The Knee

Title Page

Title: Rehabilitation following first-time patellar dislocation: a randomised controlled trial of purported vastus medialis obliquus muscle versus general quadriceps strengthening exercises

Concise Title: VM versus General Quadriceps following Patellar Dislocation

Authors:

T O Smith · R Chester · J Cross
School of Health Sciences, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ UK

N Hunt
Physiotherapy Department, Norfolk and Norwich University Hospital, Colney Lane, Norwich, UK

A Clark
Norwich Medical School, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ

S T Donell
Institute of Orthopaedics, Norfolk and Norwich University Hospital, & Norwich Medical School, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ

Corresponding Author:
Dr Toby Smith, School of Health Sciences, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ, UK. E-mail: toby.smith@uea.ac.uk. Telephone: 044 1603 593087; Fax: 044 1603 593166

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All authors can confirm that they do not have a conflict of interest in relation to this paper.

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Abstract

Purpose: Define whether distal vastus medialis (VM) muscle strengthening improves functional outcomes compared to general quadriceps muscles strengthening following first-time patellar dislocation (FTPD).

Methods: Fifty patients post-FTPD were randomised to either a general quadriceps exercise or rehabilitation programme (n=25) or to a specific-VM exercise and rehabilitation regime (n=25). Primary outcome was the Lysholm Knee Score, secondary outcomes included the Tegner Level of Activity Scale, the Norwich Patellar Instability (NPI) Score, and isometric knee extensions strength at various knee flexion ranges of motion. Outcomes were assessed at baseline, six weeks, six months and 12 months.

Results: There were statistically significant differences in functional outcome and activity levels through the Lysholm Knee Score and Tegner Level of Activity Scale at 12 months in the general quadriceps exercise group compared to the VM group (p=0.05; 95% CI: -14.0 to 0.0/p=0.04; 95% CI: -3.0 to 0.0). This did not reach a clinically important difference. There was no statistically significant difference between the groups for the NPI Score and isometric strength at any follow-up interval. The trial experienced substantial participant attrition (52% at 12 months).

Conclusions: Whilst there was a statistical difference in Lysholm Knee Score and Tegner Level of Activity Score between general quadriceps and VM exercise groups at 12 months, this may not have necessarily been clinically important. This trial highlights that the recruitment and retention of participants from this population is a challenge and should be considered during the design of future trials in this population.

Level of evidence: Therapeutic study, Level I

Keywords: Quadriceps; vastus medialis oblique; exercise; patellar dislocation; trial

1.0 Introduction

Patellar dislocation is a disabling musculoskeletal disorder which predominantly affects younger people who are engaged in multi-directional physically active pursuits [1]. The estimated incidence of patellar dislocation is between 7 [2] to 77 per 100,000 people per year [3], with a marginally greater incidence in females [2,4]. The term first-time patellar dislocation (FTPD) represents the first episode that the patella disengages completely from the femoral trochlear. It is sometimes termed primary patellar dislocation [5].

Conservative (non-operative) treatment is the treatment of choice for FTPD. Quadriceps strengthening exercises are considered one of the principal management for people following FTPD [6,7]. A United Kingdom (UK) survey of physiotherapy practice has shown that quadriceps strengthening and specific-vastus medialis obliquus (VMO) or distal vastus medialis (VM) muscle strengthening or recruitment exercises were two of the most frequently used interventions for this population [1]. However, there remains controversy regarding the prescription of quadriceps exercises or specific VM exercises for this population. Both a systematic literature review [8] and a national survey of UK musculoskeletal physiotherapists [9] indicated that specific-VM exercises can be used as an alternative to general quadriceps exercises, but equipoise exists regarding the optimal programme [10]. General quadriceps exercises are proposed to rehabilitate the entire quadriceps complex thereby providing general patellar stability [8]. Specific VM exercises are favoured in some quarters based on the assumption that the VM has an important role in preventing excessive lateral patellar translation [11]. However, questions remain regarding whether the VM can be preferentially recruited [10]. Accordingly, although some clinicians continue to prescribe specific-VM exercises [9], there is uncertainty that this can actually preferentially recruit this muscle rather than recruiting the quadriceps globally [10,12]. Nonetheless, a small number of studies have demonstrated the preferential recruitment of this muscle in either healthy or patellofemoral pain (PFP) populations [13-18]. Nonetheless no studies have assessed whether this can influence clinical outcomes in people following FTPD. It is therefore unclear whether physiotherapists should prescribe general quadriceps or specific-VM exercises to these individuals.

In this multi-centre prospective randomised controlled trial of rehabilitation following FTPD we compared a general quadriceps exercise programme with a specific-VM strengthening programme. The null hypothesis was that there was no difference in patellar stability and functional outcomes between a general quadriceps exercise programme and a specific-VM strengthening programme following FTPD at 12 months.

2.0 Materials and Methods

The study was a pragmatic multi-centre randomised controlled trial undertaken within the East of England from November 2011 to March 2014. Ethical approval was gained from the National Health Service Research Ethics Committee – East of England (Ref: 10/H0310/1). The assessment of these two strengthening regimes using a pragmatic approach meant that it was possible to assess their effectiveness in a 'real-world' scenario. Accordingly, were designed the trial following normal clinical practices for co-interventions and recruitment of participants typical of current practices, and based assessments largely on patient-reported clinical outcomes. This therefore could theoretically facilitate the generalisability of this trial's findings into current healthcare practices.

