University of Alberta

THE EFFECTS OF DEEP LEG SQUATS ON PATELLOFEMORAL PAIN SYNDROME – A SINGLE SUBJECT DESIGN STUDY

by

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ABSTRACT

Patellofemoral Pain Syndrome (PFPS) is a common knee disorder. Its etiology is not clear and appears to be multifactorial. There are several options of treatment; however none uses total knee flexion since it is thought to increase symptoms. This study was an exploratory multiple baseline-Single Subject Design that used an innovative protocol of deep squats on 11 subjects with PFPS. The objectives were to evaluate: 1) the protocol as treatment for PFPS and its feasibility and 2) how pain and function changed over time. Pain and function changed over the first half of the protocol. All subjects were compliers (20 or more days of squats), but the amount of performance varied. Eight subjects (72.7%) had a clinically relevant pain reduction, 6 performed $\geq 80\%$ however, 2 performed $\leq 32\%$ of the protocol. Overall, deep squats appear to be a promising and feasible intervention for PSPS, however more studies are necessary.

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CHAPTER 1. **INTRODUCTION**

1.1   Problem Statement

Patellofemoral Pain Syndrome (PFPS) is a common disorder of the knee. It is defined as anterior or retropatellar pain, which is exacerbated by sustained sitting, kneeling, ascending or descending stairs and squatting (1). It is estimated to be 25% to 40% of the complaints in orthopaedic and sports medicine clinics (2), both in active and non-active populations (3). It is estimated that PFPS affects 7% to 40% of adolescents and active young adults (3).

The etiology of PFPS is unclear, but appears to be multifactorial (1,4). Historically, a few studies have observed radiological differences in patellar alignment between asymptomatic and symptomatic knees, leading to the idea of a cause-and-effect relationship of lateral patellar malalignment and PFPS symptoms (5). Many theories were proposed to explain the origin of the patellar malalignment: a delayed firing or weakness of the vastus medialis obliquus (VMO), patellar tilt, tightness of the lateral knee retinaculum, hamstrings or iliotibial band, and excessive pronation of the subtalar joint (4,6,7). In addition, cartilage damage is also considered an etiological factor in PFPS. Studies have also shown a correlation between cartilage damage or decreased cartilage thickness and patients with PFPS symptoms (8-10).

Due to the many possible etiological factors, the literature describes different types of treatments. Quadriceps strengthening, patellar taping, soft tissue stretching, use of knee braces, foot orthoses, and adjusted physical activity have demonstrated some effectiveness for many patients with mild PFPS symptoms (1-3,11,12). However, the literature indicates that the quality of studies evaluating treatment effectiveness is poor

(2,13) and that there is no consensus about the ideal treatment for patients with PFPS (1,11).

In the search for a more effective treatment for PFPS, a group of physical therapists in British Columbia, Canada, developed and have been treating patients with PFPS with a new exercise protocol. The protocol is based on multiple repetitions of deep squats, which are believed to help the healing of the articular cartilage, thus decreasing their symptoms. Therefore, the objectives of this exploratory study were:

1. To evaluate and observe:

    a. Whether the protocol of deep squats was helpful to decrease pain and improve function in subjects with PFPS,

    b. Whether this protocol was feasible as treatment for PFPS (i.e. whether people can and will perform it),

2. To visually investigate how pain and function changed over the course of the treatment period,

3. To explore possible individual factors that could have influenced the outcomes of interest (i.e. pain and function).

CHAPTER 2.   **LITERATURE REVIEW**

2.1   Epidemiology of Patellofemoral Pain Syndrome

Among physically active people, females, young adults and adolescents, PFPS is one of the most frequent knee complaints, being the most common injury seen in most sports clinics (14). It represents 34% of knee injuries and 10% of all musculoskeletal disorders (2). In clinics that manage patients who have musculoskeletal problems, patellofemoral pain syndrome accounts for almost 10% of all visits (76 of 814 visits) and between 20% to 40% of all knee problems (76 of 266 visits) (1). It has also been reported that anterior knee pain was the most frequent complaint in a young population, having 9% incidence in young athletes (2). PFPS often becomes a chronic condition and can be frustrating for both the patient and the clinician to treat.

2.2   Etiology of Patellofemoral Pain Syndrome

While the etiology of PFPS is unclear, there is widespread acceptance that the primary cause is malalignment of the patella (4-6,11,13,15,16). Patellar malalignment has been defined as the abnormal positioning of the patella in any plane (17). This positioning is believed to place potentially uneven stresses on both the patella itself and the peripatellar tissues, leading to PFPS (5). However, all the patellar alignment clinical measurement techniques have been proven to have poor reliability and/or validity (5). In addition, when studies did show positive results, the subjects studied had different knee conditions -such as patella subluxation – rather than PFPS, or they were control subjects; and, the radiological studies differed in X-ray techniques, patient position for X-ray, or knee range

of motion (5). In addition, Wilson (2007) enumerated many studies that indicated no correlation between patellar alignment and PFPS symptoms (5).

Different studies have indicated that patellar positioning is not the only cause of PFPS (1,13,15,18). These authors suggest that the whole lower extremity alignment may play a role in the dynamics of the patellofemoral joint. Excessive pronation of the foot internally rotates the tibia and femur and therefore increases the resultant lateral forces on the patella (which may increase pressure and provoke pain) (1,4,15). On the other hand, it is important to consider that most biomechanical studies analyzing the relationship between foot/ lower extremity alignment and PFPS have been anecdotal or theoretical (15). Stronger evidence of this relationship is available in the clinical area, with reports regarding the effect of foot orthoses on the patient pain, function and satisfaction (15,18).

Cartilage damage is also considered one of the causes of PFPS. Magnetic resonance imaging (MRI), performed on patients with anterior knee pain, has revealed a high prevalence of patellar cartilage lesions (10). In addition, Draper et al in 2006 reported that healthy male subjects had 18% greater patellar cartilage thickness than males with PFPS, in the superior and middle area of the patella (8). However, the presence of articular cartilage damage on MRI does not imply patient symptoms (9). In 2001, Joensen et al demonstrated cartilage lesions in 17 out of 24 PFPS patients (odds ratio 7.9; 95%CI: 1.9-33), 45.8% of them had minor lesions (grade 1 -soft spots or blisters), and 4 out of 17 controls also had lesions (9). However, since articular cartilage is aneural (19-21), it has been postulated that change in the cartilage characteristics (not necessarily a cartilage lesion) could affect its proper function, placing greater stress on the highly innervated subchondral bone, promoting PFPS symptoms (8,19)

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2.3   Treatment of Patellofemoral Pain Syndrome

The wide range of possible PFPS etiologies can explain the many different types of treatments presented in the literature (1,2,4,12,12,13). Conservative physical therapy treatment is the most common management strategy for PFPS (22), and includes interventions such as: exercise, patellar taping, stretching, retraining of the hip muscles, and foot orthotics (22).

2.3.1   Exercise and Patellofemoral Pain Syndrome

The majority of the exercise programs for PFPS emphasize strengthening of the quadriceps muscle, some in particular the vastus medialis obliquus (VMO) muscle (4). It is known that exercise therapy is better than no therapy (4), but there is no evidence showing what kind of exercise – isokinetic, isometric, open kinetic chain, closed kinetic chain, specific VMO recruitment – is more beneficial for patients with PFPS (23). In fact, Bolgla et al reviewed 20 years of studies looking at exercise therapy for PFPS and concluded that all quadriceps exercises (the ones cited above) were effective in reducing pain in PFPS patients. It is important to mention, however, that some studies reviewed by Bolgla et al (23) and Earl et al (4) did not specify how long the symptoms were present, did not perform proper statistical analysis, and had a wide subject age range (older people can have degenerative problems instead of PFPS); which decrease the internal validity of the studies and therefore of the review. Even though it is known that quadriceps exercises are helpful in the treatment of PFPS, more studies with greater rigor and better subject selection are necessary.

2.3.2   Patellar Taping

Patellar taping is commonly used in PFPS treatment in an attempt to improve patellar tracking during knee flexion/extension by repositioning the patella (4). McConnell et al

(1986) stated that patellar taping places less stress in the lateral patellar area, decreasing symptoms with a 96% success rate (16). A more recent study has compared exercise programs with patellar taping against only exercise and found no statistical significant differences between groups (23).

2.3.3   Hip Musculature Retraining

There is evidence that PFPS patients have decreased strength in the gluteus medius and other hip muscles, which may dynamically influence the alignment of the lower extremity, resulting in increased stress in the lateral peripatellar area and PFPS (4,24,25). Studies highlight a decrease in pain, increase in functional status, and increase in quadriceps and hip strength after an intervention focusing on the strengthening of the hip, quadriceps and trunk muscles (26-28).

2.3.4   Foot Orthoses

As explained previously, it is believed that foot pronation can cause abnormal lower extremity internal rotation, which could position the patella more laterally in the femoral groove and provoke pain (2). In their review, Bizzini et al concluded that there was some evidence for use of foot orthotics to decrease excessive foot pronation in patients with PFPS (2). Gross et al (2003) identified 4 studies that used pain rating as clinical evidence supporting foot orthoses in PFPS treatment (15). Taken together, the four studies suggest that orthoses may decrease symptoms and improve function in patients with PFPS who demonstrate excessive foot pronation. However, the author mentions that only two of these studies provided a specific description of "excessive foot pronation" criteria and appropriately described the subject's inclusion and exclusion criteria (29,30). In addition, the common clinical test for assessing foot pronation was shown to have poor reliability

and sensitivity (31); which makes it harder to provide guidelines regarding foot characteristics of patients who might benefit from the use of foot orthoses.

2.4   Squat Exercises and Patellofemoral Pain Syndrome

The literature supports the use of exercises as treatment for patellofemoral pain syndrome (1,23,23,32). The squat is a closed kinetic chain exercise commonly used in knee rehabilitation settings, and it also can strengthen hip, thigh, and back musculature, which are very important for jumping, running and lifting (33). The squat begins with the individual in the upright position with the knees and hips fully extended. The individual squats down to the desired depth, which can be variable, and then ascends back to the upright position, in one continuous motion (33). Squats can be performed to different knee flexion angles: half squat – thighs can get parallel with the ground with approximately 0°-100° knee flexion; deep squat – as far down as possible until thighs and leg touch each other (33). Since one of the possible PFPS causes is excessive pressure between patella and femur, the half squats (up to 50° of flexion) are typically recommended for PFPS as they generate only to the moderate compressive patellofemoral forces (33-36). However, compression forces are calculated with mathematical models that try to imitate human joints, which do not provide exact physiological information. Also, with PFPS, the pain occurs during common daily activities (i.e. running, sitting, going up and down stairs) and these activities only require small knee flexion angles (up to 90°) (10,33-35). These facts lead one to question whether controlling for compressive forces really helps in the treatment of PFPS.

Cartilage damage has been investigated as a cause of PFPS. The function of cartilage depends on the interaction between the matrix (made of collagens and proteoglycans) and the interstitial fluid (20,37). With compression, the pressure increases, and the fluid is pushed out of the cartilage into the joint. When the pressure decreases, the fluid diffuses

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back into the cartilage (8,12)(8,12). This fluid flow has a role in cartilage nutrition and in chondrocyte biosynthesis (8,12,20,21,37). Since fluid flow is generated by mechanical compression (thus promoting cartilage deformation) (20,21,37); mechanical compression is thought to be crucial to the good health of articular cartilage (20,21).

Squats have already been shown to promote cartilage deformation and fluid flow (37-39). In addition, cartilage deforms only where contact between the surfaces occurs (38,39). Since the patella has different contact areas with the femur during flexion and extension and only full range of motion (0° -135°) promotes full patellar contact (33), nutrition and the health of the cartilage could be compromised in some areas, if the joint does not move through full range.

Considering the information above, the idea of treating PFPS with full range of motion exercises and joint loading, such as deep squats, seems reasonable. Besides, physical therapists in British Columbia/Canada have been using a deep squat protocol as treatment for PFPS for over a decade, and they report their clinical results to be encouraging. Their experience showed that most changes in symptoms happen during the first two weeks of treatment. While the protocol is in clinical use, no controlled study has been conducted to investigate whether it is effective.

CHAPTER 3. **METHODS**

3.1   Study Design

Considering that deep squats are an innovative and under-investigated intervention, an exploratory study was conducted using Single Subject Design (SSD) methodology. Specifically, a multiple baseline design was used. SSDs are a major experimental research category that employs prospective designs focusing on the effectiveness of a treatment in the context of a specific subject or a small group of subjects in a specific setting (40). SSDs have some advantages over traditional Group Design such as compatibility of treating an individual or small group of patients, measurement of variables highly relevant to the patient, assessment of performance over time, and design validity through the use of systematic repeated measurements (41). Group designs do not allow individual assessments, or differentiation between individual subjects who respond positively or negatively. As the objective of this study was to evaluate the symptom change and the effectiveness of deep squats as treatment for PFPS patients, and as deep squats are an exploratory, new, and controversial treatment for PFPS (because of the increased PF joint pressure), SSD was considered a good option for this study.

