

How was a recurrent dislocation diagnosed?	
Response	**Frequency of Response**
Self-Reported	15
Not Documented	5

What is the length of time between initial dislocation to last physiotherapy or surgical appointment/review (years)?	
Response	**Frequency of Response**
1 year	3
3 years	2
5 years	2
6 years	1
7 years	1
8 years	1

9 years	2
10 years	1
11 years	1
13 years	1
15 years	2
16 years	1
22 years	1
38 years	1

Appendix 39. The Lysholm Knee Score

(Patient Sheet)
(Version 1.0 ~ 17.11.09)

Please **circle** the answer which best represents your knee currently.

Limping

1 Never
2 Mild or periodically
3 Strong and continuous

Support

1 No support
2 Walking stick or crutches
3 Impossible

Restraining

1 No restraining or restraining feeling
2 Has the feeling, but no restraining
3 Occasional restraining
4 Frequent
5 Joint restrained at examination

Instability

1 Never miss a step
2 Seldom, during athletic activities or other strong-effect exercises
3 Frequently during athletic activities or other strong-effort exercises
4 (or unstable to participate)
5 Occasionally in daily activities
6 Frequently in daily activities
7 At each step

Pain

1 No pain
2 Intermittent or mild during strong-effort exercises
3 Marked during strong-effort exercises
4 Marked during or after walking more than 2 Km
5 Marked during or after walking less than 2 Km
6 Continuous

Swelling

1 No swelling
2 Upon strong-effort exercises
3 Upon usual exercises
4 Continuous

Climbing stairs

1 No problems
2 Slightly damaged
3 One step at a time
4 Impossible

Squatting

1 No problem
2 Slightly damaged
3 Not exceeding 90 degrees
4 Impossible

Total score _____

Lysholm Knee Score

(scoring sheet)
(Version 1.0 ~ 17.11.09)

Please **circle** the answer which best represents your knee currently.

Limping (5 points)

Never	5
Mild or periodically	3
Strong and continuous	0

Support (5 points)

No support	5
Walking stick or crutches	2
Impossible	0

Restraining (15 points)

No restraining or restraining feeling	15
Has the feeling, but no restraining	10
Occasional restraining	6
Frequent	2
Joint restrained at examination	0

Instability (25 points)

Never miss a step	25
Seldom, during athletic activities or other strong-effect exercises	20
Frequently during athletic activities or other strong-effort exercises (or unstable to participate)	15
Occasionally in daily activities	10
Frequently in daily activities	5
At each step	0

Pain (25 points)

No pain	25
Intermittent or mild during strong-effort exercises	20
Marked during strong-effort exercises	15
Marked during or after walking more than 2 Km	10
Marked during or after walking less than 2 Km	5
Continuous	0

Swelling (10 points)

No swelling	10
Upon strong-effort exercises	6

Upon usual exercises	2
Continuous	0

Climbing stairs (10 points)

No problems	10
Slightly damaged	6
One step at a time	2
Impossible	0

Squatting (5 points)

No problem	5
Slightly damaged	4
Not exceeding 90 degrees	2
Impossible	0

Total score _____

Appendix 40. The Short Form-12 Health Survey

Short Form-12 Health Survey
(Version 1.0 ~ 17.11.09)

Please read the items below, and ***circle*** the response which comes closest.

Question	**Response**
1) In general, would you say your health is excellent, very good, good, fair, or poor?	1 Excellent 2 Very good 3 Good 4 Fair 5 Poor
2) The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?	
First, moderate activities such as moving a table, pushing a vacuum cleaner, bowling or playing golf. Does your health now limit you a lot, limit you a little, or not limit you at all?	1 Limited a lot 2 Limited a little 3 Not limited at all
3) Climbing several flights of stairs. Does your health now limit you a lot, limit you a little, or not limit you at all?	1 Limited a lot 2 Limited a little 3 Not limited at all
4) During the past four weeks, have you accomplished less than you would like as a result of your physical health?	1 Yes 2 No
5) During the past four weeks, were you limited in the kind of work or other regular activities you do as a result of your physical health?	1 Yes 2 No
6) During the past four weeks, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?	1 Yes 2 No
7) During the past four weeks, did you not do work or other regular activities as carefully as usual as a result of any emotional problems such as feeling depressed or anxious?	1 Yes 2 No
8) During the past four weeks, how much pain has interfered with your normal work, including both work outside the home and housework? Did it interfere at all, slightly, moderately, quite a bit, or extremely?	1 Not at all 2 Slightly 3 Moderately 4 Quite a bit

5 Extremely

9) These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much time during the past 4 weeks have you felt calm and peaceful? All of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time?

1 All of the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

10) How much of the time during the past 4 weeks did you have a lot of energy? All of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time?

1 All of the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

11) How much of the time during the past 4 weeks have you felt down? All of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time?

1 All of the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

12) During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting friends, relatives etc? All of the time, most of the time, a good bit of the time, some of the time, a little of the time, or none of the time?

1 All of the time
2 Most of the time
3 A good bit of the time
4 Some of the time
5 A little of the time
6 None of the time

Thank You

Appendix 41. The Tegner Activity Score

Tegner Activity Score

(Version 1.0 ~ 17.11.09)

Please **indicate** in the spaces below the HIGHEST level of activity you are able to participate in CURRENTLY.

Level 10	Competitive sports- soccer, football, rugby (national elite)
Level 9	Competitive sports- soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball
Level 8	Competitive sports- racquetball, squash or badminton, track and field athletics (jumping, etc.), down-hill skiing
Level 7	Competitive sports- tennis, running, motorcars speedway, handball Recreational sports-soccer, football, rugby, ice hockey, basketball, squash, racquetball, running
Level 6	Recreational sports- tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week
Level 5	Work- heavy labour (construction, etc.) Competitive sports- cycling, cross-country skiing, Recreational sports- jogging on uneven ground at least twice weekly
Level 4	Work-moderately heavy labour (e.g. truck driving, etc.)
Level 3	Work-light labour (nursing, etc.)
Level 2	Work-light labour Walking on uneven ground possible, but impossible to back pack or hike
Level 1	Work-sedentary (secretarial, etc.)
Level 0	Sick leave or disability pension because of knee problems

CURRENT: Level_____

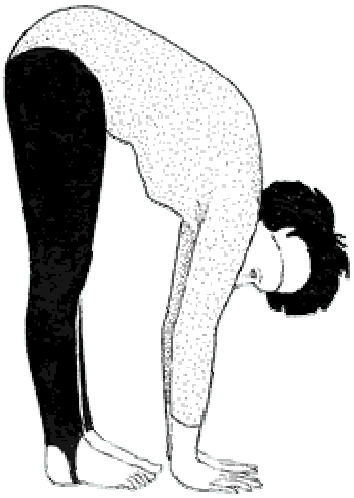
Appendix 42. Table presenting the data between the researcher and assessors in each site for their assessment of quadriceps strength using a hand-held dynamometer for two volunteers.

Centre Number	Tester	Knee Range (flexion°)	Subject 1	
			1st Reading	2nd Reading
1	**Assessor 1**	0	12.6	11.6
		30	25.7	24.6
		60	33.99	32.4
		90	21.3	24.2
	Researcher	0	9.67	10.63
		30	19.04	19.55
		60	22.46	18.76
		90	16.23	17.81
2	**Assessor 1**	0	8.77	14.07
		30	13.85	14.99
		60	22.94	18.63
		90	14.86	18.66
	Assessor 2	0	18.69	21.31
		30	19.59	17.97
		60	16.71	17.79
		90	13.89	14.35
	Assessor 3	0	11.9	16.01
		30	24.5	19.45
		60	30.21	31.7
		90	33.77	31.8
	Assessor 4	0	21.21	20.56
		30	22.29	21.63
		60	19.44	20.77
		90	17.19	17.09
	Researcher	0	6.87	7.62
		30	15.78	15.23
		60	14.94	16.98
		90	14.15	16
3	**Assessor 1**	0	10.31	12.47
		30	13.23	12.37
		60	15.09	14.86
		90	15.17	12.77
	Assessor 2	0	10.59	11.75
		30	12.94	11.42
		60	14.12	13.95
		90	14.59	12.97
	Researcher	0	11.62	10.89
		30	10.41	9.64
		60	13.79	13.07
		90	13.18	12.1

Appendix 43. The Beighton score

The Beighton modification of the Carter & Wilkinson scoring system has been used for many years as an indicator of widespread hypermobility. A high Beighton score by itself does not mean that an individual has HMS. It simply means that the individual has widespread hypermobility. Diagnosis of Hypermobility Syndrome or HMS should be made using the Brighton Criteria.

The Beighton score is calculated as follows:

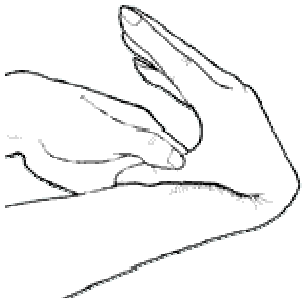


Score one point if you can bend and place you hands flat on the floor without bending you knees.

Score one point for each knee that will bend backwards.

Score one point for each elbow that will bend backwards.

Score one point for each thumb that will bend backwards to touch the forearm.



Score one point for each hand when you can bend the little finger back beyond 90°.

If you are able to perform all of above manoeuvres then you have a maximum score of 9 points. A Beighton score of 4/9 or greater (either currently or historically) indicated clinical hypermobility.

(Arthritis Research Campaign, 2007)

Appendix 44. The individual data collection scoring sheets

Individual Datasheets

Patient study number:

Assessment Period	Baseline	Six Weeks	Six Months
Assessment Date	(/ /)	(/ /)	(/ /)
Sex (m/f)			
Age (years)			
Family Hx Pat. Disl. (y/n)			
Duration since Pat. Disl (days)			
Hypermobility score (/9)			
Joint Disability of Treated Leg (y/n)			
Knee Instability on Contralateral Leg (y/n)			
Joint Disability of Contralateral Leg (y/n)			
Multi-joint Problems (upper limb/spinal) (y/n)			
Lysholm Knee Score (/100)			
Tegner Activity Score (/10)			
SF-12 (/48)			
NPIS Score			
Knee Extensor Dynamometry in:			
0º knee flexion			
30º knee flexion			
60º knee flexion			
90º knee flexion			
Duration of Physio. (weeks)			
Duration of exercises continued after discharge (weeks)			
Frequency of DNA physio. OPA			
Frequency of patella re-dislocation			
Duration between 1st and 2nd Dislocation			

DNA - Did Not Attend
NPIS – Norwich Patellar Instability Score
Physio – Physiotherapy
Hx - History
OPA – Out-Patient Appointment
Pat Disl. – Patellar Dislocation
SF-12 – Short-Form 12

Appendix 45. The *a priori* Analysis Plan.

The aims of this study were to answer the following questions:

- Is there a difference in outcome between people prescribed a general quadriceps exercise programme compared to a VMO strengthening programme following FTPD?