2.1 Eligibility criteria

The inclusion criteria were:

- Aged 16 years or over and referred to the out-patient physiotherapy departments at one of three hospitals in the East of England following FTPD.
    - A history of a single episode (traumatic or atraumatic) of patellar dislocation requiring reduction or having reported that their knee cap visibly "popped" out of joint, and
    - One of the following signs and symptoms of patellar instability:
        - (a) Apprehension when a laterally-directed force was applied to the patella
        - (b) Pain or tenderness along the medial retinaculum
        - (c) Abnormal patellar tracking or position e.g. lateralised, tilted, excursion such as the J-sign [8].
- Able to give informed written consent.

The exclusion criteria were:

- A history of two or more patellar dislocations on the same knee as the current episode of treatment. This was either self-reported or documented in the medical notes and may have been experienced at any time during the potential participant's lifetime.

- Current or potential immobilisation for longer than four weeks from injury to first physiotherapy appointment. The form or period of time within this four week window was not controlled since the current evidence-base has yet to demonstrate whether immobilisation is a significant confounder on outcome [19].
- Meniscal, anterior cruciate ligament, posterior cruciate ligament, lateral collateral ligament or medial collateral ligament injury in the same knee, determined by a negative Lachman test, anterior and posterior draw, valgus and varus stress tests, and absence of tibiofemoral joint line tenderness.
- Gross osteoarthritis changes of the patellofemoral joint [20,21] grade three or above) detected on plain x-ray.
- Previous surgical interventions on the affected knee for anterior knee pain or patellar instability symptoms.

2.2 Sample size calculation

The power calculation was based on a Lysholm Knee Score [22] (primary outcome) where a clinical difference of 15 points was considered clinically significant between individuals with or without patellar instability [23], a standard deviation of the Lysholm Knee Score after FTPD being 14 [24], a power at 0.90 with a chosen 5% significance level. This resulted in a sample size of 36 people being required, 18 per group, this was increased by 40% to account for attrition. Accordingly 50 people were recruited, 25 per group.

2.3 Randomisation

A telephone-based randomisation procedure was undertaken using an opaque numbered sealed envelope method to assign participants to either a general quadriceps exercise regime and rehabilitation (the control group) or a specific-VM exercise regime and rehabilitation (the experimental group). Stratified randomisation by site ensured that each site had an equal chance of providing both interventions to their cohorts and that the groups were balanced for differing levels of physiotherapy expertise.

2.4 Outcome Measures

Data were collected at baseline (pre-randomisation), and at six weeks, six months and 12 months post-randomisation. The primary outcome measure was the Lysholm Knee Score [20].

The secondary outcomes were:

- The NPI score [25].
- The Tegner Level of Activity Score [26].
- Isometric knee extensor muscle strength at zero, 30, 60 and 90 degrees knee flexion, assessed using a hand-held dynamometer (Basic Force Gauge, Mecmesin, Slinfold, West Sussex, UK).
- Frequency of recurrent patellar dislocation requiring Accident and Emergency or healthcare management.
- The duration and frequency of out-patient physiotherapy treatment.
- Exercise compliance using an exercise diary.
- The number of complications or adverse events. This included: the number of hospitalisations for recurrent patellar dislocation or for injury due to another reason; and physical discomfort of other musculoskeletal regions during the intervention period until discharge from physiotherapy.

The Lysholm Knee Score was adopted as the primary outcome measure since it has previously been demonstrated as a reliable and valid outcome measure for this population [24]. Whilst it was originally designed for the anterior cruciate ligament injury population (ACL) [22], instability is specially assessed in the questionnaire, and both cohort experience subjective 'knee' instability symptoms. Whilst the NPI Score [25] specifically assesses patellofemoral instability, and therefore may be deemed more reflective of the FTPD population's symptoms, this outcome measure had not been assessed for reliability or validity when commencing the trial, hence it's adoption as a secondary outcome measure. This assessment of the NPI Score's psychometric properties has subsequently been published [25].

In addition to the primary and secondary outcome measures, baseline data collected included gender, age, duration of knee instability, other joint disability of the symptomatic leg, contralateral patellar instability, disability of the contralateral leg, Beighton hypermobility score [27] and whether there was a family history of patellar dislocation.

All measurements were made by a physiotherapist in each centre, blinded to group allocation. The results of the intra- and inter-observer (each site's blinded assessor compared to the Chief Investigator) reliability scores are presented in Supplementary Table 1 and Supplementary Table 2. Based on Landis and Koch's [28] categorisation, this indicated acceptable intra-observer reliability with moderate to very good agreement between the first and second assessments made. Consequentially confidence was placed on the assessment processes across the three study centres.

2.5 Interventions

Immediately after randomisation, each individual was prescribed either specific-VM exercises or general quadriceps exercises and instructed to commence these there-after. The selection of specific-VM and general exercises was based on the findings from two systematic reviews assessing interventions for people following FTPD [8] and electromyography (EMG) preferential activation of the distal VM [13-18]. From this available EMG data, four exercises were identified which provided some evidence that the distal VM may be preferentially activated during these activities. These are presented in **Supplementary Figure 1**. The general quadriceps exercises are presented in **Supplementary Figure 2**. These were selected as the most frequently cited exercises prescribed by UK physiotherapists from the research team's national survey [9], whilst also being the analogue of the specific-VM exercises in a neutral rotational profile.