As one type of study design inside the SSD methodology, the multiple baseline design was chosen for this exploratory study because it controls for threats to internal validity such as: natural history of PFPS and maturation of symptoms without requiring that treatment be withdrawn (40). The format is based on several single-system studies, with baselines at different times and/or durations having a minimum of three data points (40,42).

3.2   Subjects

After obtaining approval from the Health Research Ethics Board of the University of Alberta (Appendix 1), male and females subjects were recruited in the Edmonton area through advertisements (Appendix 2). The advertisements were posted on the University of Alberta campus, a physical therapy clinic, a sports centre, university faculties, and through the University of Alberta International Student Network (UAISN). Subjects who responded to the advertisement went through a two-stage process to determine their suitability for the study. Firstly, a telephone and/or email screening was used to identify major exclusion criteria and to explain the study (Appendix 3). Secondly, an appointment was held at the University of Alberta where subjects were examined by a physical therapist to determine whether they were suitable for the study (i.e. they met all the inclusion criteria) (Appendix 4). At the completion of this physical examination, eligible participants were provided with an information sheet (Appendix 5), completed the informed consent (Appendix 6), and baseline outcome measures (pain and function) were taken. Patients with bilateral pain were asked to consider only the most painful knee when completing the self-reported scales (i.e. only the most painful knee was used for all measurements).

3.2.1   Inclusion and Exclusion Criteria

The inclusion criteria were based on previous studies (46,47) and included:

1. males and females 18 to 40 years old (for consent purposes, and to decrease the chance of degenerative joint diseases)

2. having retropatellar pain in 1 or both knees

3. symptom duration greater than 3 months

4. history of insidious onset (i.e. injury not related to trauma)

5. Visual Analogue Scale (for pain) ≥ 2 at interview and/or at baseline

6. pain during at least 3 of the following:

    a. manual compression of the patella against the femur at rest or while performing a quadriceps contraction with the knee extended

    b. palpation of the borders of the patella

    c. squatting,

    d. stair climbing,

    e. kneeling, or

    f. prolonged sitting.

The exclusion criteria were chosen based on current knowledge and on previous studies (46,47). The exclusion criteria were a history of:

1. concomitant injury or pathology of other knee structures (e.g. menisci, collateral and cruciate ligaments, patellar tendon, iliotibial band, pes anserinus)

2. prior knee surgery

3. patellar dislocation or subluxation

4. Sinding-Larsen-Johansson syndrome or Osgood-Schlatter disease

5. knee effusion

(All of the above were chosen in order to avoid recruiting subjects with knee problems other than PFPS, or with signs and symptoms of inflammation)

6. cancer (in order to avoid other sources of pain)

7. cognition impairment (in order to avoid problems in understanding the exercise protocol)

8. cardiac disorders (in order to avoid cardiac complications due to exercise)

9. pregnancy (in order to avoid health complications due to exercise)

10. low back, hip or foot/ankle pain (in order to avoid problems in performing the exercises)

and,

11. VAS < 2 at interview and/or at baseline (in order to allow detection of clinically relevant decrease in pain)

12. foot pronation or foot orthoses (to avoid co-interventions that could interfere with treatment outcomes since based on literature orthoses decrease symptoms in patients with PFPS) (Appendix 7)

3.2.2 Definitions

The terminology for this study was defined as:

- Deep Squats: descending and ascending squatting movement, flexing the knees to a maximum angle, and touching the back part of the thighs on the back part of the legs (hamstrings touching calf muscles).

- Baseline period: the period of time, during the study, that the subjects did not perform the deep squats protocol as treatment but answered the self-reported scales (pain and function).

- Protocol of deep squats: several pre-determined sets and repetitions of deep squats divided into 3 phases of 2 weeks each. (i) Phase 1: weeks 1 and 2, 14 days of deep squats, subjects progress from 5 sets of 10 to 5 sets of 50 (total of 1850 squats in this phase). (ii) Phase 2: weeks 3 and 4, 6 days of deep squats, subjects progress from 4 sets of 60 to 4 sets of 80 repetitions (a total of 1640 squats). (iii) Phase 3: weeks 5 and 6, 5 days of deep squats, subjects progress from 3 sets of 80 to 2 sets of 100 (a total of 1155 squats) (see page 24 – 26).

- Visual Analogue Scale (VAS): a 10 cm long line with "no pain" written in one end and "worse pain imaginable" on the other end. It is a self-reported pain scale (see page 26).

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- Kujala questionnaire: also known as Anterior Knee Pain Scale (AKPS) is a 13-item numerical scoring instrument that measures function in people with PFPS. It weigh the questions differentially for a maximum score of 100, with lower scores indicating worse function (see page 27).

- Compliance: the number of days in which the subjects performed any number of the suggested number of squats, since part of the protocol was to stop squatting when symptoms increased to unusual levels (see page 28).

- Compliers: subjects who performed any number of squats on 20 or more days (80% of the 25 total possible days of squats)

- Performance: the percentage of the protocol performed (i.e. percentage of number of squats performed over the number of squats suggested). Performance was calculated first, for each day, and then for the whole protocol (see page 29).

3.2.3   Sample Size

Portney and Watkins suggest a minimum of three subjects for a multiple baseline SSD study (42). However, the literature reviewed found samples ranging from 3-9 subjects (40,43). In order to avoid the consequences of drop-outs and trying to keep the sample size close to 9 subjects, the investigator recruited 11 subjects. All subjects were university students at the University of Alberta, and there were no drop-outs.

3.2.4   Outcomes

Pain and function were chosen as clinical outcomes. Pain is the main complain of this population and therefore it was considered the main outcome. Another complaint of subjects with PFPS is the difficulty or inability to perform their regular activities, therefore function was chosen as a secondary outcome.

3.2.5   Main Study Procedures

The 11 subjects were randomly assigned to one of the three baseline periods: 7 days, 13 days or 19 days. The baseline period was the amount of time that subjects waited for the start of treatment. During the baseline period, measurements were taken every 3 days; for example: the participant who was placed in the 7-days baseline period had measurements taken at day 1, day 4 and day 7. These 3-day measurement intervals were chosen in order to: 1- respect the multiple baseline design requirements (minimum of 3 baseline data points), 2 - give a reasonable time interval to capture any changes in the PFPS symptoms (3 days), and 3 – not make the baseline a very long waiting period for subjects (minimum 7-day baseline, maximum 19-day baseline).

The randomization was performed by asking the subjects to draw a sealed, opaque envelope with the baseline group number inside. Envelopes were opened after the subject signed the informed consent form. The investigator and the subject were not blinded to group status. The baseline group numbers were as follow: "B7" for the 7-day baseline group, "B13" for the 13-day baseline group, and "B19" for the 19-day baseline group. Each of the three envelopes had a different group number; therefore, randomly, 5 subjects were placed into B7, 5 into B13 and 4 into B19.

The study period consisted of one of the baseline periods (7, 13 or 19 days) plus the treatment period (6 weeks). The minimum amount of time that a subject was enrolled in this study was 7 weeks – for subjects in group B7-, and the maximum amount of time was 8 weeks and 5 days – for subjects in group B19. Measurements were taken every three days, considering the first appointment (interview) as day 1. The measurements were: self-reported pain and function. After the baseline period, the subjects underwent a 6-week treatment of deep squat exercises. In summary, after signing the consent letter, the baseline period started. During the baseline period, there was no treatment, since the

intention was to control for the natural progression of the disorder; and then, there were 6 weeks of treatment, as shown in Figure 1. Each subject's pain and function were measured every 3 days during the study period.
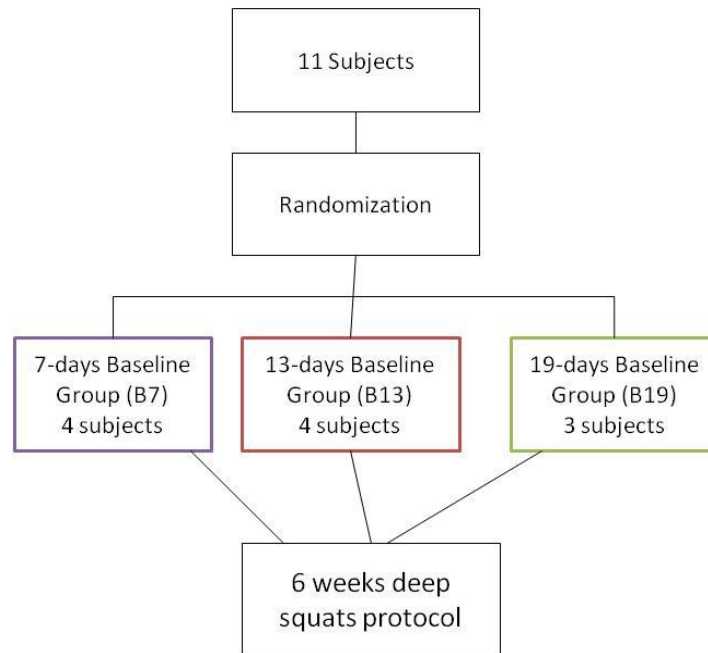
Figure 1. Study Design.

3.3   Deep Squats Protocol

As mentioned, the deep squats protocol has been performed by physical therapists in British Columbia/Canada for over a decade with good results reported. It is divided into 3 phases of 2 weeks each, where patients perform multiple sets of 2-leg deep squats (Appendix 8). Squats were performed with the feet shoulder width apart, toes slightly out and heels elevated 2-4 cm on a pad. Elevation of the heels was shown to assist the lower extremity muscles during deep squat movement (44), therefore subjects were encouraged to use the pad under their heels during week 1 and 2. After the first two weeks, participants were instructed to keep their heels fully on the floor. However, if it was not

possible to perform greater knee flexion (deeper squat) without the heel pad, the subjects were allowed to continue using it.

The movement started with the subject in neutral spine posture, with the knees tracking the second toe when descending and ascending, performing a movement similar as to taking a ball off the floor from between the subject's feet (knees were allowed to go over the toes). Subjects started with the knees in extension and were encouraged to go as far down as possible (i.e. flexing the knee as far as possible); and were instructed to stop when: "the knee gives away because of pain"; "or the pain is so great that it stops you from doing the squat"; feeling low back pain; "when feeling sufficient weakness in the legs that you can not do a squat"; feeling a painful stretch in the calf muscles, and/or lifting the heels from the floor or the pad. The squats, therefore, were not completely pain free. It was explained to the subjects that they would feel their regular pain while squatting (e.g. pain intensity about the same as when going up and down stairs or sitting for a prolonged time). However, they were instructed to stop each individual squat (i.e. not go further down) or to not perform more sets when the pain was more significant than usual. They were recommended to use comfortable, soft footwear (e.g.: running shoes), and to exercise on a non slippery, stable surface.

The protocol was divided into 3 phases. In phase one (weeks 1 and 2), each subject exercised daily, and was encouraged to reach the goal of 5 sets of 50 squats (starting with 5 sets of 10 and progressively going to 5 sets of 50). In phase two (weeks 3 and 4), each subject was encouraged to start with 4 sets of 60 and progressively reach the goal of 4 sets of 80 squats 3 times per week. In phase 3 (weeks 5 and 6), the subjects were encouraged to start with 3 set of 80 and progress to 2 sets of 100 squats, three times on week 5, and two times on week 6 (Appendix 8). The subjects were told that these numbers were the goals for the end of every phase and were instructed to progressively

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build up the amount of sets and repetitions in order to reach the goals. However, if they found impossible to reach the goals, they should perform as many squats as possible, only stopping if they felt any of the symptoms described above. They were also asked to write down the number of squats performed on each exercise day, to assess compliance to the protocol and performance.

When looking at the total volume of squats, this protocol has the greatest volume on phase 1 (around 2100 squats over 2 weeks) and the smallest volume on phase 3 (around 1165 squats over weeks 5 and 6), which is not common in physical training practices. However, when looking at progression, this protocol starts with small amount of squats per day (5 sets of 10 to 50 repetition in phase 1), and progresses to greater amounts at the end of the protocol (3 sets of 80 to 2 sets of 100 repetitions). Therefore, even though the volume decreases the number of squats per day (progression) increases as the protocol continues.

3.4   Measurements and Instruments

There were two variables measured: pain and function. Pain and function were measured every three days, from the start of baseline until the end of treatment (end of study). Pain was the main outcome, and it was measured using a Visual Analogue Scale (VAS) (45). Function was measured using the Kujala questionnaire (46). In order to follow the performance of the treatment protocol, a diary-sheet with weekly lines was provided o each subject to write down the number of squats performed on each exercise day.