- Does the NPIS correlated to previously validated outcome measures used to evaluate people following FTPD?

- Is the NPIS responsive to change during the physiotherapy rehabilitation of people following FTPD?

The Analysis Plan has therefore been constructed to address these questions.

Baseline Analysis – Descriptive Statistics

Question: Are the baseline and follow-up data set's normally or not normally distributed?

Analysis: For each outcome and measurement at each time point - Shapiro Wilks W test and histograms.

Question: What is the central tendency and spread of measurements and outcomes at each follow-up period i.e. age, duration of knee instability, isometric muscle strength (0, 30, 60, 90° knee flexion), Beighton Hypermobility Score, Tegner Level of Activity Score, Lysholm Knee Score, SF-12, NPI score?

Analysis: For data presented with a normal distribution – mean and standard deviation. For data which presented with a non-normal distribution – median and inter-quartile ranges.

Question: What was the frequency of males/females, those with a family history of patellar dislocation, presence of other joint disability of the treatment leg, presence of contralateral knee instability, or presence of multi-joint problems between the groups?

Analysis: Count frequency between each group.

Question: How many participants were lost to follow-up?

Analysis: Count frequency between each group.

Question: How successful was the stratification process between the three study sites?

Analysis: Count frequency between each group. Histogram to present findings.

Interferential Analysis

Question: Should parametric or non-parametric test be performed?

Analysis: Histograms and Shapiro Wilks W test will be used to assess the distribution of isometric muscle strength (0, 30, 60, 90° knee flexion), Tegner Level of Activity Score, Lysholm Knee Score, SF-12, NPI score, duration between initial and second dislocation, duration and number of physiotherapy, and the duration participant continued with exercises, for each group at six weeks and six months. The findings of this will indicate whether normally or not normally distributed. It will be assumed that the data set is normally distributed and that parametric test will be used.

Question: What is the level of statistical significance denoted as?

Answer: The level of statistical significance has been determined as <0.05.

Primary Analysis

Question: Is there a difference between the groups for Lysholm Knee Score at 6 weeks?

Analysis: This will be assessed using a regression analysis. P-values and 95% confidence intervals will be presented. Descriptive statistics (Mean and IQR) will be performed to assess the central tendency and distribution of the Lysholm knee scores for the two groups.

Secondary Analyses

Question: Is there a difference between the groups for Tegner Level of Activity Score, SF-12, NPI score isometric knee extension strength , duration of physiotherapy, number of physiotherapy sessions attended duration participants continued their exercises and duration to first recurrent dislocation at 6 weeks or 6 months?

Analysis: This will be assessed using a regression analysis for the six week and six month datasets independently. P-values and 95% confidence intervals will be presented. Descriptive statistics (Mean and IQR) will be performed to assess the central tendency and distribution of the outcomes for the two groups. An adjusted analysis of variables which demonstrate substantial baseline inequality will be made for all parametric analyses. If not normally distributed, a Mann-Whitney U test will be employed.

Question: Was there a difference in outcomes between each of the follow-up periods i.e. baseline to six weeks and six weeks to six months?

Analysis: This will be assessed using a Paired T-Test for each time period. P-values and 95% confidence intervals will be presented. This will be performed for each exercise group independently. Mean difference and standard deviation values will be provided to assess the size of any difference. If not normally distributed, a Wilcoxon-Matched Pairs Test will be performed.

Question: Is there a difference between the groups for the number of "did not attend" appointments or the frequency of recurrent dislocation at six weeks and six months?

Analysis: Each follow-up period will be assessed individually. Each will be assessed using the Chi^2 statistical test. P-values and 95% confidence intervals will be presented. If the dataset consists of less than twenty participants, a Fisher's Exact Test will be used instead.

Question: Is there a difference in outcome between the three study centres?

Analysis: A subgroup analysis will be performed of each analysis method using the data from each site. The described analysis of six week and six month between-group differences will be assessed using a random-effects model.

Missing Data

Question: How will missing data be handled?

Answer: Multiple imputation will be used to estimate the missing values based on estimated from the baseline and available dataset.

Affect of exercise compliance

Question: Is there a relationship between the frequency of exercise performed and clinical and functional outcomes?

Analysis: A within-group Spearman's Rank Correlation will be performed to assess whether there was a statistical relationship between exercise frequency and Tegner Level of Activity score, Lysholm Knee Score, NPI score, SF-12, isometric strength and frequency of recurrent dislocation and duration between initial and second dislocation for each group at six weeks and six months.

Question: Was there a difference between the groups in respect to the additional treatments prescribed to participants?

Analysis: This will be assessed using a Chi^2 statistical test. P-values and 95% confidence intervals will be presented. If the dataset consists of less than twenty participants, a Fisher's Exact Test will be used instead.

Validity NPI score

Question: Did the NPI score detect a difference over time i.e. baseline to six weeks and six weeks to six months?

Analysis: A Paired T-Test will be performed for each time period for each group independently. P-values and 95% confidence intervals will be presented. Mean difference and standard deviation values will be provided to assess the size of any difference. If not normally distributed, a Wilcoxon-Matched Pairs Test will be performed.

Question: What was the effect size for any changes over time?

Analysis: Effect size will be calculated as a Cohen's d statistic for each group between the different assessment periods, i.e. baseline to six weeks and six weeks to six months?

Question: Is there a statistical correlation between the NPI score and the other clinical outcome measurements of treatment improvement?

Analysis: A within-group Spearman's Rank Correlation will be undertaken to assess for a significant relationship between the Tegner Level of Activity score, Lysholm Knee Score, SF-12 or isometric knee extension results and NPI score findings at each follow-up period for each group.

Question: Do the items in the NPI score assess the same domain?

Analysis: This will be analysed using the Cronbach's alpha statistical test for internal consistency of the NPI score. This will be before for each group at each time-point. Lower 95% confidence interval values will be provided to determine the lowest possible consistency.

Question: We any of the NPI questionnaire items redundant with high or floor- ceiling effects

Analysis: The presence of floor- or ceiling effects will be examined by calculating the proportion of respondent who reported the highest or lowest values possible from this dataset for each group at each follow-up period. This will then be presented as a percentage.

Appendix 46. The randomised controlled trial Research Ethics Committee and Research Governance Committee approval letters

NHS National Research Ethics Committee Approval

09 February 2010

Mr Toby O Smith
Research Physiotherapist in Orthopaedics
Institute of Orthopaedics
The Norfolk and Norwich University Hospital
Colney Lane, Norwich
NR4 7UY

Dear Mr Smith

Study Title:	**A randomised controlled trial to compare the functional outcomes of a VMO programme to a general quadriceps regime following first-time patellar dislocation.**
REC reference number:	**10/H0310/1**
Protocol number:	**2.0**

Thank you for your letter of 27 January 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 in consultation with a selected Expert Member.

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).

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).

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, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

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

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*
Covering Letter	Mr Toby O Smith	27 November 2009
Evidence of insurance or indemnity	UEA / Zurich Municipal	25 November 2009
Letter from Statistician	E-mail, Dr	27 November 2009
Questionnaire: Protocol Appendix 9: Validated - Lysholm Knee Score (Patient Sheet)		
Questionnaire: Protocol Appendix 9: Validated - Lysholm Knee Score (scoring sheet)		
Questionnaire: Protocol Appendix 10: Validated - Short Form-12 Health Survey		
Questionnaire: Protocol Appendix 11: Validated - Tegner Activity Score		
CV: Chief Investigator / PhD Student	Toby Oliver Smith	27 November 2009
CV: Academic Supervisor		
CV: Key Investigator		26 November 2009
CV: Key Investigator		27 October 2009
Protocol Appendix 1: The Literature Search	1.0	17 November 2009
Questionnaire: Protocol Appendix 12: Non-validated - Norwich Patellar Instability Score + scoring sheet	1.0	17 November 2009
Questionnaire: Protocol Appendix 17: Validated - Beighton Hypermobility Score	Arthritis Research Campaign, 2008	
Protocol Appendix 13: Patient Exercise Diary (Weeks 1 to 11 and 11 to 52)	1.0	17 November 2009
Protocol Appendix 14: Study Flow	1.0	17 November 2009
Protocol Appendix 15: General Quadriceps Rehabilitation Group	1.0	17 November 2009
Protocol Appendix 16: VMO Exercise Rehabilitation Group	1.0	17 November 2009

Protocol Appendix 18: Individual Datasheets	1.0	17 November 2009
Protocol Appendix 19: Patient Treatment Checklist	1.0	17 November 2009
REC application	39349/93397/1/799	04 December 2009
Protocol	2.0 (clean and tracked)	27 January 2010
Participant Consent Form: Protocol Appendix 5	2.0	27 January 2010
Revised Application Checklist	IRAS 2.5	04 December 2009
Protocol Appendix 2: Flow Chart of Patient Recruitment	2.0	27 January 2010
Protocol Appendix 3: Appointment Information Covering Letter	2.0	27 January 2010
Protocol Appendix 4: Patient Information Leaflet	2.0	27 January 2010
Protocol Appendix 6: Referring Practitioner Letter	2.0	27 January 2010
Response to Request for Further Information	Letter, Mr Toby Smith	27 January 2010
Protocol Appendix 7: General Practitioner Letter	2.0	27 January 2010
Protocol Appendix 8: Participating Physiotherapy Department's Responsibilities	2.0	27 January 2010
Protocol Appendix 20: Financial Considerations	2.0	27 January 2010

Statement of compliance

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.

10/H0310/1	**Please quote this number on all correspondence**

Yours sincerely

Chair

Email: @nnuh.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL- AR2 for other studies]*

Copy to: *Sponsor Contact: , UEA*
R&D office for NHS care organisation at lead site: NNUH

Research Governance (Site-Specific) Centre One Approval

Toby Smith
School of Allied Health Professions
Queen's Building
University of East Anglia
Norwich
NR4 7TJ

14 June 2010 E-mail: @norfolk.nhs.uk

Dear Toby,

Re: 2010ORTH04. A randomised controlled trial to compare the functional outcomes of a VMO programme to a general quadriceps regime following first-time patellar dislocation.

Further to your submission of the above project to the R&D office at your project has now been reviewed and all the mandatory research governance checks have been satisfied. I am therefore pleased to inform you on behalf of that NHS permission (R&D approval) has now been granted for your study to take place at the following sites:

-

You may now begin your study at the above sites.

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign and return one copy to the R&D office at the above address. Failure to return the standard terms and conditions may result in NHS permission being revoked.

Please note, under the agreed standard terms and conditions you must inform the R&D Office at of any proposed changes to this study, whether minor or substantial, and to keep the Committee updated on progress. Please note also, if you wish to extend approval to any sites other than those listed above you must apply for this through the relevant R&D office.

If you have any queries regarding this or any other project please contact , R&D Officer, at the above address. Please note, the reference number for this study is **2010ORTH04** and this should be quoted on all correspondence.