Each individual was asked to record their exercise compliance using an exercise diary. The frequency and duration of physiotherapy sessions were decided by the treating physiotherapist and this was recorded. Physiotherapists progressed individual's treatment as they felt appropriate in accordance with the pragmatic design of the trial.

All treatments were delivered in accordance to the allocated exercise programme and general rehabilitation guidelines. The general rehabilitation programme aimed to reduce of pain, swelling, stiffness and increase range of movement and function. The allocated exercises were designed either to generally strengthen or recruit VM or the quadriceps complex dependent on group allocation. Records were kept of the additional interventions prescribed as part of the general rehabilitation programme.

The care during the injury to physiotherapy period was standardised. The standard treatment for individuals following a FTPD in each hospital was a period of immobilisation ranging from three days to four weeks in a knee extension splint followed by physiotherapy. This was not altered in this trial.

Physiotherapists treating the participants decided when to finish treatment in line with a pragmatic study design. Participants were asked to record how often they continued their exercises post-discharge in an exercise diary which was reviewed at the 12 month assessment.

2.6 Data analysis

An intention-to-treat analysis method was performed. Histograms and the Shapiro Wilk W test were used to determine the dataset's distributed at each time point. Baseline differences between the groups were determined using mean, standard deviation (SD) and frequency values for demographic and clinical outcome measures prior to treatment. At each follow-up time point, differences between the groups were assessed descriptively (mean and SD or median and inter-quartile ranges dependent on data normality) and then analysed using the Student T-test for continuous outcomes and the Fisher's Exact Test for categorical data.

The primary analysis was between-group difference in Lysholm Knee Scores at 12 months using the Mann-Whitney U-Test. The secondary analyses included the mean or median difference in Lysholm Knee Score, Tegner Level of Activity score, NPI Score and isometric knee extensor strength results between the groups at six weeks, six and 12 months, with these analysed using the Student T-Test at six weeks, and the Mann-Whitney U Test at the six and 12 month follow-up periods to respect the normality of the dataset.

The level of statistical significance was set at 0.05. Ninety-five percent confidence intervals were presented to provide an indication of the precision of the inferential statistical analyses. All statistical analyses were performed using STATA Version 11.0 (STATA Corp LP, Texas, USA).

3.0 Results

3.1 Cohort characteristics

A cohort of 50 participants were recruited, 28 were male and 22 female, with a mean age of 23 years. The baseline characteristics of the two groups are presented in Table 1. The CONSORT Flow-Chart is presented in Figure 1. Groups were balanced for the baseline characteristics and adjustment for substantial baseline imbalances was not required.

3.2 Loss to follow-up

Fifty participants were recruited to the trial. At the six week follow-up, four participants were lost to follow-up from the quadriceps exercise group and nine from the VM group, giving an attrition rate of 26%. At six months, a further six participants were lost to follow-up in the VM group, six in the quadriceps exercise group, meaning data were available for 10 participants in the VM group, and 15 in the quadriceps strengthening group. The attrition rate at six months was therefore 50%. At the final 12 months follow-up, a further two participants were lost in the general quadriceps group, meaning data were available for 10 participants in the VM group, and 14 in the quadriceps strengthening group, giving an overall attrition rate of 52%. The baseline characteristics of those who were at final follow-up and those lost to follow-up is presented in Supplementary Table 3.

There was insufficient data to perform multiple imputations to estimate missing data using STATA Version 11.0. Therefore, the original dataset was analysed using intention-to-treat principles.

3.3 Primary analysis

There was a difference of six points between the groups in Lysholm Knee Score at 12 months, with a higher functional outcome for the general quadriceps exercise group (median: 95.0) compared to the specific-VM exercise group (median: 89.0; Table 2). This difference neared statistical significance (p=0.05; 95% CI: -14.0 to 0.0).

3.4 Secondary analyses

The Lysholm Knee Score, at the six week and six month follow-up assessments, showed that the general quadriceps exercise group had a higher score indicating superior functional outcomes. The median difference between the study groups was five points at six weeks and 9.5 points at six months. However this did not reach statistical significance at the six week (p=0.38; 95% CI: -6.7 to 17.4) or 6 month (p=0.14; 95% CI: -16.0 to 4.0) follow-up assessments.

The Tegner Level of Activity Score showed that the general quadriceps exercise group presented with higher mean Level of Activity Score compared to the specific-VM group at the six week (mean: 3.9 versus 3.1), six month (median: 6.0 versus 4.5) and 12 month follow-up assessments (median: 7.0 versus 5.0). This difference did not reach statistical significance at six weeks (p=0.28; 95% CI:-0.5 to 1.7) or at six months (p=0.10; 95% CI: -4.0 to 0.0). However there was a statistically significant difference between the groups at 12 months (p=0.04; 95% CI: -3.0 to 0.0).