The Visual Analogue Scale (VAS) is a self-reported instrument that measures pain. VAS is a 100mm long line with "no pain" written in one end and "worse pain imaginable" on the other end, and it has been used in different ways in the population

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with PFPS (27,45,47-50). Subject's assessment of pain was measured with a VAS for their worst pain (VAS-W) in the preceding days (Appendix 9). The VAS-W has been evaluated in a variety of patient populations including in patients with PFPS (49). It has demonstrated good responsiveness (relative treatment effect: 1.09), and higher test-retest reliability (ICC=0.76) than the VAS for usual pain (ICC=0.56) (45). The minimally important difference (MID) on the VAS-W, to show clinically significant improvement has been reported as a decrease of 20mm (27,45).

The Kujala questionnaire, also known as Anterior Knee Pain Scale (AKPS), is a 13-item assessment tool with items weighted differentially for a maximum score of 100, with lower scores indicating worse function. The questionnaire has showed good responsiveness (relative treatment effect:1.15), and test-retest reliability (ICC = 0.81) (45), adequate validity with moderate correlation with the Visual Analog Scale (r = 0.74), and it has been used in previous studies (11,27,28,47). The minimally important difference (MID) on the Kujala scores was reported to be an increase of 10 points (45). The questions in the questionnaire are self-reported and are related to how the knee feels during performance of activities (46) (Appendix 10).

The diary-sheet was given to the subject in order to look at compliance and check the performance of the treatment protocol. The diary-sheet was a simple one-sheet table, with lines for each week of treatment, columns for each day of exercise and room on top for identification of the subject, who wrote down the information (Appendix 11). It was self-reported, and was given to each subject on the first day of treatment and collected on the last day of the study. The data of the diary sheet was used to look at compliance and performance. Methods for classifying subjects according to compliance and performance levels are detailed below.

3.5 Compliance and Performance Measurement

The data of the diary sheet was used to measure compliance and level of exercise performance. Compliance means the effort that the subject put into performing the protocol as many days as possible. The number of days in which the subjects performed any squats was taking into consideration. Compliance was measured by first, by counting how many days of the protocol each subject performed squats; and second, by calculating if this number of days was equal to or greater than 80% of the total amount of days in the protocol (total amount of days:25, 80% of 25 = 20 days). For example: if a subject performed 3 sets of 30 squats instead of the suggested 5 sets of 30, this day was counted as a compliant day. Since the protocol contained instructions to stop squats if pain or symptoms increased (i.e. the instructions said do not do the full recommended number of repetitions if pain increased), the only days not counted in the compliance measure were days in which no squats were performed. Subjects squatting in 20 days or more were considered compliers. The 80% mark was considered reasonably high compliance considering a previous study that stated most trials do not mention compliance rate (13), and it was mid-way between the 70% to 87% reported compliance of Earl et al (2011) (27).

As mentioned in the protocol, subjects were instructed to stop squatting when symptoms increased to intolerable levels. However, pain was not the only limiting factor of the number of sets and repetitions. For subjects not completing the suggested number of repetitions the limiting factor or reason for stopping was tracked if possible. The other reported limiting factors were: busy schedule, fatigue, sickness, small trips and distraction. The amount of completed sets and repetitions reached were considered as performance of the protocol.

Performance means the percentage of squats performed out of the total number of squats asked (i.e. how many squats they did). Measurement of performance followed the following rationale: 1) the protocol occurred over 25 days, 2) subjects were asked to perform a number of sets and repetitions each day, 3) the exercise day was considered complete when 80% or more of the suggested number of squats were performed, 4) the number of completed days out of 25 was used to calculate the percentage of protocol performed, and 5) performance of the subjects was classified into $\geq$ 80% of the protocol or $<$ 80% of the protocol performed. For example, if a subject performed 4 sets of 30 repetitions instead of 5 sets of 30 (80% of the amount suggested), this day was considered complete.

3.6   Data Collection – Procedures

After screening for the inclusion and exclusion criteria, five steps followed: 1- first appointment, 2-second appointment; 3- emails/ phone calls; 4- third appointment; 5- fourth appointment. All of the appointments took place at the Sports Therapy Research Lab (University of Alberta). These steps are described in detail below.

3.6.1   First appointment

At the first appointment, the investigator explained the study in detail, collected self-reported demographic data (i.e. age, gender, height, weight, duration of symptoms and level of participation in physical activities per week), and performed knee assessment. If eligible to participate, the subject received an information sheet, and was asked to sign the informed consent form. Each subject was then randomly assigned to one of the three baseline periods (B7, B13 or B19); was reminded to maintain his/her normal life style, and to inform the investigator of any instance, during the study period, in which they

ingested analgesic or anti-inflammatory medication. Each subject was reminded to complete the VAS and the Kujala questionnaire every three days starting on the first appointment. A "reminder calendar" was given to each subject, with the days of the month that they were to complete the forms. For group B7, the forms were completed on 17 different days; for group B13, on 19 different days, and for group B19 the forms were completed on 21 different days (Appendix 12). The investigator wrote down the days of the month just before handing the calendar to the subject.

3.6.2 Second appointment

The second appointment occurred after the baseline period for each subject, and was the first day of actual treatment. The procedures were as follows: 1) explanation of the deep squat, 2) performance of the deep squats by the subject and corrections by the investigator, 3) explanation of the protocol (i.e. number of sets, repetitions and use of the heel pad) 4) emphasis on performing as many sets and repetitions as possible (to achieve the goal) 5) explanation of diary-sheet of squats, 6) explanation of the instructions of what to do when knees were painful, 7) schedule of the next appointment.

During the first week of the protocol, the investigator phoned or emailed (according to subject's preference) the subjects every 2 or 3 days, to ensure they were not having any additional pain and to give any necessary instructions if they were having pain. If painful, the investigator did the following: 1- asked where the pain was; 1a- if it was muscle pain: the subject was assured that this pain was temporary and it would go away in a few days; 1b- if it was knee pain: subjects were instructed to ice the knees for 15 minutes twice a day, by putting ice in a wet towel or a package of frozen peas over the knee. If the pain increased when squatting during the first week of treatment, the subject was instructed to stop the squat at the point just before the pain increased. If necessary, the investigator would make an appointment with the subject to check the movement patterns, and give

further instructions. No subjects needed an extra appointment. If the subject decided to withdraw from the study, he/she would receive the Corbett Hall Student Physical Therapy Clinic contact information, for free physical therapy treatment. No subjects withdrew from the study.

3.6.3   Emails/phone calls

After the second appointment, each participant performed the deep squat protocol at home, and the investigator emailed or phoned each subject every 2 or 3 days during the first two weeks and, every week to 10 days during the remaining four weeks (to ensure compliance, performance and to check symptoms). The treatment lasted for 6 weeks. During this period, the investigator saw the participant three times: on the first day, on the fifteenth day (third week), and on the last day of the protocol. During this period of home exercises, the subject self-reported pain and function using the VAS and Kujala questionnaire every three days, and wrote down the number of squats performed after every exercise day.

3.6.4   Third appointment

The third appointment was scheduled for the third week of the deep squat protocol. Subjects were asked to perform the squats without the heel pad, and if needed, the performance was corrected by the investigator. This appointment counted as one of the 3 exercise days of that week. The participants were asked to hand in the Kujala and the VAS sheets previously completed in the past weeks, and to receive more forms. They were reminded to continue the protocol without the heel pad, squat down as far as possible and keep the dairy-sheet updated. They were also taught back stretches in case they felt low back soreness after performing the squats. The stretches were: 1-seating on heels stretch (i.e. knees and hips totally flexed, abdominal area touching thighs, knees on the floor, arms stretched above head, hands on the floor); 2-diagonal stretch (i.e. laying

supine, one leg crosses over the body, bending the knee, twisting the back, shoulders stay on the floor, one leg at the time)

3.6.5 Fourth appointment

The fourth appointment occurred after the last day of exercises, and represented the conclusion of the treatment and the study period for the subjects. The subjects handed in the last self-reported measurement scales (Kujala and VAS) and the diary-sheet.

3.7 Ethical Considerations

The participation of subjects in this study was voluntary. They received an information letter which had a brief description of the study's purpose and duration, the squats protocol, possible risks for the participant, issues of confidentiality, how to withdraw from the study and contact information of different resources in case of questions and complaint.

The investigator anticipated only two possible risks: first - no improvement with treatment, and secondly - exacerbation of the symptoms. No subjects reported exacerbation of symptoms. However, 1 subject (S5) reported low back pain at the end of the protocol. All participants' personal information, such as: telephone number, address, name, age and gender were kept confidential. The patient's forms were numbered and kept in a locked file desk. The subjects had the opportunity to withdrawn from the study at any time without prejudice, and if they had chosen to withdraw from the study, their data and/or information would not be used in the study. No subject withdrew from the study.

3.8   Statistical Analysis

Descriptive data for outcomes of interest for all 11 subjects were observed and analyzed. According to the objectives of this study, the analysis was performed as follows:

1.   To evaluate and observe: a) whether the protocol of deep squats was helpful in decreasing pain and improving function in subjects with PFPS, and b) whether this protocol was feasible as treatment for PFPS;

- Individual statistical analysis of each subject's pain and function before, during, and immediately after the treatment were performed using the 2-standard deviation band method (2 SD). The 2 SD band method is a typical statistical method used in SSDs (40,41,51). The 2-SD band was performed as described in the literature: the mean and the standard deviation of the baseline data points were computed, then, bands representing 2 SD were drawn on the graph, above and below the mean of the baseline data points. A significant change was present when two or more consecutive data points in the treatment period fell outside the 2SD bands ($\alpha=0.05$) (51).

- Individual clinical analysis (clinical relevance) of pain and function was performed comparing the mean differences (baseline and phase 3) to their documented minimally important difference (MID). The mean difference was calculated by subtracting the mean value of the Phase 3 data points from the mean value of the baseline data points ($m_d = m_{p3} - m_b$). The MID for the instruments used in this study were previously established (45,52) as follows: a decrease of $\geq$ 2cm in VAS for pain, and increase of $\geq$ 10 points in the Kujala questionnaire for function. When the pain and/or function mean differences were

greater than or equal to the values above, they were considered to be clinically relevant.

- Individual compliance to the protocol, performance of the protocol, and possible limiting factors were assessed.

2. To visually investigate how pain and function changed over the course of the treatment period:

- The data points of all subjects were combined in two charts to allow visual inspection of the change of pain and function during baseline and treatment periods (as commonly done in Multiple Baseline Single Subject Design studies) (42).

3. To explore possible individual factors that might have influenced the main outcome of interest (i.e. pain),

- Subject data was observed and its influence on the outcomes of interest was explored.

CHAPTER 4. **RESULTS**

4.1 Subject Characteristics

Subject demographics are presented in Table 1. Eleven subjects were included in this study: 10 females and 1 male. Table 1 presents the characteristics of all subjects, in terms of: weight (kilograms), height (centimetres), age (years), duration of symptoms (months) and gender (female or male). Table 1 also presents the mean and standard deviation of these characteristics for all subjects combined. The subjects seem to be similar in weight, height and age, but not duration of symptoms. However, all subjects had chronic PFPS, since symptoms had been present for 5 months or longer (mean: 4 years), which was reported to be characteristic of the majority of the population with PFPS (53).

Subjects	Weight (kg)	Height (cm)	Age (years)	Duration of Symptoms (months)	Gender
S 1	61	169	24	24	F
S 2	62	177	26	72	F
S 3	57	160	27	9	F
S 4	73	182	27	12	M
S 5	58	168	26	5	F
S 6	58.5	167	24	36	F
S 7	74	176	29	36	F
S 8	71	162	24	120	F
S 9	57	177	20	72	F
S 10	67.5	174	30	120	F
S 11	50	152	24	5	F

Table 1 Descriptive statistics of all subjects who participated in the study.

4.2 Individual Analysis (Objective 1)

Individual results are presented in ascending order of the subject's numbers, and include information regarding the number of days performing squats and the percentage of the protocol performed, along with pain and function analysis using the 2-Standard Deviation band method (statistical analysis) and comparison of the pain and function mean differences with its MIDs (clinical analysis). This information met objective 1 of the study (see page 11).

Subject 1

Subject 1, female, 61kg, 169cm, 24 years of age, duration of the symptoms: 2 years, in both knees, but more on the right (right side reported),in group B7 (7-day baseline); pain when squatting with weights, and with prolonged sitting (driving). Physical Activity: running 40 minutes 3 times per week.