Yours sincerely

Research Governance (Site-Specific) Centre Two Approval

Research and Development

Mr Toby Smith
Institute of Orthopaedics
Norfolk and Norwich University Hospital
Colney Lane
Norwich
NR4 7UY

07 October 2010

Dear Mr Smith

07/10
REC ref: 10/H0310/1
A randomised controlled trial to compare the functional outcomes of a VMO programme to a general quadriceps regime following first time patellar dislocation.

Thank you for sending documentation relating to the above study.

This study has been reviewed by the Trust's Research Governance Committee and we can confirm that the Trust is willing for this work to take place.

I would like to take this opportunity to remind you that the Trust manages all research in accordance with the requirements of the Research Governance Framework. In order to comply with the above, if the study is not completed within one year from the date of this letter, a report summarising the progress of the study should be submitted to the R&D Office. In the case of multi-centre studies this is usually provided by the Chief Investigator/Clinical Trials Unit. Alternatively, we can supply a blank form for you to complete: please contact us for a copy. Any published articles or reports resulting from the study, which may be produced at a later date, should also be forwarded, to ensure a complete record is held here.

If our department can be of any further assistance please do not hesitate to contact me.

Yours sincerely

Research and Development Manager

This letter has been signed on behalf of
Chair of The Research Governance Committee

Cc
Rehabilitation Services Manager

Enc. Version control document

Research Governance (Site-Specific) Centre Three Approval

Mr Toby O Smith
School of Allied Health Professioms
University of East Anglia
Norwich
NR4 7TJ

23 September 2010

Dear Mr Smith

Re: 2010ORTH04 (62-03-10) A randomised controlled trial to compare the functional outcomes of a VMO programme to a general quadriceps regime following first time patellar dislocation.

Thank you for submitting the above project for local research governance approval. I am pleased to inform you that **after completion of GCP Training by all Research Team members,** your project has been given full approval and you may begin your research at the following site:

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign both copies returning one copy to the Research Governance office at the above address and keeping the other in your study file. Failure to return the standard terms and conditions may affect the conditions of approval.

Please note, under the agreed Standard Terms and Conditions of Approval you must inform the R&D department of any proposed changes to this study and submit annual progress reports to the R&D department.

If you have any queries regarding this or any other project please contact Research Governance Administrator, at the above address. Please note, the reference number for this study is **2010ORTH04S (62-03-10)** and this should be quoted on all correspondence.

Yours sincerely

Director of Research & Development

Enc

Appendix 47. Table presenting the raw data regarding recruitment rate of the RCT for each study centre.

Month	Centre Number	Total	Cumulative Total
September 2010	1	0	0
	2	NR	NR
	3	NR	NR
October 2010	1	1	1
	2	NR	NR
	3	NR	NR
November 2010	1	2	3
	2	1	1
	3	0	0
December 2010	1	0	3
	2	1	2
	3	1	1
January 2011	1	0	3
	2	0	2
	3	0	1
February 2011	1	0	3
	2	1	4
	3	1	2
March 2011	1	0	3
	2	1	5
	3	1	3
April 2011	1	0	3
	2	1	6
	3	5	8
May 2011	1	0	3
	2	2	8
	3	0	8
June 2011	1	1	4
	2	2	10
	3	0	8
July 2011	1	1	5
	2	0	10
	3	1	9
August 2011	1	0	5
	2	0	10
	3	3	12

NR – Not Recruiting

Appendix 48. Assessment for normality of non-imputated dataset using Shapiro-Wilk W test of the complete dataset (i) and by individual site (ii)

(i) Analysis by Complete Dataset		
Outcome	**Z-value**	**P-value**
Six week dataset		
Isometric extensor muscle strength – 0° flexion	0.05	0.48
Isometric extensor muscle strength – 30° flexion	-0.16	0.56
Isometric extensor muscle strength – 60° flexion	0.08	0.78
Isometric extensor muscle strength – 90° flexion	0.88	0.19
Tegner Level of Activity Score	-0.98	0.84
Lysholm Knee Score,	0.94	0.17
SF-12	2.48	0.01
NPI score	1.63	0.05
Number of DNAs	4.65	0.00
Duration of exercising	3.08	0.00
Number of physiotherapy sessions	1.93	0.03
Duration of physiotherapy (weeks)	4.17	0.00
Recurrent dislocation events	0.88	0.19
Duration to first recurrent dislocation	0.88	0.19
Six month dataset		
Isometric extensor muscle strength – 0° flexion	0.97	0.16
Isometric extensor muscle strength – 30° flexion	10.00	0.00
Isometric extensor muscle strength – 60° flexion	-0.20	0.58
Isometric extensor muscle strength – 90° flexion	1.67	0.05
Tegner Level of Activity Score	-1.78	0.96
Lysholm Knee Score,	3.13	0.00
SF-12	2.48	0.00
NPI score	0.90	0.18
Number of DNAs	NE	NE
Duration of exercising	1.62	0.05
Number of physiotherapy sessions	0.88	0.19
Duration of physiotherapy (weeks)	-1.04	0.85
Recurrent dislocation events	0.88	0.19
Duration to first recurrent dislocation	0.88	0.19

(ii) Analysis by Individual Site		
Outcome	**Z-value**	**P-value**
Centre 1		
Isometric extensor muscle strength – 0° flexion	0.35	0.36
Isometric extensor muscle strength – 30° flexion	-0.37	0.64

Isometric extensor muscle strength – 60° flexion	0.32	0.38
Isometric extensor muscle strength – 90° flexion	0.25	0.40
Tegner Level of Activity Score	0.46	0.32
Lysholm Knee Score	0.16	0.44
SF-12	-0.70	0.76
NPI score	-2.28	0.99
Number of DNAs	NE	NE
Duration of exercising	2.79	<0.01
Number of physiotherapy sessions	0.86	0.20
Duration of physiotherapy (weeks)	0.01	0.50
Centre 2		
Isometric extensor muscle strength – 0° flexion	1.60	0.05
Isometric extensor muscle strength – 30° flexion	-0.58	0.72
Isometric extensor muscle strength – 60° flexion	0.27	0.39
Isometric extensor muscle strength – 90° flexion	1.40	0.08
Tegner Level of Activity Score	-1.65	0.95
Lysholm Knee Score	-0.55	0.70
SF-12	1.10	0.13
NPI score	-0.52	0.70
Number of DNAs	3.48	<0.01
Duration of exercising	3.84	<0.01
Number of physiotherapy sessions	-2.39	0.99
Duration of physiotherapy (weeks)	3.83	<0.01
Recurrent dislocation events	0.88	0.19
Duration to first recurrent dislocation	0.88	0.19
Centre 3		
Isometric extensor muscle strength – 0° flexion	-0.68	0.75
Isometric extensor muscle strength – 30° flexion	0.46	0.32
Isometric extensor muscle strength – 60° flexion	1.59	0.94
Isometric extensor muscle strength – 90° flexion	0.80	0.21
Tegner Level of Activity Score	-1.55	0.94
Lysholm Knee Score	-1.55	0.94
SF-12	1.68	0.05
NPI score	1.86	0.03
Number of DNAs	2.79	<0.01
Duration of exercising	2.48	<0.01
Number of physiotherapy sessions	-3.82	0.99
Duration of physiotherapy (weeks)	-0.92	0.18

Appendix 49. An example of a study centre recruitment graph.

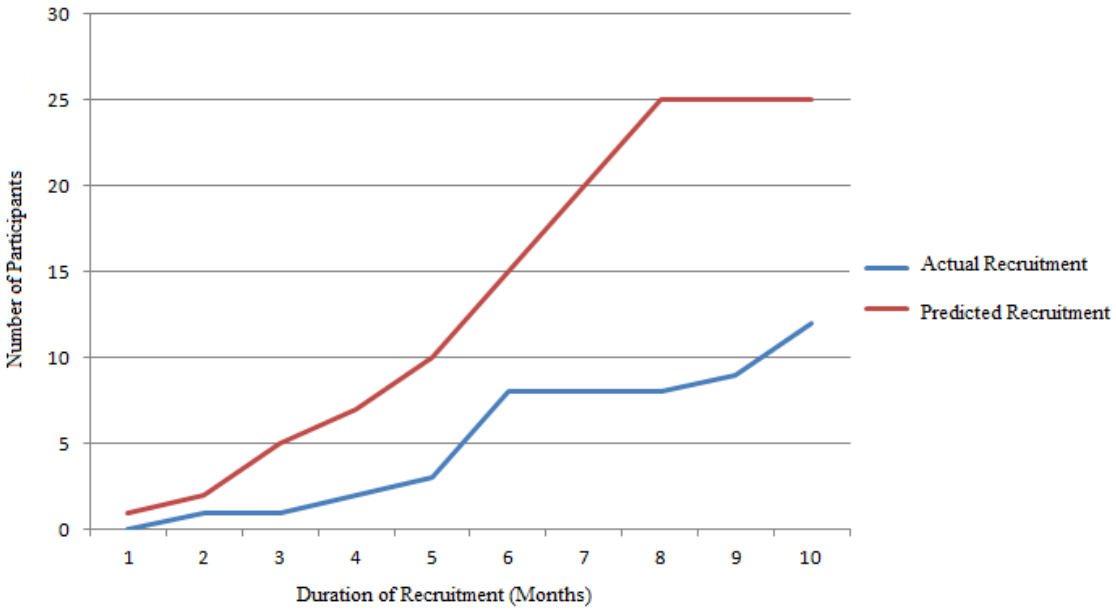
Appendix 50. An example of a study centre recruitment poster.