Whilst the NPI Scores were similar between the groups at six weeks (Table 2), the general quadriceps exercise group reported lower NPI Scores, indicating a lower perception of instability symptoms at six months (10.2 versus 16.3) and 12 months follow-up (3.2% versus 7.3%). Whilst there was no statistical difference between the groups at six weeks (p=0.72; 95% CI: -7.6 to 10.8) or 12 months (p=0.23; 95% CI: -2.0 to 11.2), this reached borderline statistical significance at six months (p=0.06; 95% CI: -0.4 to 20.3).

The isometric knee extension strength showed no statistically significant difference between the VM and general quadriceps exercise groups at six weeks, six months or 12 months following commencement of rehabilitation ($p \geq 0.49$). There was no apparent trend in results between the two groups. At six weeks, the VMO group demonstrated greater knee extension strength at the zero and 30º isometric extension measurements, whereas the general quadriceps group demonstrated greater values for the 60º and 90º measurements. At six months, all but the 90º isometric measurement reported as higher in the VM compared to quadriceps exercise group. In contrast, the 12 month data indicated that the general quadriceps groups reported the higher isometric knee extension strength measurements at 0º and 90º, whereas the VM group's values where greater at the 30º and 60º (Table 2).

Two patients experienced recurrent patellar dislocation during the 12 months follow up; one at three weeks, and one at 26 weeks post-FTPD. Both participants were randomised to the VM exercise group. One further complication was noted during the 12 month follow-up. One patient, randomised to the general quadriceps group, experienced a patellar subluxation at six weeks post-randomisation.

A summary of the physiotherapy interventions received by participants is presented in Table 4. There was no significant difference between the groups regarding the duration participants adhered to the exercise intervention (p=0.11; 95% CI: -5.0 to 0.0), duration of physiotherapy (p=0.11; 95% CI: -5.0 to 0.0), number of physiotherapy sessions (p=0.16; 95% CI: -2.0 to 0.0) or number of appointments which participants did not attend (p=0.69; 95% CI: 95% CI: 0.0 to 0.0).

The two groups received similarly co-interventions in addition to their allocated strengthening/muscle recruitment intervention. There was however a statistical difference in the frequency that proprioceptive exercises (p=0.04) and tibiofemoral mobilisation techniques (p=0.01) were used, with a greater proportion of the VM group being prescribed these interventions compared to the general quadriceps exercise group.

4.0 Discussion

The findings of this trial suggest that whilst there was a statistical difference in Lysholm Knee Score and Tegner Level of Activity Score between general quadriceps and VM exercise groups at 12 months, this may not have necessarily been clinically important. There was no statistically or clinical significant difference for other measures or other time-points. Therefore there appears to be no significant difference in outcome between these two exercise regimes when used in conjunction with a general rehabilitation programme for people following FTPD.

Two studies have previously compared clinical outcomes for people prescribed general quadriceps or VM exercises in patients with PFP [29,30]. Both concurred with this trial's findings that there was little clinical or statistical difference in outcomes when individuals were prescribed general quadriceps exercises compared to specific-VM exercises. However there were major interventional differences between these trials and the current work. Both previous 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 [31]. Additionally the specific-VM exercises prescribed in Bennell et al's [29] study were performed with the lower limb in external rather than internal rotation. This contradicts the current evidence on preferential VM recruitment [17]. Furthermore, given that the PFP population present with different clinical features to FTPD cohorts [32], 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-VM over general quadriceps exercises is largely reaffirmed by the findings of this RCT. This therefore questions any assumption that there is a superiority of one intervention over another for clinical decision-making.

Although the minimally clinically important difference (MCID) of the Lysholm Knee Score has documented as 8.9 points in the ACL injury population [33], this has been estimated as being 15 points for the FPTD population [23]. Therefore this trial's difference of nine points at 12 months may provide non-clinically significant findings. However, the limited difference between the groups for this and other outcomes and follow-up intervals may be attributed to a Type 2 statistical error. The power calculation required a minimum of 18 individuals in each group to detect a statistical difference in Lysholm Knee Score if one existed. This was not met at any of the follow-up periods due to a high attrition rate, in which 52% percent of the potential cohort was lost to follow-up at 12 months. This finding mirrors the only other previous trial undertaken in the UK of people following FTPD, which similarly demonstrated difficulties in the recruitment and retention of participants following FTPD [34]. The only major difference between the follow-up strategies employed in this study was the adoption of a multi-centre recruitment and data collection policy which may have further contributed to high attrition.

The principal objective of a muscle strengthening exercise programme is to increase muscle strength [35]. Numerous studies have demonstrated that isometric and isokinetic quadriceps exercises can significantly increase knee extension strength over three week [36], eight week [37] and five month periods [38]. Whilst the specific-VM exercise programme used in this trial was based on EMG studies which have demonstrated an ability to preferentially recruit the VM [13-18], it was expected that this exercise programme could also increase knee extension strength [30,39]. Whilst not statistically significant, there were small mean differences in isometric knee extension strength between the groups at each follow-up period. This is plausible as resistance exercises have demonstrated an ability to increase muscle cross-section area as early as nine weeks after commencing an exercise programme [40]. Furthermore, neural factors have an important role in muscle strength gains [41]. 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 [41]. Similarly Farthing et al [42] 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 beginning an isometric exercise programme [42]. Whilst justifying how isometric strength can increase from baseline, the above studies were undertaken on uninjured people. It therefore remains unclear whether the increase in isometric muscle strength demonstrated in this trial can be attributed to these findings, or whether exercise response differs due to the inflammatory responses during early tissue repair following FTPD. Furthermore, the previous literature in patellar instability has focused on strength rather than recruitment and muscle control. Given that people following FTPD principally experience instability symptoms, the issue of muscle recruitment to control patellar tracking during dynamic tasks may be more valuable in symptom management and rehabilitation. Accordingly, further consideration on control and methods of assessing muscle recruitment for control during dynamic tasks frequently cited as associated with instability symptoms [1], may be valuable.