The measures taken during baseline and treatment for Subject 1 are shown in Figure 2. The analysis of the data with the 2-Standard Deviation band showed a non-significant decrease in pain, and a non-significant improvement in function (Figure 2). The mean differences for pain and function are presented in Table 2. The decrease in pain was clinically relevant, but observed improvements in function were limited due to an apparent ceiling effect in the Kujala scale. The subject reached the highest levels of function by the end of treatment and, based on the Kujala questionnaire, she could not improve further. Subject 1 did squats on 22 days and performed 72% of the protocol (Table 3). Missing data points are due to the absence of completed forms. The subject forgot to return 4 VAS(s) and 3 Kujala questionnaires; resulting, for the pain graph, in four missing points (two in phase1, one in phase 2 and 3), and for the function graph, three missing data points (one point in phase 1, 2 points in phase 2). Subject 1 did not ice

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her knee, felt more knee pain at the end of second week of the protocol, but did not have any other complaints.

Figure 2. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 1. Dashed red line represents the limits of the 2-Standard Deviation band, and the straight purple line represents the mean of the baseline data points. Pain measurement on the Visual Analogue Scale for Worse pain. Function measurement on the Kujala questionnaire.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	3.6	1.1	2.5	Yes
Function (Kujala)	92.3	97.6	5.3	Ceiling effect ?

Table 2. Mean values for pain and function for subject 1.

Protocol	
days performing squats	% of the protocol performed
22	72%

Table 3. Days doing squats and percentage of the protocol performed for subject 1.

Subject 2.

Subject 2, female, 62kg, 177cm, 26 years of age, duration of the symptoms: 6 years, in both knees, but more in the left knee (reported), in group B7 (7-day baseline); pain when going up and down stairs, and with prolonged sitting. Physical Activity: walk her dog every second day.

The measures during baseline and treatment for subject 2 are shown in Figure 3. The analysis of the data with the 2-Standard Deviation band showed a non-significant decrease in pain, and a non-significant improvement in function (Figure 3.). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 4. Neither pain nor function differences were clinically relevant. Compliance with the protocol and percentage of the protocol performed are presented in Table 5. Subject 2 did squats in 23 days and performed 28% of the protocol. During Phase 2, she performed several sets of 10 to 20 repetitions, trying to achieve the total number of expected squats of each day; for example: 4x10+4x15+2x20+1x5= 150 squats (when the expected was 5x30). For Phase 3 and 4 she did the same, but increased the number of repetitions: sets of 30 to 50. However, the total number of squats reached only half of the expected amount.

Figure 3. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 2. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	4.5	4.3	0.1	No
Function (Kujala)	87.7	88	0.3	No

Table 4. Mean values for pain and function for subject 2.

Protocol	
days performing squats	% of the protocol performed
23	28%

Table 5.Days doing squats and percentage of the protocol performed for subject 2.

Subject 3.

Subject 3, female, 57kg, 160cm, 27 years of age, duration of the symptoms: 9 months, in both knees, but more the left knee (reported), in group B7 (7-day baseline); pain when going up and down stairs (down being worse), and with prolonged sitting. Physical Activity: running 8 to 10 km (45-60 min) 5 times per week.

The measures during baseline and treatment for Subject 3 are shown in Figure 4. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, and a significant improvement in function (Figure 4). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 6. Both differences in pain and function were clinically relevant. Subject 3 did squats in all 25 days and performed 100% of the protocol (Table 7). She did not ice her knee, and did not feel knee pain in any specific time of the protocol.

Figure 4. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 3. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	4.4	0.7	3.7	Yes
Function (Kujala)	82	92.8	10.8	Yes

Table 6. Mean values for pain and function for subject 3.

Protocol	
days performing squats	% of the protocol performed
25	100%

Table 7. Days doing squats and percentage of the protocol performed for subject 3.

Subject 4

Subject 4, male, 73kg, 182cm, 27 years of age, duration of the symptoms: 1 year, in the left knee, in group B7 (7-day baseline); pain when squatting, going up and down stairs, kneeling, and with prolonged sitting. Physical Activity: playing badminton once or twice/week.

The measures during baseline and treatment for Subject 4 are shown in Figure 5. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, and a significant improvement in function (Figure 5). His pain increased severely at the end of the treatment due to a small adverse event not related to the protocol (hit his knee). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 8. Both pain and function mean differences were clinically relevant. Days performing squats and percentage of the protocol performed are presented in Table 9. Subject 4 did squats in 23 days and performed 32% of the protocol. He did not ice his knee, reported by email increased knee pain at the end of phase 1, which did not match with the self-reported pain scale (see Figure 12). Subject 4 also reported that he accidently hit his knee into a chair on the last week of treatment (justifying the increase in pain and decrease in function). Uneven or missing data points were due to the absence of completed forms (subject forgot to return them).
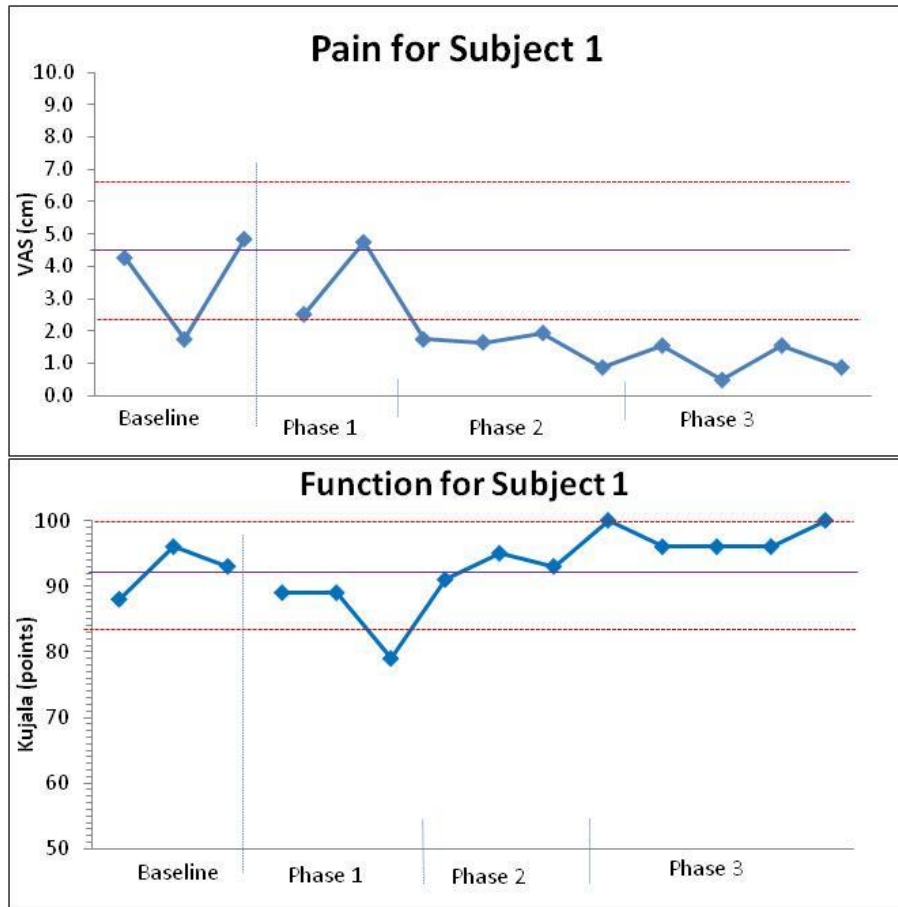
Figure 5. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 4. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	6.9	2.5	4.4	Yes
Function (Kujala)	60.7	80.3	19.6	Yes

Table 8. Mean values for pain and function for subject 4.

Protocol	
days performing squats	*% of the protocol performed*
23	32%

Table 9. Days doing squats and percentage of the protocol performed for subject 4.

Subject 5.

Subject 5, female, 58kg, 168cm, 26 years of age, duration of the symptoms: 5 months, in the left knee, in group B13 (13-day baseline); pain when squatting, going up and down stairs (more upstairs), and kneeling. Physical Activity: yoga (once/week) and bicycle (twice/week).

The measures during baseline and treatment for Subject 5 are shown in Figure 6. The analysis of the data with the 2-Standard Deviation Band Method showed a significant decrease in pain, and a significant improvement in function (Figure 6). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 10. Both differences in pain and function were clinically significant. Number of days doing squats and percentage of the protocol performed are presented in Table 11. Subject 5 did squats in 25 days and performed 92% of the protocol. At the end of the protocol, she complained about low back pain. She felt knee pain at the end of the third week of the protocol, and iced her knee twice in total.
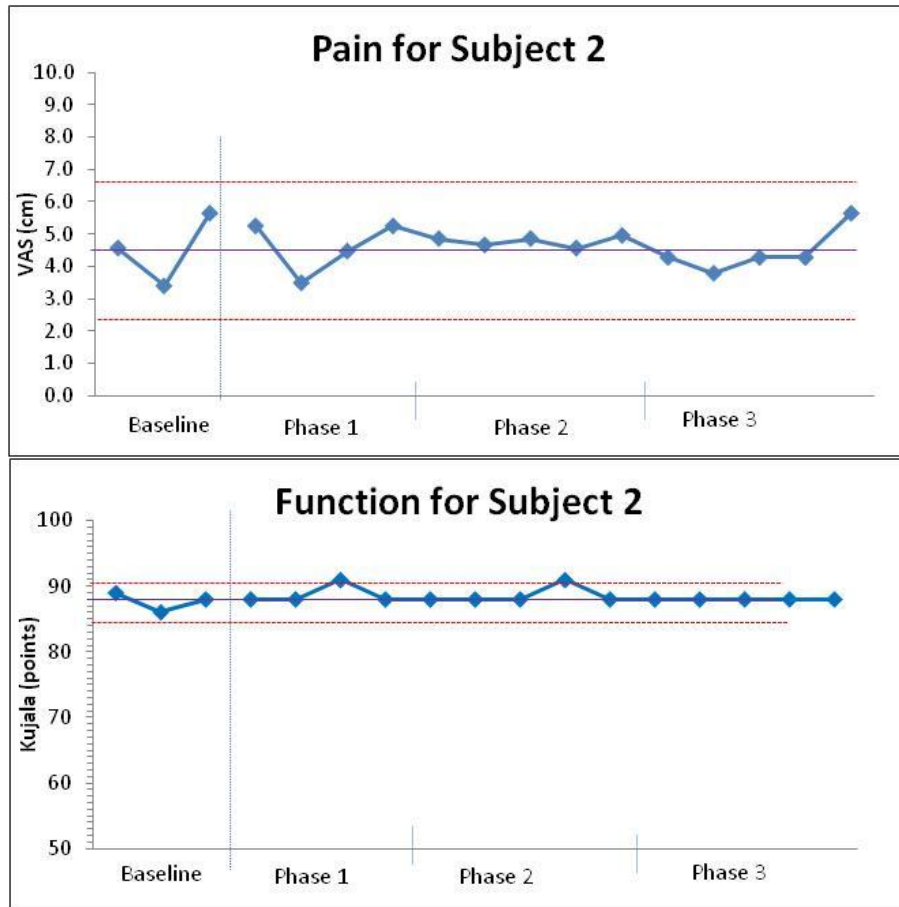
Figure 6. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 5. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	3.9	0.7	3.1	Yes
Function (Kujala)	81.2	97	15.8	Yes

Table 10. Mean values for pain and function for subject 5.

Protocol	
days performing squats	% of the protocol performed
25	92%

Table 11. Days doing squats and percentage of the protocol performed for subject 5.

Subject 6.

Subject 6, female, 58.5kg, 167cm, 24 years of age, duration of symptoms: 3 years, in the left knee, in group B13 (13-day baseline); pain when going up and down stairs, and when kneeling. Physical Activity: ran 10km 3 or 4 times/week. She started taping her knee before the study, and noted decrease of pain when running because of this taping.