A randomised controlled trial to compare the functional outcomes of a VMO programme, to a general quadriceps regime following first-time patellar dislocation

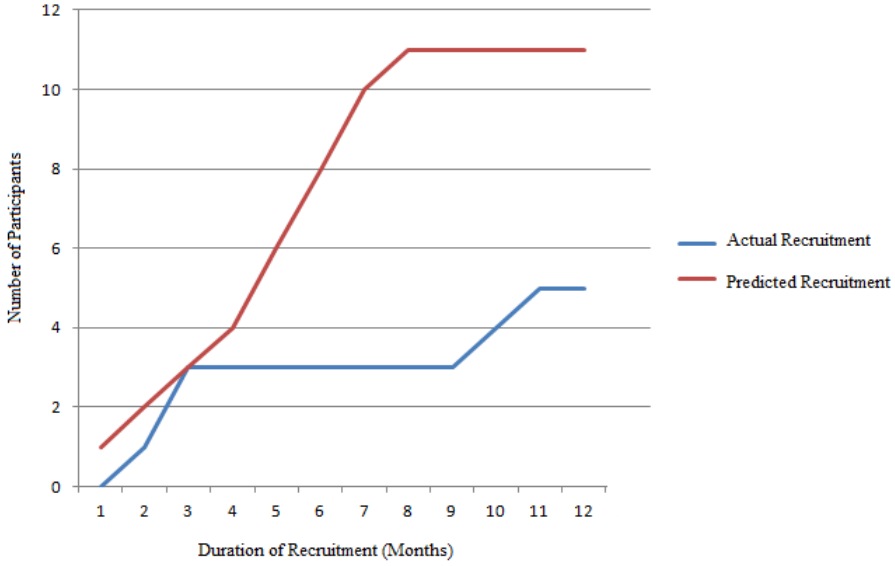
Recruitment Progress Graphs – September 2011

Blue Line – Estimated recruitment rate based on hospital number survey
Red Line – Current cumulative recruitment rate

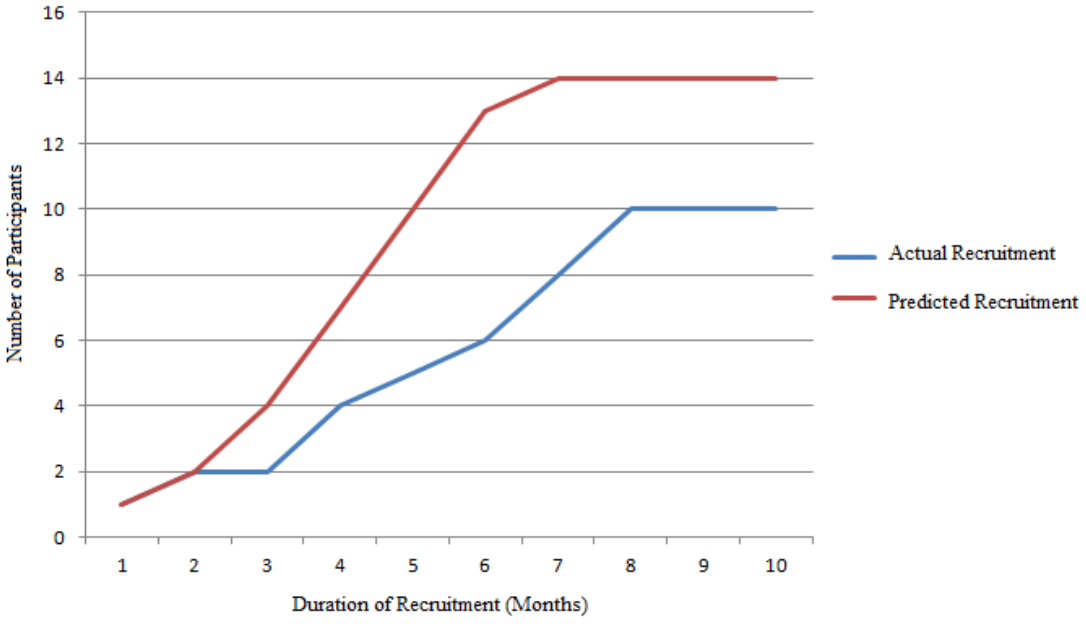
XXXX Hospital



XXXX Hospital



XXXX Hospital



Appendix 51. Screening Log
(Version 1.0 ~ 15.05.2012)

Study: A pragmatic, multi-centre RCT to assess the feasibility of a trial to compare the functional outcomes of a specific-VMO exercise, a general quadriceps strengthening and a proprioceptive exercise programme following first-time patellar dislocation.

Site:

Date Screened	Date Referral Received	Initial of Screener	Considered Eligible (Y/N)	Considered Ineligible (Y/N). If No, for which criterion

Appendix 52. Participant Covering Letter
(Version 1.0 ~ 15.05.2012)

School of Allied Health Professions
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

(DATE)

Dear

A research project is being undertaken at the Physiotherapy Department at your local hospital. The project is in preparation towards a larger study comparing three different exercises for people following knee cap or patellar dislocation. Since you have been referred to one of these departments, please find attached an Information Sheet about the study which provides some information on why we are doing this project, what it involves, and how we are going to use the results of this project.

If you have any questions now, please feel free to contact me on toby.smith@uea.ac.uk or 01603 593087.

I look forward to speaking to you,

Yours faithfully

Mr Toby O Smith
Chief Investigator
Lecturer in Physiotherapy
University of East Anglia, UK.

Appendix 53. Participant Information Sheet
(Version 1.0 ~ 15.05.2012)

University of East Anglia

A pragmatic, multi-centre feasibility RCT to compare the functional outcomes of a specific-VMO exercise, a general quadriceps strengthening and a proprioceptive exercise programme following first-time patellar dislocation

Investigator: - Mr Toby O Smith MSc BSc (Hons) MCSP

You are being invited to take part in a medical research study. You have been sent this form as you may be suitable to help in this study. However, before you make a decision to participate, it is important that you fully understand why the project is being undertaken, and what it will involve. Please read this information sheet carefully, and discuss it with friends and relatives. If there is anything, which you are not sure about, please ask for further clarification before you decide whether or not you wish to participate.

Thank you for reading this.

What is the purpose of this study?
You are about to begin a programme of physiotherapy treatment for your knee cap, or patella. It is not clear what exercises are most effective to help people recover from this injury. The main purpose of this current study is to act as a small "testing" study to see if a larger study is needed to investigate this areas, and if so, to find out how best to design such a larger study.

Why have I been chosen?
You have been referred to your local Physiotherapy Department because your knee cap has dislocated or "popped out". You are 16 years of age, or older. You do not have any other knee ligament injuries and your knee cap has not "popped out" before. You will be one of 84 patients taking part, 28 patients will receive a general thigh strengthening exercises and standard rehabilitation treatment, and 28 will receive VMO (vastus medialis oblique muscle) exercises and standard rehabilitation treatment, whilst 28 will receive balance (proprioceptive) exercises and a standard rehabilitation treatment. This research is being carried out at 10 hospitals across the south of England, including centres in XXX, XXX, XXX and XXX.

Do I have to take part in the study?
It is up to you to decide whether or not to take part. Your participation in the study is entirely voluntary. If you did decide to participate in the study, you will be asked to sign

a consent form when you attend your first physiotherapy appointment. This will be witnessed by your Physiotherapist, who will also sign the form. You will then be given a copy of the signed and dated consent form to keep. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I decide to take part?
If you decided to participate, then you will enter the study. When you attend your first physiotherapy appointment, the physiotherapist will assess your knee. If the physiotherapist feels that you will be suitable to participate in the study, they will say so, and you can tell them if you wish to take part or not. If you say yes then one of the department's Physiotherapists will ask you to fill in 3 questionnaires and an assessment sheet, and ask you some questions about your knee and your other joints. They will also briefly assess your knee strength and movement as well as assess your knee's ability to detect what position it is in, or it's joint position sense. This will be performed by using 2 small detectors stuck to your thigh and knee whilst you are asked to bend you knee to different positions. The whole assessment should take approximately 20 minutes in total.

You will then be randomised to receive your physiotherapy treatment with either the proprioceptive, specific-VMO exercises or the general thigh strengthening exercises. Which group you will be in, will be determined by the Chief Investigator picking a card out of a bag which will either have 'VMO,' 'Quadriceps Exercises' or 'Proprioceptive' written on it. Using this method, you have a 33%:33%:33% chance of being in either of the groups. We do this because sometimes we do not know which way of treating patients is best, and so we need to make comparisons between groups to compare treatments. The people are selected into the groups by chance to try and give the researchers more confidence to state that the results of each subject are due to their treatment, rather than how they were selected.

If you are in the general thigh strengthening exercise group, then the physiotherapist will teach you a series of exercises to encourage your knee to regain movement, strength and co-ordination. You may receive treatments such as ultrasound, or hands-on treatments, as well as advice regarding ice. You may also be referred to a Gym Class to progress your rehabilitation using machines such as bikes, treadmill machines and stepping machines. The physiotherapist will tailor your rehabilitation to meet your specific treatment requirements and targets, getting you better, and allowing you to return to the activities you wish to return to. You will also work through the progressions to make the exercise harder as you get better, as recommended by your physiotherapist. You would be advised to continue the exercises taught to you by your physiotherapist, for as long as you wish once you have been discharged by the physiotherapist. You will be asked to mark how often you do your exercises using an Exercise Diary provided by your treating physiotherapist.

If you are in the specific VMO muscle exercise group, you will receive the same treatment as the normal treatment programme, but, rather than performed the general thigh strengthening exercises, you will be taught some specific strengthening exercises to

strength the VMO muscle, the muscles on the inner part of your knee. The exercises you would be taught include squeezing a ball between your knees as you squat down a little against a wall, a mini-squatting exercise knee dips from a step, and a gentle exercise pushing your foot in an inwards against a table. Each exercise would be taught to you by the physiotherapist when your knee feels comfortable enough to perform these tasks. You will also work through the progressions to make the exercise harder as you get better, as recommended by your physiotherapist. You would be advised to continue these exercises for as long as you wished once you have been discharged by the Physiotherapy department. As with the other group, you will be asked to mark how often you do your exercises using an Exercise Diary provided by your treating physiotherapist.

Likewise, if you are in the Proprioceptive or Balance exercise group, you will receive the same treatment as the normal treatment programme, but, rather than performed the other general thigh or VMO strengthening exercises, you will be taught some specific strengthening exercises to improve your leg's balance and co-ordination. The exercises you would be taught include balancing on one leg, balancing whilst squatting, throwing and catching a ball whilst balancing and exercises with gym-balls and wobble-boards. All equipment will be provided to you and each exercise will be taught to you by the physiotherapist when your knee feels comfortable enough to perform these tasks. You would be advised to work through the progressions to make the exercise harder, as recommended by your physiotherapist. You would be advised to continue these exercises for as long as you wished once you have been discharged by the Physiotherapy department. As with the other groups, you will be asked to mark how often you do your exercises using an Exercise Diary provided by your treating physiotherapist.

Six weeks after beginning your physiotherapy, the same Physiotherapist who assessed you at the start of the study will again ask you to fill in the same 3 questionnaires and an assessment sheet given to you at the start of your treatment. They will ask you if your knee cap has "popped out" again during the last six weeks. They will also assess your knee strength, movement and proprioception, the same way as in the earlier assessment. This should take approximately 20 minutes in total.

This same assessment procedure will also be repeated six months after you have begun your physiotherapy. Again, this should take approximately 20 minutes each time. Once this is completed, you have finished this part of the study. However you may be asked whether you wish to participate in a final discussion group, were we will ask you some questions about the study to gauge if you feel it could be improved in the future. This discussion will be with other patients, physiotherapists, hospital staff and the research team as we feel your opinions of the study are important. This is entirely voluntary and you can choose to participate in this part of the study if you wish.

What do I have to do?
All you need to do is follow what your physiotherapist will instruct you to do, and not to do any other exercises or activities which they have not told you to do.

What are the possible disadvantages and risks of taking part?
There are no specific disadvantages in taking part in this study. Patients who are potentially at risk from performing any of the exercises for your condition have been excluded from the study purposely. However, if you feel anxious about any part of the study, you are free to withdraw from the study without having to give a reason.

As your physiotherapist will explain during your rehabilitation, there is the potential for pain, discomfort and inconvenience during your rehabilitation following the normal treatment programme, particularly in the first few weeks. However, the addition of the study exercises should not increase or decrease this potential for discomfort.