Only two participants experienced recurrent patellar dislocations during the study period. This low frequency may have been expected given the relatively short follow-up period. The optimal follow-up period to assess recurrent patellar dislocation has been estimated at two to three years post-FTPD [43]. Nonetheless, the finding of a low recurrent dislocation rates is particularly important given that the specific-VM exercise group performed their exercises in differing degrees of lower limb rotation and limb rotation has been associated with patellar instability [2,4]. These results suggested that specific-VM exercises did not place individuals at greater risk of re-injury.

Three key limitations should be considered when interpreting the results of this trial. Firstly, the anticipated drop-out rate was 40%, assumed from 27 studies which had assessed the conservative management of individuals following FTPD [8]. Actual attrition was 52%. It was not possible to determine what the cause of this attrition was since these participants were lost to all follow-up. This attrition was a major unexpected finding and future studies with people following FTPD should consider this when determining their *a priori* sample size. Secondly, the integrity of the medial patellofemoral ligament (MPFL) has been identified as a potential prognostic indicator for FTPD given its importance in maintaining lateral patellar restraint [44]. Individuals with a rupture of the MPFL possess a greater risk of recurrent patellar instability compared to those whose MPFL remain intact [45]. Since the MPFL may not be ruptured in all cases following FTPD even though there may be an elongation or partial tear, there may have been a difference between the groups in the proportion of MPFL deficit in each group [46,47]. This remains unknown as MRI was not normally undertaken as routine in the three study centres. Finally, isometric strength measurements demonstrated a large variation amongst individuals. Given the small sample size for the follow-up assessment, this may have skewed the results from a true-treatment effect. Further assessment of this outcome with larger follow-up cohorts would be required to determine the importance of this finding.

As Table 4 illustrates, although a number of other treatments where used as part of the general rehabilitation programmes of each group, there was only a significant difference between the groups for two of the interventions (proprioceptive exercises/tibiofemoral mobilisations). The decision not to control the co-interventions prescribed was made to follow the pragmatic study design adopted. Furthermore, there is no evidence that these specific interventions have a significant treatment effect which could have accounted for between group differences.

Three key areas for further study have been identified. Firstly, there remains controversy regarding the potential for the VM to be preferentially activated [17]. Specific-VM exercises were selected on an assumption that they preferentially recruit the VM [17]. However there is a body of evidence to suggest that this is not possible [17]. Therefore the non-statistically significant differences in results could be attributed to not being able to recruit this muscle. Secondly, the previous EMG data is based on asymptomatic or PFP populations. It is unknown whether these findings are generalisable to the FTPD population. Therefore, further research to assess whether these findings are reflective of the FTPD population is warranted. Finally, previous papers by Bennell et al [29] and McConnell [11] have suggested that these exercises should be performed in conjunction with an EMG biofeedback system. This is to increase visual and audio feedback of VM recruitment to assist in the "retraining" this muscle's activity [31]. No studies have specifically assessed the efficacy of this intervention following FTPD. Four studies have assessed the effectiveness of EMG biofeedback units with PFP populations and these have all demonstrated an improvement in the early clinical outcomes [37,48-50]. Consequently the efficacy of biofeedback alone remains unclear for PFP and FTPD populations. Further study to assess EMG biofeedback is therefore required before considering its use as an adjunct to exercise.

5.0 Conclusions

This trial indicated that whilst there was a difference in Lysholm Knee Score and Tegner Level of Activity Score between the exercise groups, there was no statistically or clinical significant difference for these measures during the first 12 months post-commencement of rehabilitation following a FTPD. However participant attrition may be a major problem in the investigation of this population. Further investigation of the capability of specific-VM exercises to preferentially activate the VM in people following FTPD, and the potential importance of MPFL rupture for this population is warranted to understand the exercise prescription for people post-FTPD to minimise the potential for long-term instability and functional disability.

Funding: The conduct of this study was funded by Action Arthritis (http://www.actionarthritis.org/).

Conflicts of Interest: No author has any conflicts of interest to declare.

Ethical Considerations: This study was approved by the National Health Service Research Ethics Committee – East of England (Ref: 10/H0310/1), the Norfolk and Norwich Research Governance Committee (2010ORTH04 62-03-10), Norfolk Primary Care Research Governance

(2010ORTH04) and Queen Elizabeth Hospital, Kings Lynn Research Governance (07/10-10/H0310/1).

Acknowledgements

We would like to thank the Out-Patient Musculoskeletal Physiotherapy Departments at Lowestoft Hospital (Mr David Sweeting), Queen Elizabeth Hospital, Kings Lynn (Mrs Kate Preston and Mr Nigel Taggat), and the Norfolk and Norwich University Hospital (Mrs Claire Howlett, Mr Chris Wheeler and Mrs Charlotte Harrison) for their assistance the recruitment, treatment and data collection of participants to this trial.