The measures during baseline and treatment for Subject 6 are shown in Figure 7. The analysis of the data with the 2-Standard Deviation band showed a non-significant decrease in pain, and no improvement in function (Figure 7). Perhaps the non-significant improvement in function was again due to a ceiling effect, since there was not much room to improve on the scale. The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 12. Neither differences in pain nor function were clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 13. Subject 6 did squats in 23 days and performed 80% of the protocol. Subject 6 felt knee and hip pain at the end of second week of the protocol; she iced her knee for 10 minutes twice, and did not tape her knee to squat.
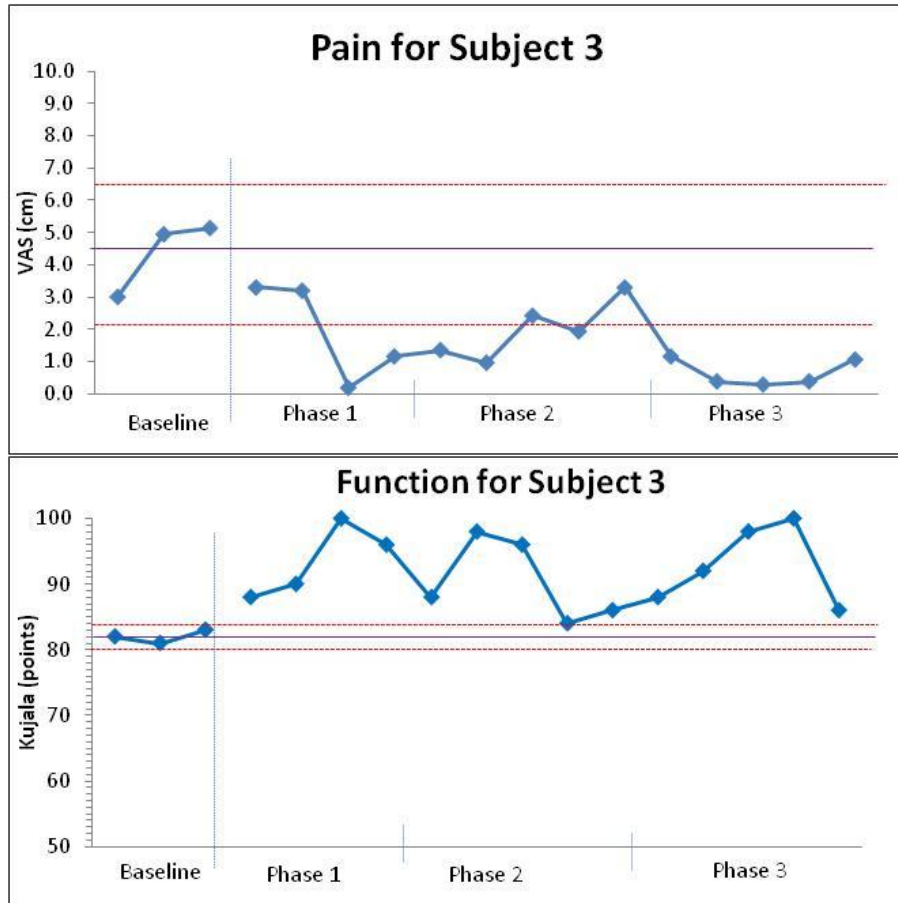
Figure 7. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 6. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	*Mean Phase3*	*Mean Difference*	*Clinically Relevant?*
Pain (VAS)	4	2.2	1.8	No
Function (Kujala)	82.2	89.8	7.6	No (ceiling effect?)

Table 12. Mean values for pain and function for subject 6.

Protocol	
days performing squats	*% of the protocol performed*
23	80%

Table 13. Days doing squats and percentage of the protocol performed for subject 6.

Subject 7.

Subject 7, female, 74kg, 176cm, 29 years of age, duration of the symptoms: 3 years, in both knees but more in the left knee (reported), in group B13 (13-day baseline); pain when going up and down stairs, and prolonged sitting. Her pain was just distal to the patella, and she had audible clicking during squats. Physical Activity: salsa or swing dance once/week.

The measures during baseline and treatment for Subject 7 are shown in Figure 8. The analysis of the data with the 2-Standard Deviation band showed a non-significant decrease in pain, but an improvement in function (Figure 8). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 14. Neither pain nor function differences were clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 15. Subject 7 did squats in 21 days and performed 60% of the protocol. Subject 7 felt knee pain during 20 or more days of the protocol, never iced her knee, but felt pain relief after stretching the quadriceps muscle.
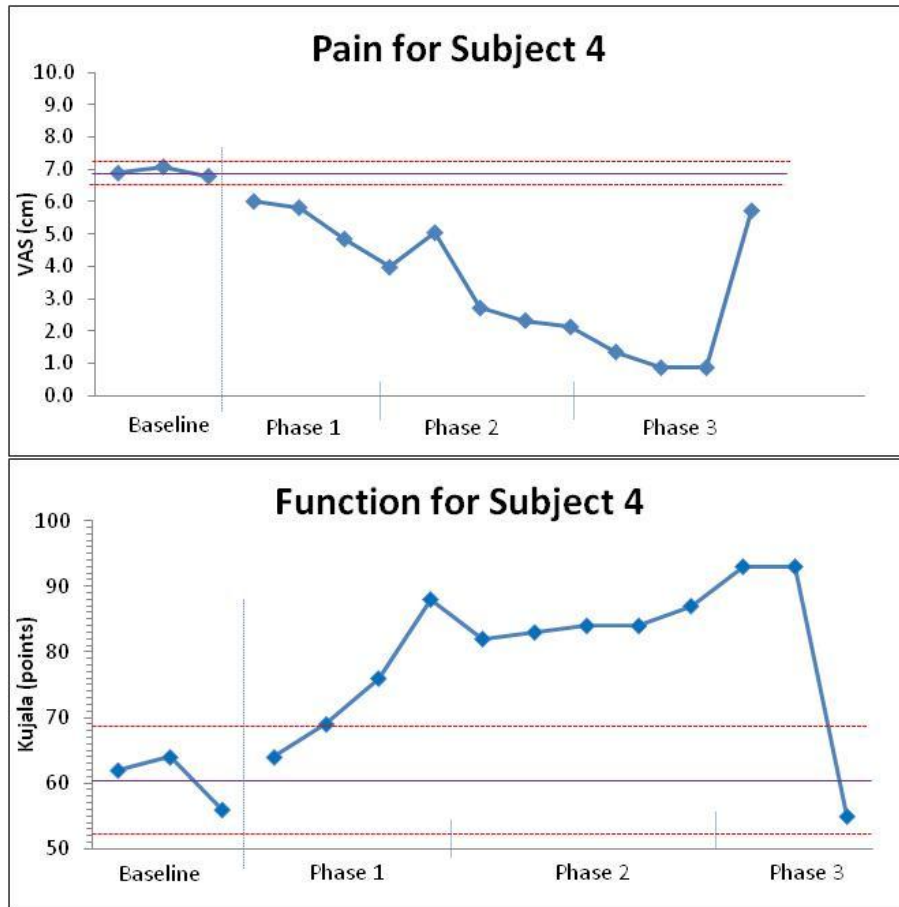
Figure 8. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 7. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant
Pain (VAS)	7	7.1	+0.1	No
Function (Kujala)	55.6	59.6	4	No

Table 14. Mean values for pain and function for subject 7.

Protocol	
days performing squats	% of the protocol performed
21	60%

Table 15. Days doing squats and percentage of the protocol performed for subject 7.

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Subject 8.

Subject 8, female, 71kg, 162cm, 24 years of age, duration of the symptoms: 10 years, in both knees but more in the left knee (reported), in group B13 (13-day baseline); pain when going up and down stairs or hills, prolonged sitting and standing, while sleeping (needed to place pillows below knees). Physical Activity: walked 30 minutes once/twice week.

The measures during baseline and treatment for Subject 8 are shown in Figure 9. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, and a significant improvement in function (Figure 9). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 16. Both pain and function differences were clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 17. Subject 8 did squats in 24 days and performed 32% of the protocol. Subject 8 reported improvement of the knee pain while sleeping, however, not when descending stairs.
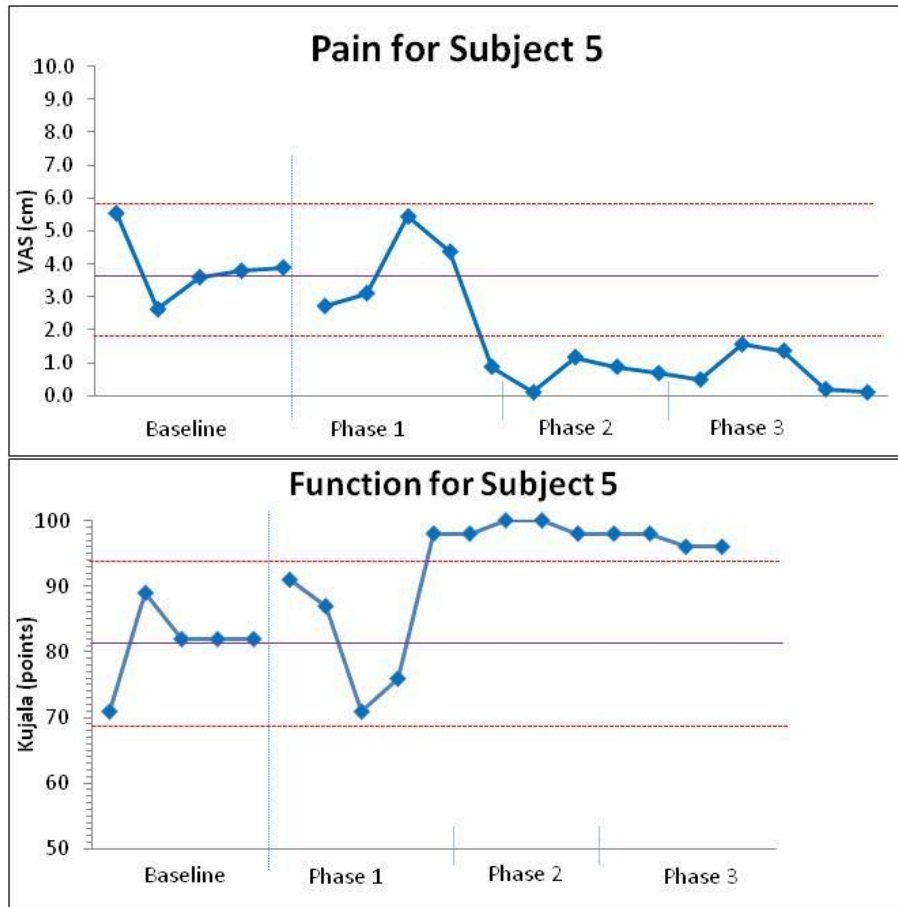
Figure 9. Measurement of pain and function were during baseline, treatment and just after treatment for subject 8. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	6.2	2.7	3.5	Yes
Function (Kujala)	73.8	90.6	16.8	Yes

Table 16. Mean values for pain and function for subject 8.

Protocol	
days performing squats	% of the protocol performed
24	32%

Table 17. Days doing squats and percentage of the protocol performed for subject 8.

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Subject 9.

Subject 9, female, 57kg, 177cm, 20 years of age, duration of the symptoms: 6 years, in the right knee, in group B19 (19-day baseline); pain when going up and down stairs, kneeling and prolonged sitting. Physical Activity: volleyball and basketball practices and games, 4 times per week.