What are the possible benefits of taking part in the study?
There are no benefits to you by taking part. It is hoped that the information we get from this study may help to determine whether patients with patella or knee cap dislocation should receive VMO muscle exercises, general thigh strengthening exercises or proprioception/balance exercises in the future.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment being studied. If this happens, the Chief Investigator (Toby Smith) will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw the Chief Investigator will make arrangements for your care to continue. If you decide to continue in the study, you will be asked to sign an updated consent form.

Also, on receiving new information the Chief Investigator might consider it to be in your best interests to withdraw you from the study. He will explain the reasons and arrange for your care to continue.

What if something goes wrong?
If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

Will I get paid for participating?
You will not be paid for your participation. However, since it is expected that you would have been discharged from your Physiotherapy Department by the time your six month assessment is made, your parking fees and mileage will be compensated, so you will also not incur any expense by participating in the study.

Will my taking part in this study be kept confidential?
If you consent to take part in the research study, any of your medical records may be inspected by responsible individuals from your hospital or from regulatory authorities

where it is relevant in this study, for the purposes of analysing the results. They may also be looked at by responsible individuals from your hospital or from regulatory authorities to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital.

Your General Practitioner and the person who referred you to the Physiotherapy Department, will be notified of your participation in this study.

Once the study has been completed, once all data has been processed, all original data sheets and coding forms will be destroyed.

What will happen to the results of the research study?
Approximately a year after you have finished participating in the study, it is anticipated that the findings will be published in an orthopaedic medical or physiotherapy journal. This will not include any information that directly identifies you. If you wish to obtain a copy of the final report, please contact the Chief Investigator (Toby Smith) who will be able to help.

Who is organising and funding the research?
The research is being organised by the Chief Investigator Toby Smith who is a Lecturer in Physiotherapy, and is collaborated with XXX, XXX and XXX from the University of XXX. The study shall be funded by XXXX, to cover the costs of the equipment, expenses and the Physiotherapist's time. The Chief Investigator conducting the research is not being paid for undertaking this study.

Who has reviewed the study?
This study has been reviewed by the XXXX in order to gain ethical approval before commencing.

Who do I contact for further information?
If you wish for more information about the study, please contact the Chief Investigator Toby Smith at the University of East Anglia on 01603 593087.

Thank you for reading through this information sheet, and thank you for participating in the study if you choose to do so.

Appendix 54. Consent Form
(Version 1.0 ~ 15.05.2012)

University of East Anglia

Centre Number:
Study Number:
Patient Identification Number for this trial:

A pragmatic, multi-centre feasibility RCT to compare the functional outcomes of a specific-VMO exercise, a general quadriceps strengthening and a proprioceptive exercise programme following first-time patellar dislocation

Investigators: - Mr Toby O Smith MSc BSc (Hons) MCSP

Please could you read through, initial the boxes and sign the space provided below.

(1) I confirm that I have read the attached "Participant Information Sheet" dated 15.04.12 (version 1.0) for the above study and that I have had the opportunity to ask questions. ☐

(2) I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical or legal rights being affected. ☐

(3) I understand that sections of my medical notes may be looked at by responsible individuals from the participating hospital or from regulatory authorities where it is relevant in this study. I give permission for these individuals to have access to my records. ☐

(4) I agree to take part in the above study. ☐

(5) I agree that my GP will be informed of my participation in this study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Physiotherapist (witness)	Date	Signature

1 for Patient; 1 for Principal Investigator; 1 to be kept with hospital notes

Appendix 55. Participant's Referrer Letter
(Version 1.0 ~ 15.05.2012)

School of Allied Health Profession
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

(DATE)

Dear Mr/Ms/Dr

Re: **Patient Name**
Patient Hospital Number, Address and Date of Birth
Patient's Registered General Practitioner

Thank you for referring this patient to the Physiotherapy Department at the XXX hospital.

The above patient has consented to participate in a medical study. The objective of this study is to assess the feasibility of a study comparing the functional and clinical outcomes of patients treated with a specific vastus medialis oblique muscle exercises, to a general quadriceps exercise regime, to a proprioceptive exercise programme following a first-time patellar dislocation. The Orthopaedic and Physiotherapy Departments at the participating hospital have been involved in the development of this study and have agreed for their patients to participate in the trial.

The study has been passed through the XXXX Research Ethics Committee, the XXXX Research Governance Committee, where it was approved before any subjects were approached. In addition to yourself, the patient's General Practitioner has also been notified of their involvement in this trial.

The patient is expected to be involved in the study over the next six months. They will be assessed before beginning their rehabilitation, at six weeks and six months after commencing their treatment, by a Physiotherapist in the Out-Patient Physiotherapy Department, at the participating hospital. After which time, they will have completed the study. They may also be asked to comment on their experiences of the trial as part of a focus group once they have finished the study.

If you have any questions regarding the study, its procedures and protocols, or anything at all, then please feel free to contact me at the University of East Anglia on 01603 593087 or by email on toby.smith@uea.ac.uk, and I will be happy to answer any questions.

Yours faithfully,

Mr Toby O Smith
Chief Investigator
Lecturer in Physiotherapy
University of East Anglia, Norwich.

Appendix 56. Participant's General Practitioner Letter
(Version 1.0 ~ 15.05.2012)

School of Allied Health Profession
University of East Anglia
Norwich Research Park
Norwich
NR4 7TJ

(DATE)

Dear Dr

Re: **Patient Name**
Patient Hospital Number, Address and Date of Birth
Patient's Registered General Practitioner

The above patient has consented to participate in a medical study. The objective of this study is to assess the feasibility of a study comparing the functional and clinical outcomes of patients treated with a specific vastus medialis oblique muscle exercises, to a general quadriceps exercise regime, to a proprioceptive exercise programme following a first-time patellar dislocation.

The Orthopaedic and Physiotherapy Departments at the participating hospital have been involved in the development of this study and have agreed for their patients to participate in the trial. The study has been passed through the XXXX Research Ethics Committee, the XXXX Research Governance Committee, where it was approved before any subjects were approached.

Your patient is expected to be involved in the study over the next six months. They will be assessed before beginning their rehabilitation, at six weeks and six months after commencing their treatment, by a Physiotherapist in the Out-Patient Physiotherapy Department, at the participating hospital. After which time, they will have completed the study. They may also be asked to comment on their experiences of the trial as part of a focus group once they have finished the study.

If you have any questions regarding the study, its procedures and protocols, or anything at all, then please feel free to contact me at the University of East Anglia on 01603 593087 or by email on toby.smith@uea.ac.uk, and I will be happy to answer any questions.

Yours faithfully,

Mr Toby O Smith
Chief Investigator
Lecturer in Physiotherapy
University of East Anglia, Norwich.

Appendix 57. Recruitment Log

(Version 1.0 ~ 15.05.2012)

Study: A pragmatic, multi-centre RCT to assess the feasibility of a trial to compare the functional outcomes of a specific-VMO exercise, a general quadriceps strengthening and a proprioceptive exercise programme following first-time patellar dislocation.

Site:

For each box, please date when this was completed and initial who this was completed by.

Participant Code	Eligibility Assessed	Covering Letter Sent	PIL Sent	Referrer Letter Sent	GP Letter Sent	Consented (Y/N)

PIL – Participant Information Leaflet; N – No; Y – Yes

Appendix 58. Proprioceptive Participant Exercise Sheet

(Version 1.0 ~ 15.05.2012)

All exercises should be performed with your shoes off. These will be progressed as per the instructions by your physiotherapist.

Wall squats with Swiss ball

Position the Swiss ball in the mid part of your back between you and a wall. Heels should be approximately 15 inches from the wall. You should have your feet shoulders width apart. From a fully upright standing position, squat down to a half squatting position (approximately 60° knee bend). Hold this position for **30** seconds, then slowly slide up until upright again.

Starting Exercise

Progression

Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then -
(2) Double Leg with Eyes Closed
(3) Single Leg with Eyes Open
(4) Single Leg with Eyes Closed
(5) Single Leg with Hand Weights Eyes Open
(6) Single Leg with Eyes Closed

Pillow balance throwing and catching

Standing on two pillows, facing a wall 30 inches away. Balance on both feet. Throw a ball to a wall and catch it on its return. Alter the point, angle and height the ball is thrown. Repeat **30** times initially.

Starting Exercise

Progression

Loading Progression:

(1) Increase Duration/Repetitions/Speed of Throwing/Catching cycle – and then -
(2) Single Leg
(3) Single Leg with Rucksack
(4) Single Leg with Rucksack with increasing weight

Bridging with Swiss Ball

Lying supine with Swiss ball in mid-back. Initially knees bend to a right angle (90° flexion). Maintain position. Hold this position for **30** seconds, then rest. Repeat in quarter knee bend position (45° flexion). Hold this position for **30** seconds, then rest.

Starting Exercise

Progression

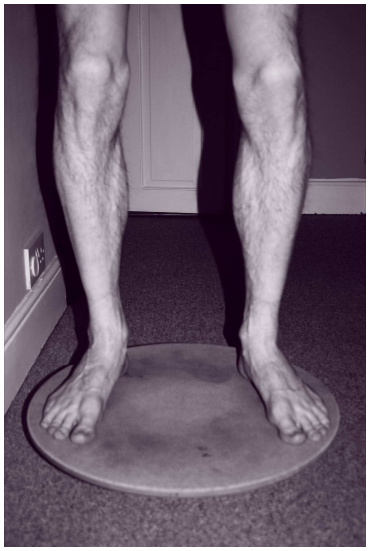
Loading Progression:

(1) Increase Duration in hold position, then Repetitions and later Speed – and then -
(2) Single Leg at 90° and 45°

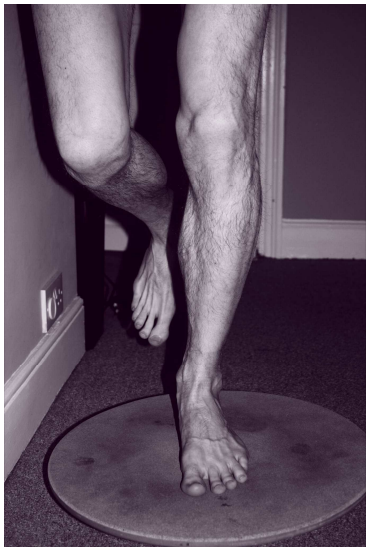
(3) Single Leg at 90° and 45° holding hand weights
(4) Single Leg at 90° and 45° throwing and catching a ball above head

Wobble-board Exercises

Standing on a wobble-board. Double leg stand in slight knee bend. Try and maintain the board level for **30** seconds. Then rest.