Legends for Figures and Tables

Figure 1: Trial CONSORT Flow Diagram

Table 1: Demographic characteristics and baseline data

Table 2: Between-group difference of VM versus General Quadriceps exercise groups at each follow-up interval

Table 3: Complications

Table 4: Physiotherapy delivery between the two randomised groups

Supplementary Table 1. The intra-class coefficient values from the evaluation of intra-observer reliability for the assessment of quadriceps extension strength.

Supplementary Table 2: The intra-class coefficient values from the evaluation of inter-observer reliability for the assessment of quadriceps extension strength.

Supplementary Table 3 Baseline characteristics of participants at 12 month follow-up versus those lost to follow-up.

Supplementary Figure 1: VM Exercise Rehabilitation Group

Supplementary Figure 2: General Quadriceps Rehabilitation Group

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Figure 1: Trial CONSORT Flow Diagram

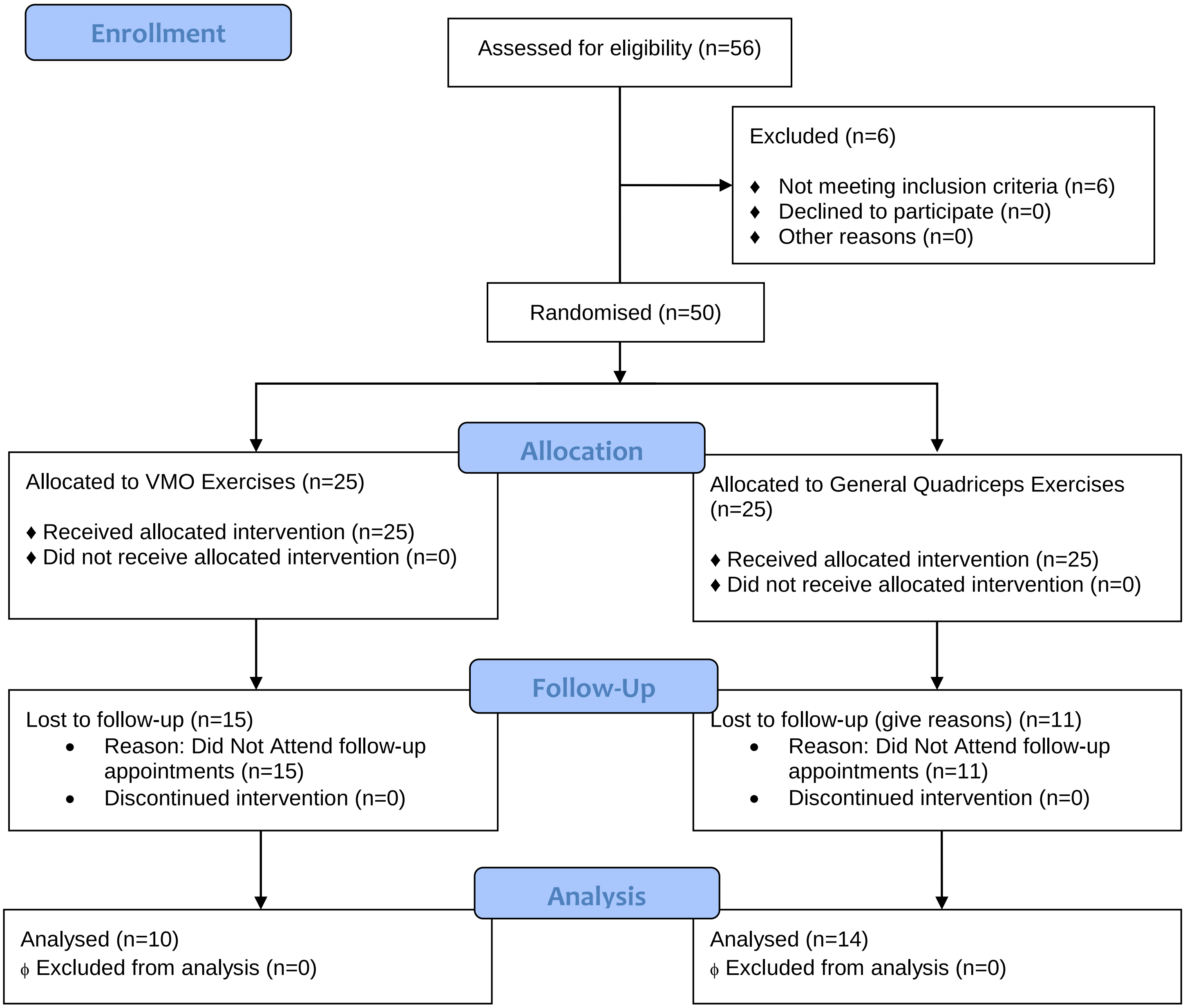

Table 1 Demographic characteristics and baseline data

	Specific-VM Exercise Group	**General Quadriceps Exercise Group**
Number of Participants	25	25
Mean (SD) age (years)	23.9 (7.5)	23.0 (6.9)
Gender (m/f)	14/11	14/11
Mean (SD) duration since FTPD (days)	22.2 (24.1)	27.9 (29.6)
Family history of PFI (yes/%)	2 (8)	0 (0)
Ipsilateral lower limb injury (yes/%)	4 (16)	0 (0)
Contralateral PFI (yes/%)	4 (16)	2 (8)
Contralateral lower limb injury (yes/%)	0 (0)	1 (4)
Multi-joint injury/pathology (yes/%)	1 (4)	1 (4)
Mean (SD) Beighton Hypermobility Score	3.2 (3.3)	2.6 (2.5)
Mean (SD) Isometric knee extension strength at 0˚ flexion (N)	35.8 (38.9)	33.4 (43.8)
Mean (SD) Isometric knee extension strength at 30˚ flexion (N)	85.9 (58.8)	89.9 (50.5)
Mean (SD) Isometric knee extension strength at 60˚ flexion (N)	97.9 (48.5)	116.2 (65.4)
Mean (SD) Isometric knee extension strength at 90˚ flexion (N)	100.4 (64.9)	118.3 (89.2)
Mean (SD) Tegner Activity Score	2.3 (1.8)	2.5 (2.1)
Mean (SD) Lysholm Knee Score	42.5 (24.8)	46.1 (29.2)
Mean (SD) NPI Score	34.8 (26.5)	29.3 (24.5)

F – Female; FTPD – First Time Patellar Dislocation; M – Male; N – Newtons; NPI Score – Norwich Patellar Instability Score; PFI – Patellofemoral Instability; VM – Vastus Medialis