The measures during baseline and treatment for Subject 9 are shown in Figure 10. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, and a significant improvement in function (Figure 10). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 18. Both differences in pain and function were clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 19. Subject 9 did squats in 25 days and performed 84% of the protocol. Subject 9 iced her knee every day during the first week of treatment.
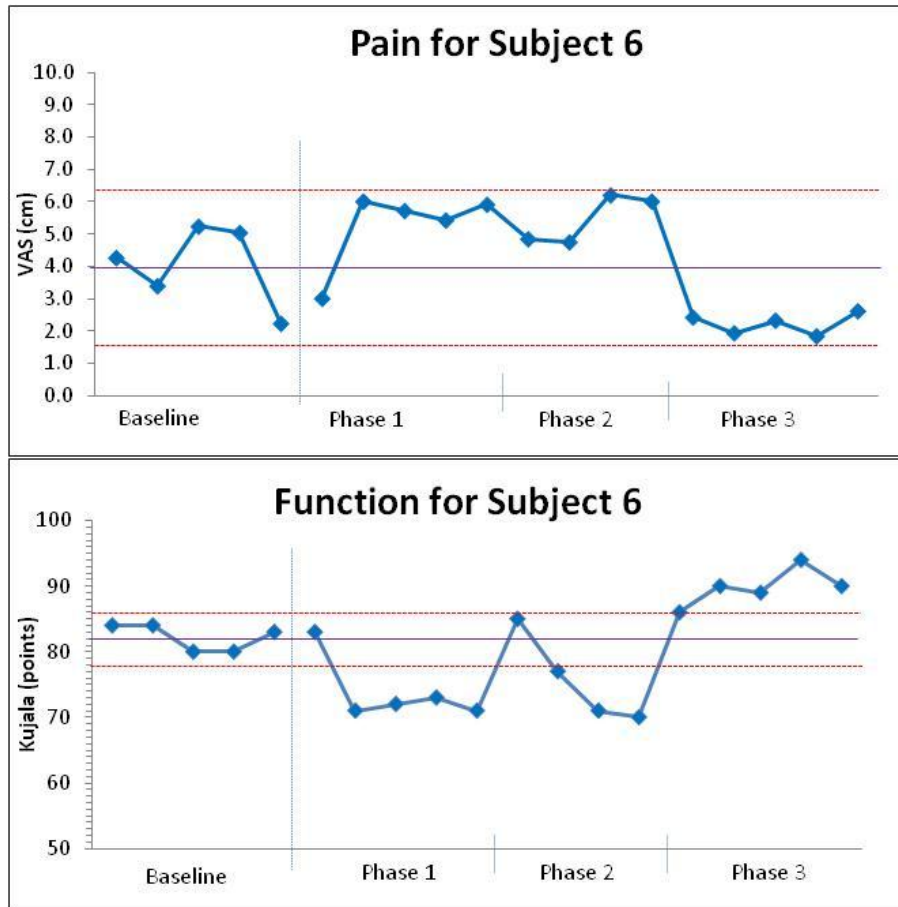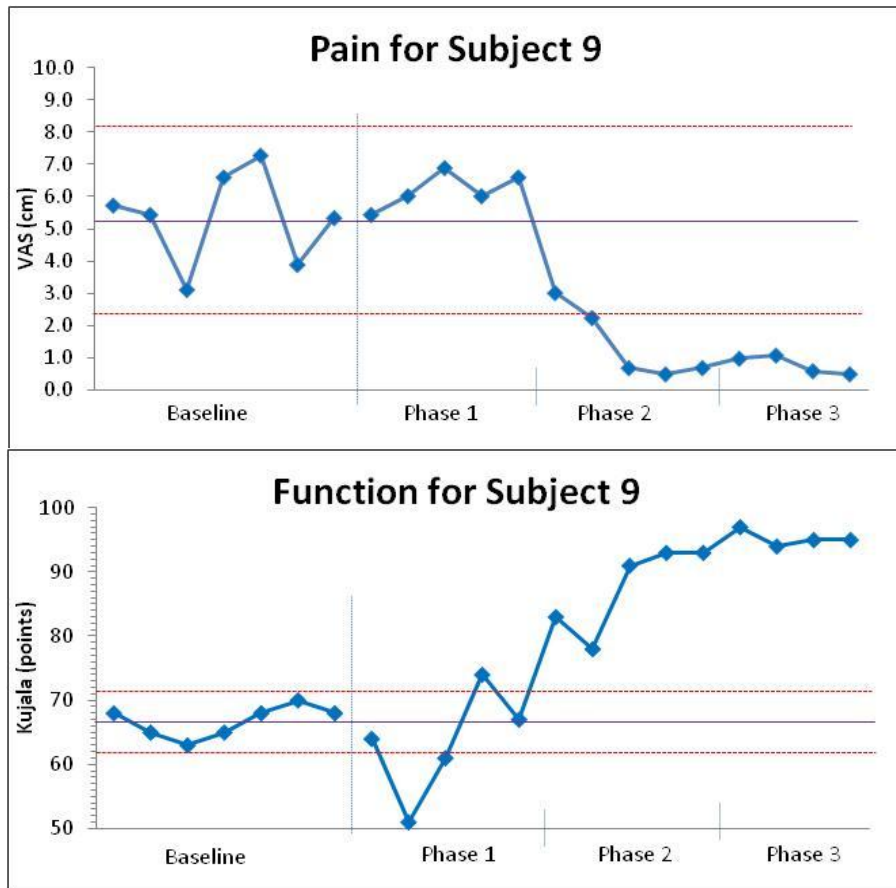
Figure 10. Measurement of pain and function were during baseline, treatment and just after treatment for subject 9. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	5.3	0.8	4.5	Yes
Function (Kujala)	66.7	95.3	28.5	Yes

Table 18 Mean values for pain and function for subject 9.

Protocol	
days performing squats	% of the protocol performed
25	84%

Table 19. Days doing squats and percentage of the protocol performed for subject 9.

Subject 10.

Subject 10, female, 67.5 kg, 174 cm, 30 years of age, duration of the symptoms: 10 years, in both knees but more in the right knee (reported), in group B19 (19-days baseline); pain when going up and down stairs/hill, and prolonged sitting. She played soccer during her college studies (between 19 to 22 year of age); and in one season she had a cortisone shot to her knee due to pain. Physical Activity: played soccer and volleyball once a week, practiced yoga once a week.

The measures during baseline and treatment for Subject 10 are shown in Figure 11. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, but no improvement in function (Figure 11). Perhaps the non-significant improvement in function was again due to a ceiling effect, since there was not much room to improve on the scale. The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 20. Only the pain difference was clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 21. Subject 10 did squats in 24 days and performed 96% of the protocol. Subject 10 iced her knee three times per week (after soccer, volleyball and yoga) during the first two weeks of treatment.
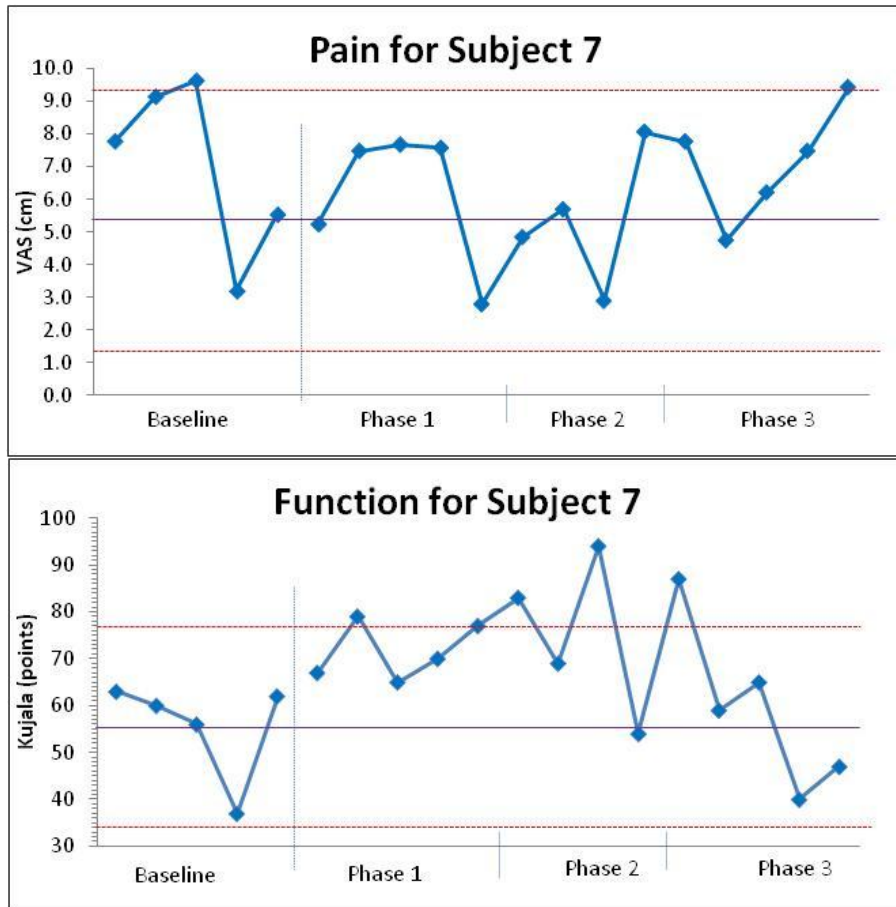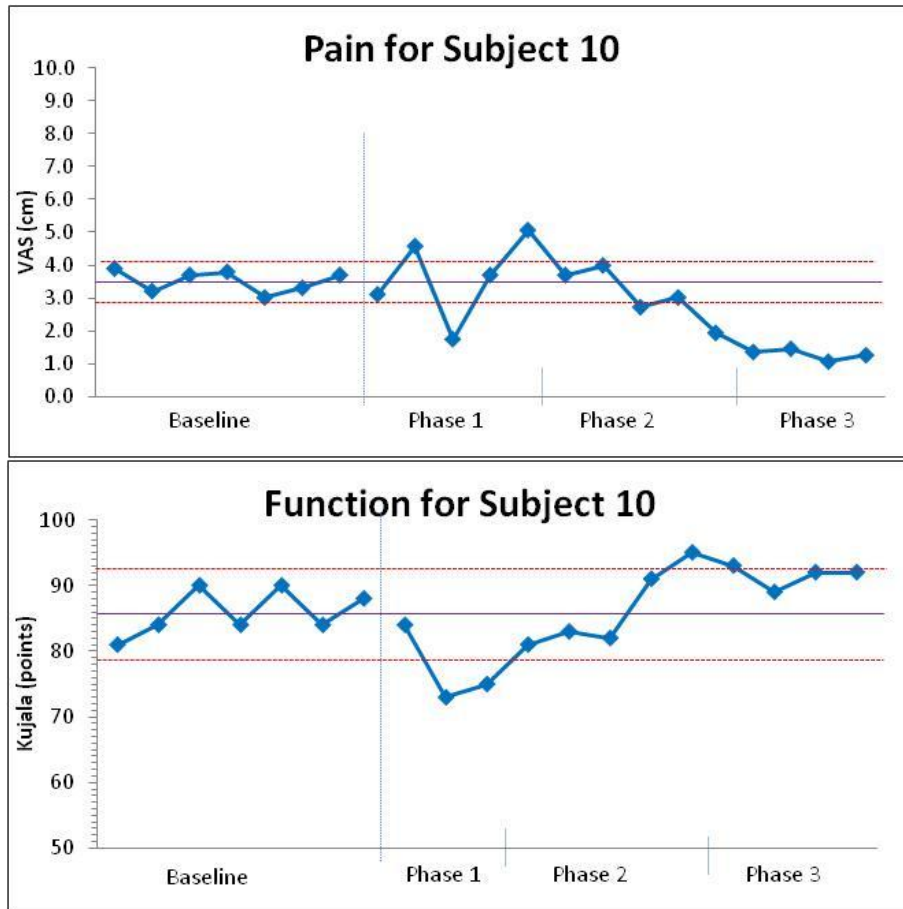
Figure 11. Measurement of pain and function were during baseline, treatment and just after treatment for subject 10. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	3.5	1.3	2.2	Yes
Function (Kujala)	85.9	91.5	5.6	No (ceiling effect?)

Table 20. Mean values for pain and function for subject 10.

Protocol	
days performing squats	% of the protocol performed
24	96%

Table 21.Days of squats and percentage of the protocol performed for subject 10.

Subject 11.

Subject 11, female, 50 kg, 152 cm, 24 years of age, duration of the symptoms: 5 months, right knee, group B19 (19-day baseline); pain when squatting, kneeling, and prolonged sitting. Physical Activity: played hockey and spinning (cycling) once a week.