Starting Exercise



Progression

Loading Progression:

(1) Increase Duration in hold position – and then -
(2) Double Leg with Eyes Closed
(3) Single Leg with Eyes Open
(4) Single Leg with Eyes Closed
(5) Single Leg with Hand Weights Eyes Open
(6) Single Leg with Weighted Rucksack Throwing and Catching a Ball against a Wall

Please record the frequency of your exercises using the Exercise Diary

General Rehabilitation Programme

To be given to all patients if decided upon by treating physiotherapist

- Knee Rom exercises
- Ice
- Ultrasound of medial retinacular region
- Hamstring/Calf stretches
- Glutei exercises
- Proprioception balance exercises
- Manual therapies – lateral retincular frictions/medial glides
- Tibiofemoral mobilisations
- Acupuncture
- Ultrasound and inferential combined
- Tubigrip and compression bandage treatments.
- Gym programme
- Taping techniques

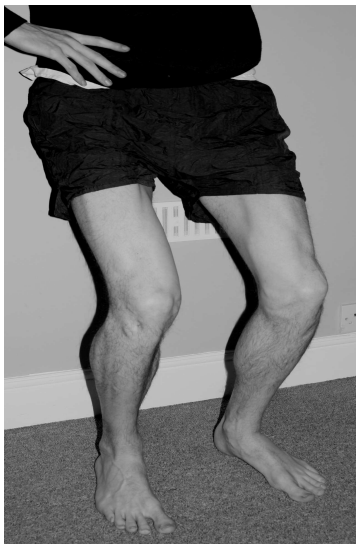
Appendix 59. General Quadriceps Participant Exercise Sheet

(Version 1.0 ~ 15.05.2012)

All exercises should be performed with your shoes off. These will be progressed as per the instructions by your physiotherapist.

Wall Slide Exercise

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. From a fully upright standing position, squat down to a half squatting position. Hold this position and tighten your tight muscles to draw your knee caps up. Hold this for **20** seconds, then relax and slowly slide back up until upright again.



Starting Exercise

Progression

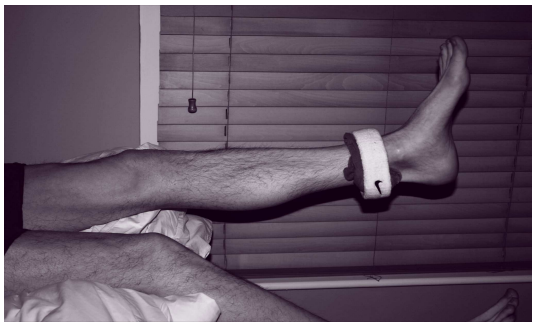
Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then –
(2) Performed on a Single (affected) Leg
(3) Single Leg with Hand Weights of progressively increased weight
Single Leg with Reversed Rucksack of progressively increased weight

Straight Leg Raise

Lying on your back, with your head supported with a couple of pillows, legs out straight and relaxed. Draw your toes and foot up towards your head, pressure your knee down straight into the bed, and raise you whole leg straight up into the air. Raise your leg so that it is about **10** centimetres off the bed. Hold for **20** seconds, and then relax your leg down into the bed.

Starting Exercise



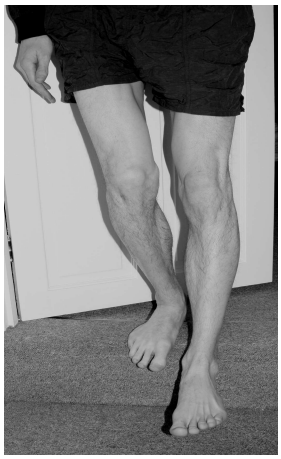
Progression

Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then –
(2) Addition of ankle weight of progressively increased weight

Leg Dips

Standing on a step or wooden box, approximately 4 to 6 inches high. Your "injured" leg should be on the top of the box or step. Then slowly over a **10** second period lower your uninjured leg off the step to touch the floor, making the injured knee work. Once your toes have touched the floor then slowly return to straighten your injured knee over a **10** second period. You may initially need to hold onto a banister or wall during this exercise, but as you get better try to exercise without such a support.



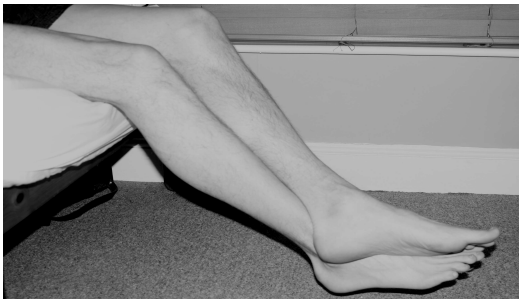
Starting Exercise **Progression**

Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then –
(2) Addition of ankle weight on contralateral limb with progressively increased weight.
(3) Addition of ankle weight on contralateral limb with progressively increased weight and Hand Weights of progressively increased weight.
(4) Addition of ankle weight on contralateral limb with progressively increased weight and Rucksack of progressively increased weight.

Isometric Quadriceps

Sitting on a chair, with your injured leg's knee slightly bent (40°). Place you unaffected foot over your injured leg's ankle. Push you injured leg forwards against your unaffected leg so that you are resisting this movement. Touch the muscle on the inside part of your knee to feel the contraction during this exercise. Hold this contract for **20** seconds, and then relax.



Starting Exercise

Progression before adding resistance

Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then -
(2) Addition of ankle weight of progressively increased weight

Please record the frequency of your exercises using the Exercise Diary

General Rehabilitation Programme

To be given to all patients if decided upon by treating physiotherapist

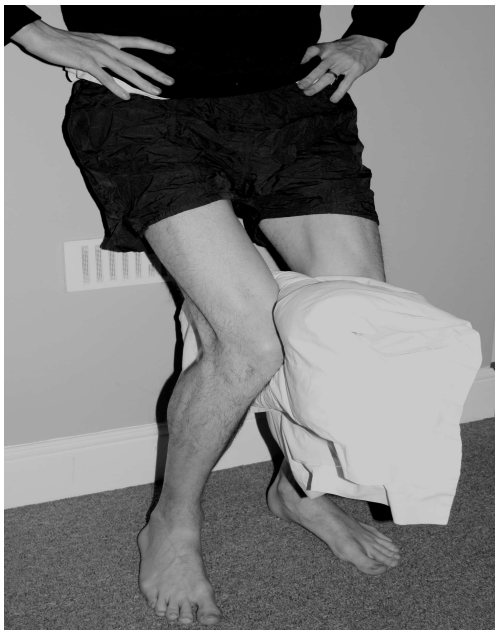
- Knee Rom exercises
- Ice
- Ultrasound of medial retinacular region
- Hamstring/Calf stretches
- Glutei exercises
- Proprioception balance exercises
- Manual therapies – lateral retincular frictions/medial glides
- Tibiofemoral mobilisations
- Acupuncture
- Ultrasound and inferential combined
- Tubigrip and compression bandage treatments.
- Gym programme
- Taping techniques

Appendix 60. VMO Participant Exercise Sheet
(Version 1.0 ~ 15.05.2012)

All exercises should be performed with your shoes off. These will be progressed as per the instructions by your physiotherapist.

Modified Wall Slide Exercise

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. Place a fat towel between your knees. From a fully upright standing position, squat down to a half squatting position. Then push your knees together, squeezing into the towel. Hold this position and squeeze for **20** seconds, then relax and slowly slide back up until upright again.

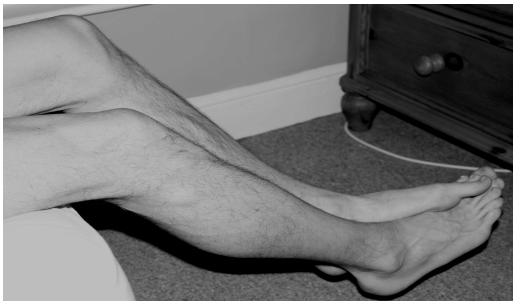


Loading Progression:

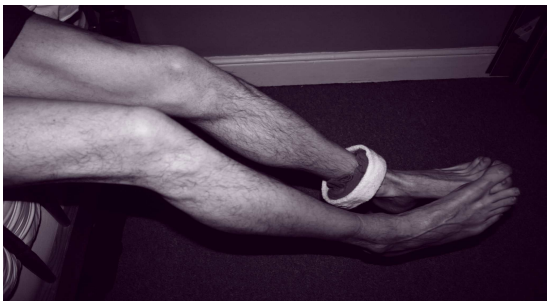
(4) Increase Hold Period and Repetitions and later Speed – and then -
(5) Exercise with Hand Weights of progressively increased weight
(6) Exercise with Reversed Rucksack of progressively increased weight

Isometric Quadriceps and Tibial/Femoral Internal Rotation

Sitting on a chair or the edge of a bed, with your injured leg turned inward, and knee slightly bent (40°). Place you unaffected foot over the side of your injured leg's foot. Try to turn you injured leg's foot inwards and then, at the same time push your injured leg forwards all against your unaffected foot so that you are resisting this movement. Touch the muscle on the inside part of your knee to feel the contraction during this exercise. Hold this contract for **20** seconds, and then relax.



Starting Exercise



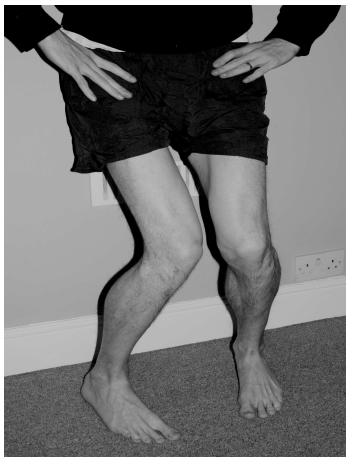
Progression

Loading Progression:

(3) Increase Hold Period and Repetitions and later Speed – and then -
(4) Addition of ankle weight of progressively increased weight

Isometric Quadriceps with hip rotation in semi-squatting position

Place your back against the wall with the heels approximately 3 inches from the wall. You should have your feet shoulders width apart. Point your feet inwards so that your whole leg is turned inwards to about a 2 o'clock and 10 o'clock position. Slide down the wall so that your knees are slightly bent (to about 30 degrees). Tighten your thigh muscles up as tight as you can. Hold for **20** seconds. Then relax and slowly slide back up the wall until in an upright position again.

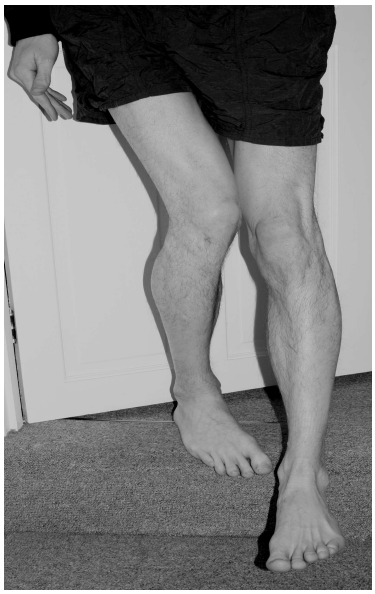


Loading Progression:

(1) Increase Hold Period and Repetitions and later Speed – and then -
(2) Single Leg Semi-Squatting position on affected limb
(3) Single Leg Semi-Squatting position with Hand Weights of progressively increased weight
(4) Single Leg Semi-Squatting position with Reversed Rucksack of progressively increased weight.