Table 2 Between-group difference of VM versus General Quadriceps exercise groups at each follow-up interval

	Six-Weeks			Six Months			Twelve Months		
	Mean (SD)		Statistical Difference† (p-value; 95% CI)	Median (IQR)		Statistical Difference‡ (p-value; 95% CI)	Median (IQR)		Statistical Difference‡ (p-value; 95% CI)
	VM (n=16)	General Quads (n=21)		VM (n=10)	General Quads (n=15)		VM (n=10)	General Quads (n=14)	
Lysholm Knee Score	73.0 (18.8)	78.3 (17.2)	0.38 (-6.7, 17.4)	84.5 (79.0-95.0)	95.0 (83.0-100.0)	0.14 (-16.0, 4.0)	89.0 (81.0-95.0)	95.0 (90.0-100.0)	0.05 (-14.0, 0.0)
Tegner Activity Score	3.3 (1.5)	3.9 (1.8)	0.28 (-0.5, 1.7)	4.5 (4.0-5.0)	6.0 (3.0-9.0)	0.10 (-4.0, 0.0)	5.0 (5.0-6.0)	7.0 (5.0-8.0)	0.04 (-3.0, 0.0)
NPI Score	15.3 (11.7)	16.9 (14.9)	0.72 (-7.6, 10.8)	16.3 (6.4-29.7)	10.2 (0.0-15.6)	0.06 (-0.40, 20.3)	7.3 (1.7-12.6)	3.2 (0.0-10.8)	0.23 (-2.0, 11.2)
Isometric knee extension strength at 0˚ flexion (N)	93.5 (47.1)	83.9 (38.4)	0.50 (-38.1, 19.0)	110.9 (50.6-159.2)	94.4 (81.3-143.2)	0.82 (-37.6, 51.2)	91.5 (75.0-126.5)	102.5 (83.6-136.5)	0.62 (-46.0, 35.9)
Isometric knee extension strength at 30˚ flexion (N)	167.1 (66.5)	164.7 (70.2)	0.91 (-48.7, 43.8)	177.0 (124.2-202.4)	170.5 (136.2-196.4)	0.82 (-46.0, 66.2)	190.4 (178.2-236.1)	186.6 (146.1-250.5)	0.62 (-44.6, 95.1)
Isometric knee extension strength at 60˚ flexion (N)	172.0 (56.1)	180.3 (74.1)	0.71 (-36.8, 53.5)	216.9 (148.9-236.6)	204.5 (136.3-253.0)	0.89 (-54.7, 59.0)	230.4 (158.8-267.1)	228.7 (154.7-281.5)	0.83 (-78.5, 82.3)
Isometric knee extension strength at 90˚ flexion (N)	177.6 (63.8)	181.6 (75.0)	0.86 (-43.4, 51.5)	189.8 (148.5-237.7)	245.0 (134.3-267.4)	0.49 (-82.8, 36.6)	247.9 (178.8-281.1)	258.4 (172.2-286.6)	0.62 (-91.9, 55.1)

† - Student T-Test; ‡ Mann-Whitney U Test

CI – Confidence Intervals; N – Newtons; n – number of participants; NPI Score – Norwich Patellar Instability Score; Quads – Quadriceps Exercises; VM – Vastus Medialis Exercises

Table 3 Complications

	Frequency		**Statistical Difference† (p-value; 95% CI)**
	VM (N=16)	**General Quads (n=21)**	
Recurrent Dislocation (Yes/%)	2 (12.5)	0 (0)	0.08 (-0.0, 0.2)
Duration from FTPD to second patellar dislocation in weeks (Mean/SD)	14.5 (16.3)	0 (0)	0.08 (0.0, 0.0)
Number of dislocations in 12 months	3	0	0.03 (1.2, 1.6)
Complications	0	1 (PFJT Subluxation)	0.22 (-0.0, 0.1)