The measures during baseline and treatment for Subject 11 are shown in Figure 12. The analysis of the data with the 2-Standard Deviation band showed a significant decrease in pain, and a significant improvement in function (Figure 12). The mean values and mean differences for pain and function during baseline and phase 3 are presented in Table 22. Both pain and function mean differences were clinically relevant. Number of days doing squats and percentage of the protocol performed are presented in Table 23. Subject 11 did squats in 25 days and performed 100% of the protocol. Subject 11 did not complain of knee pain during the protocol.
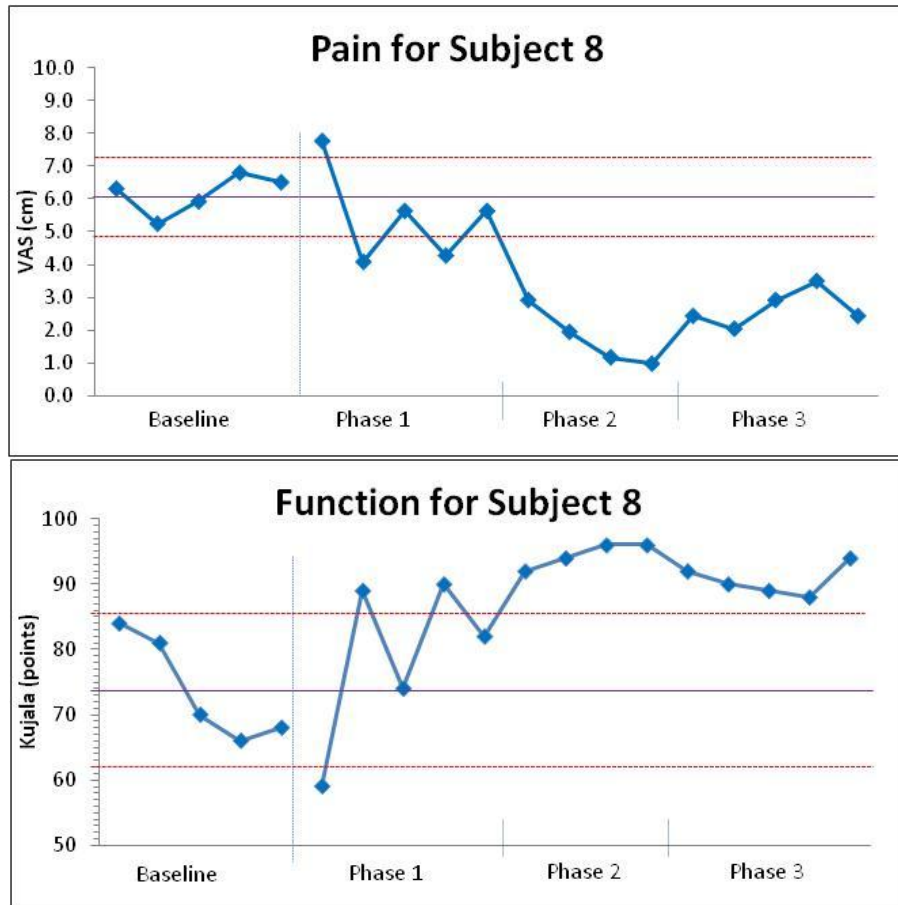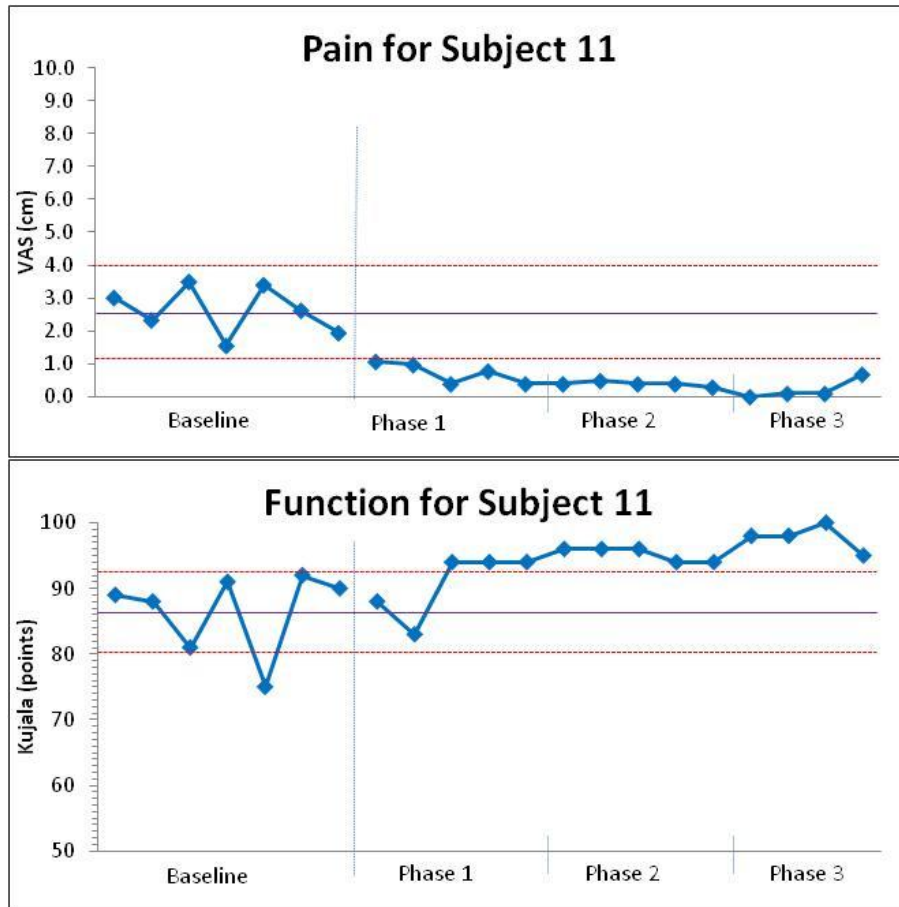
Figure 12. Measurement of pain and function taken during baseline, treatment and just after treatment for subject 11. Dashed line represents the limits of the 2-Standard Deviation band, and the straight line represents the mean of the baseline data points. Pain on the Visual Analogue Scale for Worse pain. Function on the Kujala questionnaire for PFPS.

	Mean Baseline	Mean Phase3	Mean Difference	Clinically Relevant?
Pain (VAS)	2.6	0.2	2.4	Yes
Function (Kujala)	86.6	97.8	11.2	Yes

Table 22. Mean values for pain and function for subject 11.

Protocol	
days performing squats	% of the protocol performed
25	100%

Table 23. Days of squats and percentage of the protocol performed for subject 11.

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4.3 Changes in Pain and Function over Time (Objectives 1 and 2)

4.3.1 Pain (VAS)

Figure 13 shows how the pain changed during baseline and protocol periods for all subjects. Visually, most subjects had a decrease in pain when comparing baseline to the end of the treatment; except for subjects 2 and 7 (no pain decrease) and subject 4 (hit his knee at the end of the protocol period). The change in pain visually appears to be more evident around the third week of the protocol (see arrow Figure 13) for all subjects.
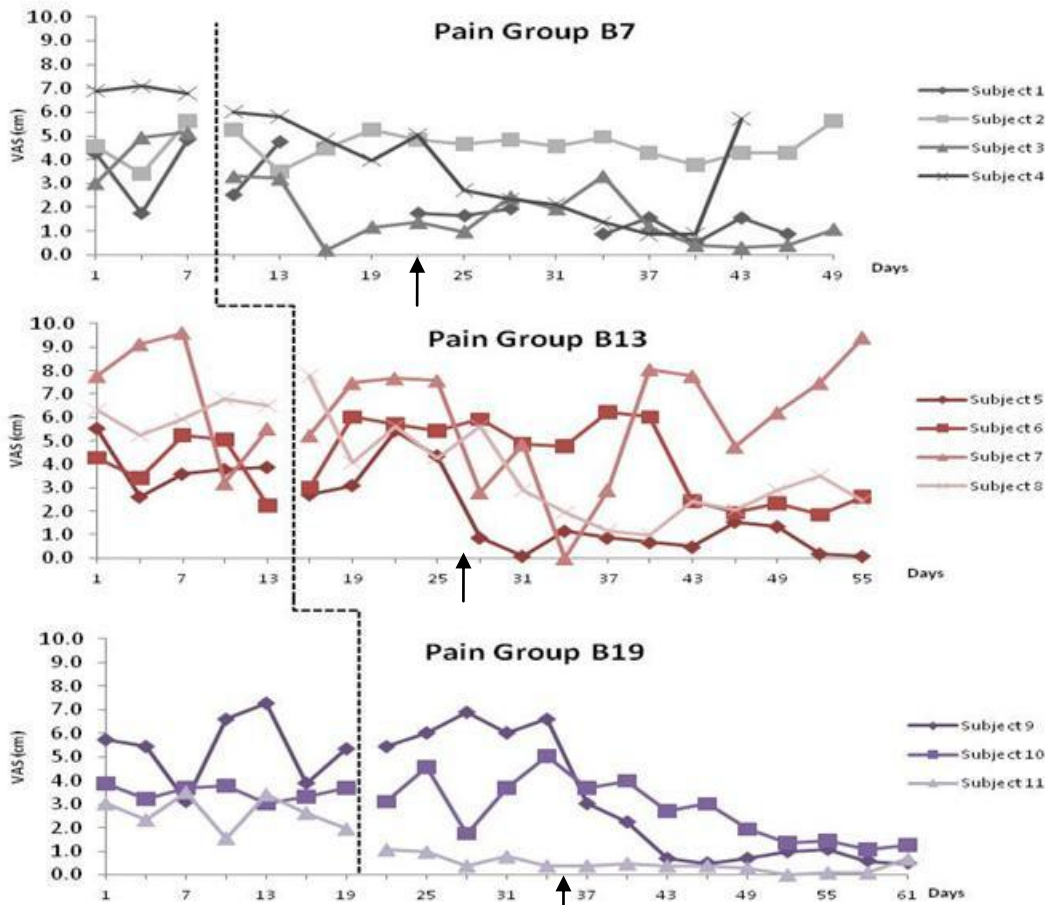
Figure 13. Pain level for all subjects, before treatment and during the treatment (left and right side of the dashed line, respectively). The arrows indicate the third week of the protocol.

4.3.2 Function (Kujala Questionnaire)

Figure 14 shows how the function changed during baseline and protocol periods for all subjects. Visually, most subjects had an increase in function when comparing baseline to the end of the treatment; except for subjects 2 and 7 (no increase) and subject 4 (hit his knee). The change in function visually appears to be more evident during the second week of treatment (see arrows Figure 14) and more steady after the second week, except for subjects 2 and 7. However the variability among subjects is high.
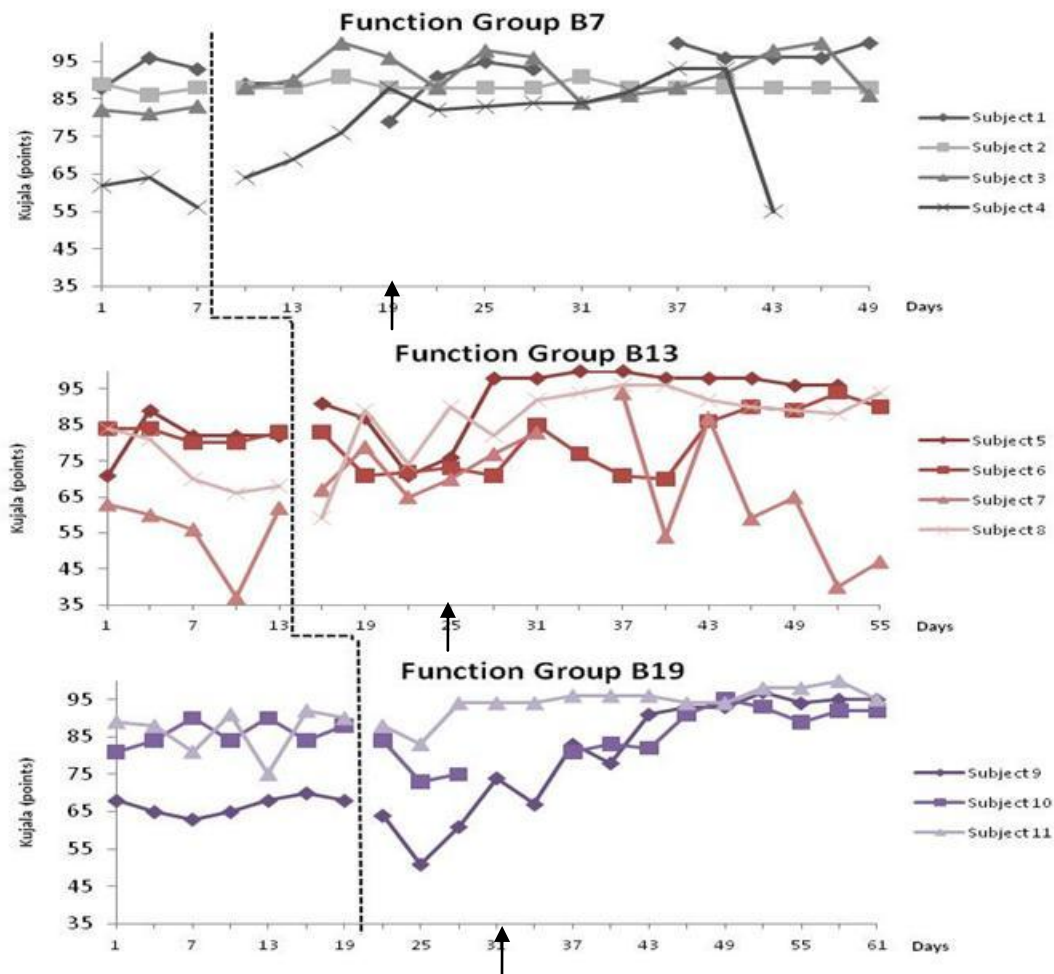
Figure 14. Function scores for all subjects, before treatment and during the treatment (left and right side of the dashed line, respectively). The arrows indicate end of second week of the protocol.

4.4   Combined Analysis (Objectives 1 and 3)

Individual subject data is presented in Table 24 to show comparison between subjects. All 11 subjects were classified as compliers, however, performance varied. The number of days performing squats, the percentage of the protocol performed, the reported limiting factor to doing the protocol (pain, no pain, and/or other), the mean function score at baseline, and the clinical relevance of the outcomes of interest (i.e. pain and function) are presented in Table 24. The limiting factor "other" refers to any reported limitations that were not knee pain (fatigue, busy schedule, sickness, small trips and distraction).