Leg Dips in Internal Tibial/Femoral Rotation

Standing on a step or wooden box, approximately 4 to 6 inches high. Your "injured" leg should be on the top of the box or step so that your foot and toes are pointing at approximately a 2 o'clock or 10 o'clock position so that you leg is rotated inwards. Then slowly over a 5 second period lower your uninjured leg off the step to touch the floor, making the injured knee work. Once your toes have touched the floor then slowly return to straighten your injured knee over a **20** second period. You may initially need to hold onto a banister or wall during this exercise, but as you get better try to exercise without such a support.



Starting Exercise

Progression

Loading Progression:

(5) Increase Hold Period and Repetitions and later Speed – and then –
(6) Addition of ankle weight on contralateral limb with progressively increased weight.
(7) Addition of ankle weight on contralateral limb with progressively increased weight and Hand Weights of progressively increased weight.
(8) Addition of ankle weight on contralateral limb with progressively increased weight and Rucksack of progressively increased weight.

Please record the frequency of your exercises using the Exercise Diary

General Rehabilitation Programme

To be given to all patients if decided upon by treating physiotherapist

- Knee Rom exercises
- Ice
- Ultrasound of medial retinacular region
- Hamstring/Calf stretches
- Glutei exercises
- Proprioception balance exercises
- Manual therapies – lateral retincular frictions/medial glides
- Tibiofemoral mobilisations
- Acupuncture
- Ultrasound and inferential combined
- Tubigrip and compression bandage treatments.
- Gym programme
- Taping techniques

Appendix 61. Interventional Checklist

(Version 1.0 ~ 15.05.2012)

Please **tick** in the applicable box which treatments you perform for each treatment session.

Patient study number:

Grade of Treating Physiotherapist:

Intervention	Treatment 1 Date:	Treatment 2 Date:	Treatment 3 Date:	Treatment 4 Date:	Treatment 5 Date:	Treatment 6 Date:	Treatment 7 Date:	Treatment 8 Date:	Treatment 9 Date:	Treatment 10 Date:
Discomfort from another MSK regions since last Rx										
Modified Wall Slide Exercise										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric Quadriceps with hip rotation in semi-squatting position										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Leg Dips in Internal Femoral and Tibial Rotation										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric Quadriceps and Tibial Internal Rotation										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Wall slide in neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric quadriceps in semi-squat neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										

Leg dips in neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric quadriceps in neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Wall squat with Swiss Ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Double leg balance throwing ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Double leg bridge on Swiss ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Wobble board exercise										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Knee Rom exercises										
Ice										
Ultrasound of medical retinaculum										
Hamstring stretches										
Calf Stretches										
Glutei exercises										
Proprioception exercises										
Lateral retinaculum frictions										
Medial Patellar Glides										
Tibiofemoral Mobilisations										
Inferential/Ultrasound combined										
Acupuncture										
Gym programme										
Taping Techniques										
Tubigrip and compression bandage										
Other-										
Other-										
Other-										

MSK – Musculoskeletal Rx – Treatment Prog - Progression

Intervention	Treatment 11 Date:	Treatment 12 Date:	Treatment 13 Date:	Treatment 14 Date:	Treatment 15 Date:	Treatment 16 Date:	Treatment 17 Date:	Treatment 18 Date:	Treatment 19 Date:	Treatment 20 Date:
Discomfort from another MSK regions since last Rx										
Modified Wall Slide Exercise										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric Quadriceps with hip rotation in semi-squatting position										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Leg Dips in Internal Femoral and Tibial Rotation										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric Quadriceps and Tibial Internal Rotation										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Wall slide in neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric quadriceps in semi-squat neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Leg dips in neutral										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Isometric quadriceps in neutral										
Prog 1.										

Prog 2.										
Prog 3.										
Prog 4.										
Wall squat with Swiss Ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Double leg balance throwing ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Double leg bridge on Swiss ball										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Wobble board exercise										
Prog 1.										
Prog 2.										
Prog 3.										
Prog 4.										
Knee Rom exercises										
Ice										
Ultrasound of medical retinaculum										
Hamstring stretches										
Calf Stretches										
Glutei exercises										
Proprioception exercises										
Lateral retinaculum frictions										
Medial Patellar Glides										
Tibiofemoral Mobilisations										
Inferential/Ultrasound combined										
Acupuncture										
Gym programme										
Taping Techniques										
Tubigrip and compression bandage										
Other-										
Other-										
Other-										

MSK – Musculoskeletal Rx – Treatment Prog - Progression

Appendix 62. Participant Exercise Diary

(Version 1.0 ~ 15.05.2012)

Participant Study Number:

Treatment Day / Date	Exercises Completed (Tick if completed)	Treatment Day / Date	Exercises Completed (Tick if completed)
1 (0 week)		41	
2		42 (6 weeks)	
3		43	
4		44	
5		45	
6		46	
7 (1 week)		47	
8		48	
9		49 (7 weeks)	
10		50	
11		51	
12		52	
13		53	
14 (2 weeks)		54	
15		55	
16		56 (8 weeks)	
17		57	
18		58	
19		59	
20		60	
21 (3 weeks)		61	
22		62	
23		63 (9 weeks)	
24		64	
25		65	
26		66	
27		67	
28 (4 weeks)		68	
29		69	
30		70 (10 weeks)	
31		71	
32		72	
33		73	
34		74	
35 (5 weeks)		75	
36		76	
37		77 (11 weeks)	
38			
39			
40			

Patient Exercise Diary (Weeks 11 to 26)

Treatment Week	Exercises Completed (Tick if completed)
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	

Appendix 63. Knee Extension Isometric Strength Procedure

(Version 1.0 ~ 15.05.2012)

Participant is positioned sitting. The leg is bare to reduce external influence. Participant's arms positioned across their body, seated on the edge of an elevated plinth, feet raised above the ground. This formalised position was stipulated so participants are unable to gain leverage from their upper limbs or contralateral leg.

A hand-held dynamometer (Basic Force Gauge, Mecmesin, Slinfold, West Sussex, UK) is used throughout the testing procedure. The dynamometer probe is positioned on the anterior aspect of the tibia, three centimetres above the medial malleous. The assessor is positioned in front of the participant as depicted in Figure 1.

Four pre-determined angles are chosen at random for the assessed knee. These are 0, 30, 60 and 90 degrees knee flexion. These values will be randomised using a concealed allocation method of sealed envelopes. The assessor will extract a sealed envelope one-by-one before the each test is carried out.

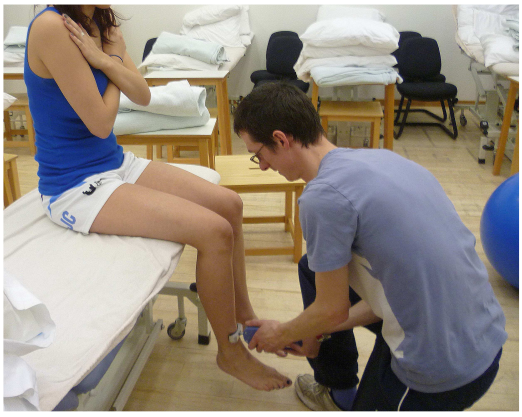


Figure 1

Prior to the test each participant is given verbal encouragement, instructed to "to push as hard as possible through the dynamometer". The participant knee would be positioned in the desired knee flexion angle confirmed through goniometry. Once the probe is positioned the participant is then instructed to push for 5 seconds. The commands throughout this period are "push, push, push, push" by the assessor. The maximum reading provided by the dynamometer will be recorded in Newton's.

The participant is provided with a 30 second intervals before the next randomly allocated assessment measurement is performed. This procedure is continued until all four angles are recorded in the datasheet. Once completed, the dynamometer's probe is cleaned with an alcohol wipe.

Appendix 64 (i). Methods and population characteristics for the 17 studies which have assessed the reliability of knee joint position sense measurement methods.

Study	Population				JPS AX Method	Number of examiners	Intra-Ax Interval (days)
	N	Gender (m/f)	Age (years)	Pathology			
Fatoye et al [2008]	20	7/13	9.9	10 JHS; 10 Healthy controls	Angular motion chair - Passive positioning of limb with subject passively returning to initial position for 25° and 10° knee flexion.	1	7
Fischer-Rasmussen et al [2001]	15	14/1	27.7	Healthy	Electrogoniometer Method in sitting – Active and passive positioning of limb with subject active returning to initial position 15°, 25° and 35° knee flexion angles.	1	7
Ghiasi and Akbari [2007]	15	N/S	18-25	Healthy	Electrogoniometer Method – Active positioning of limb with subject active returning to initial position 45°, 60° and 90° knee flexion angles. Assessed in supine and standing.	1	7
Kiefer et al [1998]	40	23/17	22.5	Healthy	Electrogoniometer Method – active positioning of limb to 15°, 30°, 45° and 60° in sitting and standing position. Patient instructed to actively flex knee to target angle then to actively returning to initial position.	1	14
Kramer et al [1997]	48	14/34	24	24 PFPS 24 Healthy	Electrogoniometer Method – Active positioning of limb with subject active returning to initial position 15°, 30°, 45° and 60° knee flexion angles. Assessed in sitting and standing.	1	3 to 14
Marks [1995]	8	0/8	67.9	OA knee (Gd 3 Kel-Law)	Angular motion chair - passive positioning of limb with subject actively returning to initial positions in 45° to 75° knee flexion.	1	10
Marks et al [1993]	10	0/10	65.9	TFJT OA	Image-recorded knee motion – active positioning of limb with subject actively returning to initial position for 5 tests between 20° to 40° knee flexion. Performed before and after muscle contraction exercise.	2	42
Mir et al [2008]	N/S	N/S	N/S	N/S	Image -recorded knee motion – active positioning of limb with subject actively returning to initial position	N/S	N/S

					for 30° knee flexion from full extension and 60° flexion in semi-squat position.		
Nobori et al [2009]	10	0/10	19.5	Healthy	Angular motion chair - passive positioning of limb with subject passively returning to initial position for 65°, 75° and 85° knee flexion.	2	Same session
Olsson et al [2004]	39	22/17	27	Healthy	Electrogoniometer Method – active positioning of limb with subject actively returning to initial position for 30°,50°,70° when assessed in sitting or 40°, 70°, 100° when assessed in prone.	1	7
Petrella et al [1997]	40	N/S	16 aged 19-27; 24 aged 60-86	Healthy	Electrogoniometer Method – active positioning of limb from 10° to 60° in standing. Subject instructed to actively flex knee to target angle then to actively returning to initial position with semi-squat.	2	7
Pincivero et al [2001]	20	20/0	24.2	Healthy	Angular motion chair – prone – Maintained position with isometric contraction. Once resistance removed, expected to maintain in target position. Target angles 15°, 30° and 60° knee flexion.	1	7 to 14
Piriyaprasarth et al [2008]	35	9/26	31	Healthy	Electrogoniometer Method – Active positioning of limb with subject active returning to initial position 0° and two flexion angles. Assessed in sitting, supine and standing.	2	0.5
Selfe et al [2006]	32	17/15	31.9	PFPS	Angular motion chair - passive positioning of limb with subject passively returning to initial position for 20° and 60° knee flexion; active positioning of limb with subject notify when initial position for 20° and 60° knee flexion when passively moved a second time.	1	Same session
Stillman and McMeeken [2001]	20	10/10	19.9	Healthy	Image -recorded knee motion – passive positioning of limb with subject actively returning to initial position for 45° knee flexion. Performed standing with mini-squats and sitting.	1	Same session
Stillman et al [2002]	44	9/35	21.1	Healthy	Image -recorded knee motion – passive positioning of limb with subject actively returning to initial position for 15° from the subject's full passive knee extension range.	1	Same session
Stillman et al [1998]	40	40/0	22.8	Healthy	Image-recorded knee motion – passive positioning of limb with subject actively returning to initial position	1	Same session

		for 20°, 40° and 60° knee flexion. Performed before and after muscle contraction exercise.