† - Chi-Squared Test

CI – Confidence Intervals; FTPD – First Time Patellar Dislocation General Quads – General Quadriceps exercises; SD – Standard Deviation; VM – Vastus Medialis exercises

Table 4 Physiotherapy delivery between the two randomised groups

	Frequency		Statistical Difference (p-value)
	VM (n=25)	General Quads (n=25)	
Number of DNAs (Median; IQR)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.69
Number of PT sessions (Median; IQR)	3.0 (2.0-4.0)	4.0 (2.0-6.0)	0.16
Duration of PT in weeks (Median; IQR)	6.0 (4.0-6.0)	6.0 (5.0-7.0)	0.11
Duration of exercising in weeks (Median; IQR)	6.0 (4.0-6.0)	6.0 (6.0-8.0)	0.11
Interventions provided to each exercise programme			
Modified wall slide exercise	25	0	**N/E**
Isometric quadriceps with hip rotation in semi-squatting position	25	0	**N/E**
Leg dips in internal femoral and tibial rotation	25	0	**N/E**
Isometric quadriceps and tibial internal rotation	25	0	**N/E**
Wall slide in neutral	0	25	**N/E**
Isometric quadriceps in semi-squat neutral	0	25	**N/E**
Leg dips in neutral	0	25	**N/E**
Isometric quadriceps in neutral	0	25	**N/E**
Knee Rom exercises	7	9	0.54
Ice	6	7	0.75
Ultrasound of medical retinaculum	6	7	0.75
Hamstring stretches	2	4	0.38
Calf Stretches	2	5	0.22
Glutei exercises	9	4	0.11
Proprioception exercises	6	1	**0.04**
Lateral retinaculum frictions	6	11	0.14
Medial Patellar Glides	1	0	0.31
Tibiofemoral Mobilisations	7	0	**0.01**
Inferential/Ultrasound combined	2	1	0.55
Acupuncture	0	0	1.0
Gym programme	2	0	0.15
Taping techniques	14	12	0.57
Tubigrip and compression bandage	3	2	0.64
Straight leg raise	2	1	0.55
Inner range quadriceps strengthening	8	8	1.00
Gait Re-education	6	6	1.00
Static Quadriceps in neutral	10	4	0.06

Running	1	2	0.55
Bike	7	6	0.75
Ankle ROM exercises	0	1	0.31
	4	2	0.38

DNA – Did Not Attend; N/E – Not estimated; ROM – Range of Motion; PT – Physiotherapy

Supplementary Table 1 The intra-class coefficient values from the evaluation of intra-observer 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	0.00, 0.96
	Assessor 2	0.79	0.00, 0.99
	Assessor 3	0.90	0.10, 0.99
	Assessor 4	0.90	0.12, 0.99
3	Assessor 1	0.45	0.00, 0.95
	Assessor 2	0.62	0.00, 0.97

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

Supplementary Table 2 The intra-class coefficient values from the evaluation of inter-observer reliability for the assessment of quadriceps extension strength.

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

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

Supplementary Table 3. Baseline characteristics of participants at 12 month follow-up versus those lost to follow-up.

	Participants lost to final follow-up	**Participants at final follow-up**
Number of Participants	26	24
Group Allocation (General Quadriceps Exercises/VM Exercises)	16/10	10/14
Mean (SD) age (years)	23.2 (7.4)	23.8 (6.0)
Gender (m/f)	12/14	17/7
Mean (SD) duration since FTPD (days)	23.0 (34.2)	30.1 (29.6)
Family history of PFI (yes/%)	2 (7.7)	0 (0.0)
Ipsilateral lower limb injury (yes/%)	1 (3.8)	3 (12.5)
Contralateral PFI (yes/%)	1 (3.8)	5 (20.8)
Contralateral lower limb injury (yes/%)	0 (0.0)	1 (4.2)
Multi-joint injury/pathology (yes/%)	1 (3.8)	1 (4.2)
Mean (SD) Beighton Hypermobility Score	3.3 (3.1)	2.4 (2.7)
Mean (SD) Isometric knee extension strength at 0˚ flexion (N)	28.0 (34.9)	43.2 (46.3)
Mean (SD) Isometric knee extension strength at 30˚ flexion (N)	81.8 (51.4)	93.1 (61.2)
Mean (SD) Isometric knee extension strength at 60˚ flexion (N)	109.5 (63.2)	106.2 (61.9)
Mean (SD) Isometric knee extension strength at 90˚ flexion (N)	106.9 (83.7)	116.8 (79.4)
Mean (SD) Tegner Activity Score	2.5 (1.9)	2.5 (1.9)
Mean (SD) Lysholm Knee Score	48.4 (27.0)	44.2 (26.9)
Mean (SD) NPI Score	28.4 (26.0)	34.1 (24.3)

F – Female; FTPD – First Time Patellar Dislocation; M – Male; N – Newtons; NPI Score – Norwich Patellar Instability Score; PFI – Patellofemoral Instability; VM – Vastus Medialis

Supplementary Figure 1: VM Exercise Rehabilitation Group

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.

Supplementary Figure 2: General Quadriceps Rehabilitation Group

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.