Ax – Assessment; F – Females; Gd – Grade; JHS – Joint Hypermobility Syndrome; JPS – Joint Position Sense; Kel Law – Kellgren-Lawrence; m – males; PFPS – Patellofemoral Pain Syndrome; OA – Osteoarthritis; TFJT – Tibiofemoral Joint

Appendix 64 (ii). Results of the 17 studies which have assessed the reliability of knee joint position sense measurement methods.

JPS Testing Method (Position/Pathology)	Study	Intra-Rater Reliability (ICC)	Inter-Rater Reliability (ICC)
Image Capture			
Passive positioning-active replication (Sitting/Healthy)	Stillman et al [1998]	RE 3.9°±3.1; AE 4.9°±2.7	N/A
Passive positioning-active replication (Sitting/Healthy)	Stillman and McMeeken [2001]	RE 3.4°±2.1; AE 3.7°±1.9	N/A
Passive positioning-active replication (Sitting/Healthy)	Stillman et al [2002]	RE -0.8°±2.0; AE 2.2°±1.2	N/A
Passive positioning-active replication (Sitting/Healthy after exercise)	Stillman et al [1998]	RE 2.5°±2.9; AE 4.1°±1.4	N/A
Passive positioning-active replication (Standing/Healthy)	Stillman and McMeeken [2001]	RE -0.6°±1.4; AE 2.0°±0.7	N/A
Passive positioning-active replication (Standing/NS)	Mir et al [2008]	R=0.99	N/A
Active positioning-active replication (Standing/OA)	Marks et al [1993]	0.43-0.56	0.81
Electrogoniometer			
Active positioning-active replication (Sitting/Healthy)	Piriyaprasarth et al [2008]	0.86 to 0.87	0.68 to 0.79
Active positioning-active replication (Supine/Healthy)	Piriyaprasarth et al [2008]	0.75 to 0.76	0.58 to 0.71
Active positioning-active replication (Standing/Healthy)	Piriyaprasarth et al [2008]	0.87 to 0.88	0.57 to 0.80
Active positioning-active replication (Standing/Healthy)	Petrella et al [1997]	R=0.88	N/A
Active positioning-active replication (Sitting/Healthy)	Olsson et al [2004]	0.31-0.82 AE 4.2°	N/A
Active positioning-active replication (Prone/Healthy)	Olsson et al [2004]	0.17-0.75 AE 5.1°	N/A
Active positioning-active replication (Standing & Supine/Healthy)	Ghiasi and Akbari [2007]	0.91-0.99	N/A
Active positioning-active replication (Sitting & Standing/Healthy)	Kiefer et al [1998]	0.08-0.67	N/A
Active positioning-active replication (Sitting/Healthy)	Kramer et al [1997]	0.18 - 0.67	N/A
Active positioning-active replication (Sitting/PFPS)	Kramer et al [1997]	0.58-0.79	N/A
Active positioning-active replication (Standing/Healthy)	Kramer et al [1997]	0.17-0.59	N/A
Active positioning-active replication (Standing/ PFPS)	Kramer et al [1997]	0.42-0.63	N/A
Active positioning-active replication (Sitting/Healthy)	Fischer-Rasmussen et al [2008]	R=0.70	N/A
Passive positioning-active replication (Sitting/Healthy)	Fischer-Rasmussen et al [2008]	R=0.80	N/A
Dynamometer/Angular Motion Chair			
Active positioning-passive replication (Sitting/PFPS)	Selfe et al [2006]	Mean target error 7.4°-10.2°	N/A
Passive positioning-active replication (Sitting/OA)	Marks [1995]	0.36 (1.18 SEM)	N/A
Passive positioning-passive replication (Sitting/PFPS)	Selfe et al [2006]	Mean target error 4.5°-7.2°	N/A
Passive positioning-passive replication (Sitting/10° knee flexion/Healthy)	Fatoye et al [2008]	0.26 (CI: -4.27,7.07)	N/A
Passive positioning-passive replication (Sitting/25° knee flexion/Healthy)	Fatoye et al [2008]	0.39 (CI: -3.43,6.23)	N/A
Passive positioning-passive replication (Sitting/10° knee flexion/JHM)	Fatoye et al [2008]	0.18 (CI: -5.96,9.76)	N/A
Passive positioning-passive replication (Sitting/25° knee flexion/JHM)	Fatoye et al [2008]	0.56 (CI: -10.76,10.16)	N/A
Passive positioning-passive replication (Sitting/Healthy)	Nobori et al [2004]	0.86	0.73

Isometric hold-angle replication (Prone/Healthy)	Pincivero et al [2001]	0.43-0.89 (4.60-5.54 SEM)	N/A

AE – Absolute error; CI – 95% confidence intervals; ICC – Intra-class correlation coefficient; JHM – Joint Hypermobility; N/A - Not assessed; NS – Not stated; OA – Osteoarthritis; PFPS – Patellofemoral Pain Syndrome; R – Pearson Correlation Coefficient R Value; RE – Relative error; SEM – Standard error of mean

Appendix 65. Joint Position Sense Procedure

(Version 1.0 ~ 15.05.2012)

Participant is positioned in sitting. The leg is bare to reduce external influence. A second individual, either member of ward or clinic staff, or a relative of the participant attends throughout as a chaperone since participants will be asked to close their eyes during part of the testing procedure.

Four pre-determined angles are chosen at random for the assessed knee. These are 10, 30, 60 and 80 degrees. These values will be randomised using a concealed allocation method of sealed envelopes. The assessor will extract a sealed envelope one-by-one before the each test is carried out.

An electrogoniometer is used to determine the given angles exactly (Model SG150, Biometrics, Gwent, UK). This consists of 2 blocks, connected to a measuring unit. These blocks are applied to the skin of the lateral thigh and the lateral lower leg with double sided tape, as depicted in Figure 1. The two blocks are then connected to a computer unit to display the knee range of movement angle.

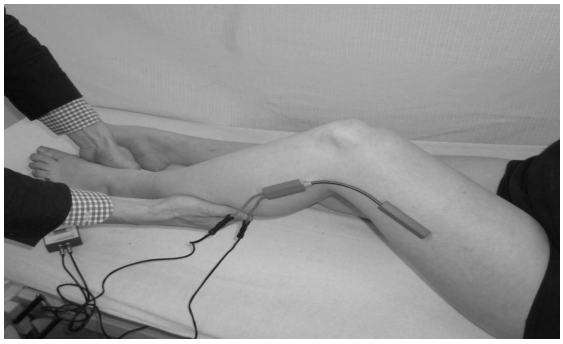


Figure 1

The starting position is 0 degrees flexion. The participant is asked to flex their knee into one of the pre-determined angles of knee flexion as measured using the electrogoniometer. Once this angle is reached, this is held for 5 seconds. The participant is asked to return their knee to 0 degrees flexion. The participant is then asked to close their eyes so this cannot assist the replication of the knee angle. After a one second delay, the participant is asked to bend their knee back to the target position. They will be asked to confirm that the knee angle is that they perceive as being the target angle. After each measurement the knee is returned to 0 degrees flexion for a 10 second period. This will be repeated 6 times for each target angle. The data from the sixth measurement will be recorded on the datasheet. This would be repeated for each of the pre-determined test angles.

After all test angles have been completed, the electrogoniometer blocks are removed and cleaned with an alcohol wipe.

Appendix 66. Patient Reported Subjective Outcome
(Version 1.0 ~ 15.05.2012)

Participant study number:

Date:

Compared to before you started physiotherapy, how does your knee ***currently*** feel.

Please tick the best response in the box below.

	Tick
A lot better	
A little better	
About the same	
A little worse	
A lot worse	

Appendix 67. Individual Data Sheet

(Version 1.0 ~ 15.05.2012)

Participant study number:

Assessor initials:

Assessment Period	**Baseline**	**Six Weeks**	**Six Months**
Assessment Date	(/ /)	(/ /)	(/ /)
Sex (m/f)			
Age (years)			
Family Hx Pat. Disl. (y/n)			
Duration since Pat. Disl (days)			
Hypermobility score (/9)			
Joint Disability of Treated Leg (y/n)			
Knee Instability on Contralateral Leg (y/n)			
Joint Disability of Contralateral Leg (y/n)			
Multi-joint Problems (upper limb/spinal) (y/n)			
Lysholm Knee Score (/100)			
Tegner Activity Score (/10)			
SF-12 (/48)			
Test 1 Ax 1			
Isometric Knee Extension values at:			
0º knee flexion			
30º knee flexion			
60º knee flexion			
90º knee flexion			
Test 1 Ax 2			
Isometric Knee Extension values at:			
0º knee flexion			
30º knee flexion			
60º knee flexion			
90º knee flexion			
Test 2 Ax 1			
Isometric Knee Extension values at:			
0º knee flexion			
30º knee flexion			
60º knee flexion			
90º knee flexion			
Test 2 Ax 2			
Isometric Knee Extension values at:			
0º knee flexion			
30º knee flexion			
60º knee flexion			
90º knee flexion			
Test 1 Ax 1			
JPS values at:			

10º knee flexion			
30º knee flexion			
60º knee flexion			
80º knee flexion			
Test 1 Ax 2			
JPS values at:			
10º knee flexion			
30º knee flexion			
60º knee flexion			
80º knee flexion			
Test 2 Ax 1			
JPS values at:			
10º knee flexion			
30º knee flexion			
60º knee flexion			
80º knee flexion			
Test 2 Ax 2			
JPS values at:			
10º knee flexion			
30º knee flexion			
60º knee flexion			
80º knee flexion			
Duration of exercises continued after discharge (weeks)			
Frequency of DNA physio. OPA			
Frequency of patellar re-dislocation			
Duration between 1st and 2nd Dislocation			

DNA - Did Not Attend
NPIS – Norwich Patellar Instability Score
Physio – Physiotherapy
Hx – History
OPA – Out-Patient Appointment
Pat Disl. – Patellar Dislocation
SF-12 – Short-Form 12
JPS – Joint Position Sense