Subjects	Number of days performing squats	Percentage of the protocol performed	Reported Limitation (number of days)	Mean function at baseline (Kujala)	Clinically Relevant decrease in pain?	Clinically Relevant improvement in function?
S 2	23	28%	Other + Pain (4)	87.7	No	No
S 7	21	60%	Pain (>20)	55.6	No	No
S 6	23	80%	Pain (6)	82.2	No	No(?)
S 4	23	32%	Other + Pain (4)	60.7	Yes	Yes
S 8	24	32%	Other	73.8	Yes	Yes
S 1	22	72%	Pain (8)	92.3	Yes	No(?)
S 9	25	84%	Pain (4)	66.7	Yes	Yes
S 5	25	92%	No	81.2	Yes	Yes
S 10	24	96%	Pain (5)	85.9	Yes	No(?)
S 3	25	100%	No	82	Yes	Yes
S 11	25	100%	No	86.6	Yes	Yes

Table 24. Summary of the results: number of days performing squats, percentage of the protocol performed, reported limitation to performing squats, function score at baseline, and clinical relevance for decrease in pain and improvement in function. Subjects who managed to

perform more than 80% of the protocol are shaded. Question mark (?) means the presence of a possible ceiling effect.

4.4.1 The Four Possible Outcomes

The subjects in this study could have had 4 possible results regarding performance and outcomes (low/high performance, with relevant/not relevant outcomes). All four results occurred in this study:

    I.   Low performance and no relevant improvement in outcomes (S2)

    II.   High performance but no relevant improvement in outcomes (S7 and S6)

    III.   Low performance but relevant improvement in outcomes (S4 and S8)

    IV.   High performance and relevant improvement in outcomes (S1, S9, S5, S10, S3 and S11).

4.4.2 Exploring Factors that could have Influenced Outcomes

- Compliance

All 11 subjects were considered compliers because they had 20 or more days performing squats during the protocol (80% or more of the total number of days). Eight out of 11 subjects had a clinically relevant decrease in pain (72.7%). Six out of 11 subjects had a clinically relevant improvement in function. From all subjects who had a relevant pain decrease (8 subjects), only 2 did not have an improvement in function (possible ceiling effect) (S1 and S10).

- Performance

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Six subjects performed ≥ 80% or more of the protocol: S6, S9, S5, S10, S11 and S3. Five of them had a clinically relevant pain decrease (83%). Four had a clinically relevant improvement in function (S10: possible ceiling effect)

Five subjects performed < 80% of the protocol: S2, S4, S8, S7 and S1. Three of them had a clinically relevant pain decrease: S4, S8 and S1 (60%). Two had a clinically relevant improvement in function. S1 had a possible ceiling effect.

- Reported Limitation

Three subjects did not report any limiting factor for performing the exercises prescribed: S5, S3, and S11 (27%). All of them had a clinically relevant pain decrease and improvement in function.

From the 3 subjects who reported no limiting factors, 2 performed 100% of the protocol and 1 performed 92% (S5 did only 75% of squats in one day).

Three subjects had mainly "other" as limiting factor for performing the squats such as: fatigue, busy schedule, sickness, small trips and distraction (S2, S4 and S8) (27%). Two of these subjects had a clinically relevant pain decrease and improvement in function (S4 and S8).

From the 3 subjects who reported "other" as limiting factor, all performed ≤ 32% of the protocol.

Five subjects had knee pain as limiting factor: S7, S1, S6, S9, and S10 (45%). Three of them had a clinically relevant pain decrease (S1, S9 and S10), one had a clinically relevant improvement in function (S9) and 2 had a possible ceiling effect (S1 and S10).

From the 5 subjects who reported knee pain as limiting factor, 3 performed ≥ 80% of the protocol (S6, S9 and S10), 1 performed 72% (S1) and 1 performed 60% (S7).

- Function at baseline

Seven subjects had a function score at baseline ≥ 80 points: S2, S1, S6, S5, S10, S3 and S11 (64%). Five of them had a clinically relevant pain decrease (S1, S5, S10, S3 and S11). Three had a clinically relevant improvement in function (S5, S10 and S11) and 2 had a ceiling effect (S1 and S10)

From the 7 subjects with function scores ≥ 80 points, five performed ≥ 80% of the protocol: S6, S5, S10, S3 and S11 (71%); and 1 performed 72% of the protocol (S1).

Four subjects had a function score at baseline < 80 points: S4, S8, S7, and S9 (36%). Three of them had a clinically relevant pain decrease and improvement in function (S4, S8, and S9).

From the 4 subjects with function scores < 80 points, 1 subject performed ≥ 80% of the protocol: S9.

- Summary: Pain reduction and Function Improvement

From the 8 subjects who had a pain decrease, 6 had a clinically relevant improvement in function and 2 had a possible ceiling effect.

From the 8 subjects who had a pain decrease and function improvement, 6 (75% of subjects) performed more than 70% of the protocol (S1, S3, S5, S9, S10, and S11) and, 5 of them had a high function score at baseline (S9 was the exception).

From the 8 subjects who had a pain decrease, 2 performed only 32% of the protocol and also had a low function score at baseline (S4 and S8) (25% of subjects).

Figure 15 (below) summarizes most of the information above. It groups the subjects into who performed $\geq$ 80% of the protocol and < 80% of the protocol, their reported limiting factors, and clinically relevant pain decrease and function improvement.
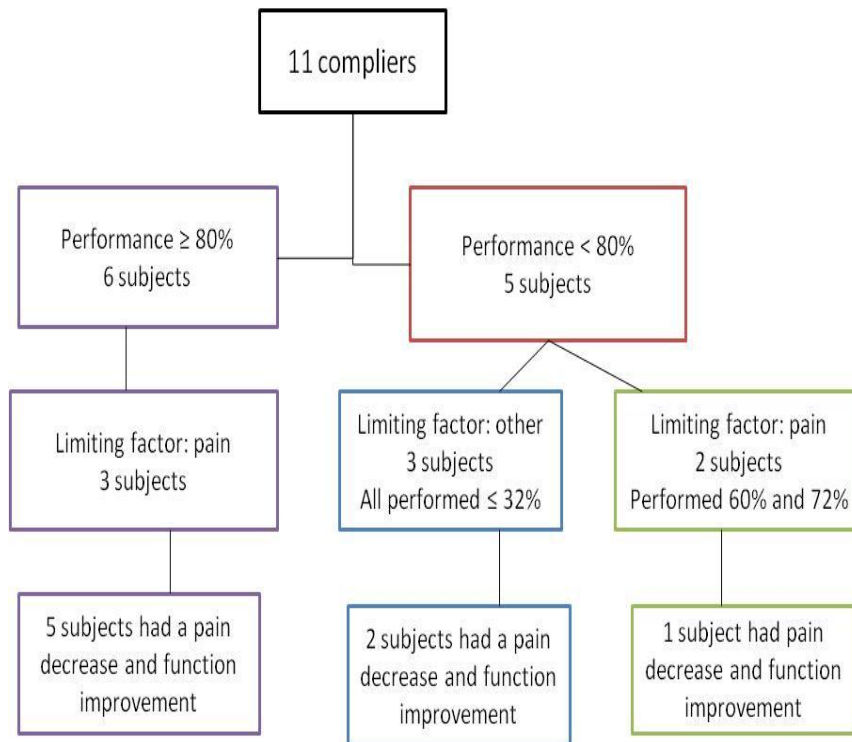
Figure 15. Chart summarizing and grouping the results of the study.

CHAPTER 5. **DISCUSSION**

5.1   Introduction

The present study was an exploratory evaluation of a new exercise protocol for treatment of chronic PFPS. The protocol involved 25 days of deep squats distributed over 6 weeks. The number of sets and repetitions of squats were outlined per day and goals to reach every two weeks were set. The deep squats were mainly performed at home. To accomplish objective 1, compliance, performance and outcomes were analyzed. Of the 11 subjects who participated in the present study, all attempted squats for more than 20 days (80% of the total number of days) and thus were considered compliers. Eight of these 11 subjects (72.8%) had a clinically relevant decrease in pain (VAS scale). Six of them had also a clinically relevant improvement in function and the other 2 subjects had a possible ceiling effect. Considering just this information, the protocol looks promising and it seems feasible to be applied for the treatment of PFPS. However, not all subjects performed the same number of squats. This information was summarized in Table 24 and Figure 15 and will be discussed later in this chapter.

To accomplish the second objective, temporal changes in pain and function scores were examined over the intervention phase of the study. Wide variability was seen in subject response to the squatting protocol. For pain, there is a trend of improvement around the third week of the treatment period (Figure 13). On the other hand, greater improvement in function was observed during the first two weeks of treatment (Figure 14).

To accomplish the third objective, possible factors that could have influenced the outcomes (pain and function) were explored (Table 24 and Figure 15). These results will be discussed later in this chapter.

5.2 Discussion of Main Findings

5.2.1 Comparing Results with Previous Literature

The main finding of this study was that 8 of 11 subjects (72.8%) had a clinically relevant decrease in pain (VAS scale) after performing the deep squats protocol. This part of the discussion compares the clinically relevant pain reduction observed in the present study with studies that investigated effects of treatments for PFPS. Only one SSD study was found in this area (54). Other studies were randomized control clinical trials (28,48,55), a case series (27), a case reports (26), and a before and after group comparison (56). Since one of the main outcome of the present study was pain, pain was the main aspect compared among the studies. One study used two scales to measure pain, VAS (minimally important difference: 20mm) and Numeric Pain Rating Scale (NPRS) (minimally important difference: 2 points) (57).

The mean values of pain at baseline and phase 3, for all 11 subjects, were: 47.3mm and 21.6mm respectively, resulting in a mean decrease of 25.7mm (clinically relevant) and a change of 54.3% (decreased in pain level). These values were compared to other studies that are summarized in Table 26.

Taking into consideration that most of the studies discussed bellow can not be directly compared to the present study, due to methodological differences, this part of the discussion is mainly an observation of the similarities and differences between the present study and some of the existing literature.

In the present study, the values of the present study (mean pain decrease = 25.7mm, and change = 54.3%) are similar to other studies. Syme et al., (2009), reported a decrease of 26.3mm (55%) and 23.2mm (45%) when comparing VMO training and taping, with general quadriceps strengthening (55). Crossley et al., (2002), reported a pain reduction of 40mm (57%) when comparing taping, mobilization, strengthening, and home exercises with placebo treatment (48). Alaca et al., (2002), had a reduction of 30.8mm (49.3%) after an isokinetic program (50). Sultive et al., (2004) found after use of orthoses and activity modification 60% of their subjects had a pain reduction of 29.3mm (60.5%) (31). In the present study, 60% of the subjects who performed less than 80% of the protocol also had a pain reduction. Iverson et al., (2008), reported a reduction of 3.5 points (39.7%) but only a smaller percentage of the sample improved (42%) (58). Fukuda et al., (2010), found a clinically relevant decrease in pain during stairs ascending (2.2 points (42.3%)) and descend (2.6 points (53%)) after hip and knee musculature strengthening but not after knee musculature strengthening alone (28). Powers et al (2004) reported a decrease of 20mm (43.4%) when wearing knee braces (56).

Three studies reported greater results regarding changes in pain levels, when compared to the values of the present study. One was a SSD study, one was a case report, and the other a case series. Earl et al., (2010) described a case series of 19 women who underwent a 8-week program of core and hip muscle strengthening. Their results were a decrease of 35mm (87.5%) in pain levels on average, in only 78.9% the subjects (15 out of 19), which is close to the number of subjects who reported reduction in pain in the present study (72.8%, 8 out of 11 subjects). The case report study had a pain level decrease of 50mm (100%) for subject A, and 80mm (80%), decrease for subject B after a core and hip muscle strengthening program (26). The calculated values for the SSD study

were a decrease of 90mm (90%) of change, when using a foot orthoses (together with quadriceps strengthening) (59).

Three other studies presented poorer results than the values of the present study. McPoil et al., (2011) reported that 60% of their participants had a "clinically significant reduction (60%) in pain" (60). Keet et al., (2007), described "no difference" when comparing no tape versus medial patellar taping (49). Ng et al (2002) did not have a clinically relevant result (decrease of 11mm) after medial patellar taping (61). Table 26 summarizes all of the studies mentioned above, and provides more information about each study.

Study Type	Content; (Duration of treatment)	Sample	Gender, Age; Duration of Symptoms	Pain Outcome Instrument	Pre/Post Mean Difference ; Pre/Post Percentage of Change (%)
Present study	Effect of a 6 week protocol of deep squats	n=11	Females and males; 20-30; >5months	VAS	-25.7mm (54.3%)
Syme et al 2009; randomized control trial	compared the effectiveness of (1) VMO specific training + McConnell taping versus (2) general quadriceps strengthening; (8 weeks)	(1)n=21 (2)n=22	Males and females 16-40 years >3months	VAS	(1) -26.3mm (55%), (2)-23.2mm (45%)
McPoil et al (2011); cross over study	compared the pain and comfort of contour versus flat orthoses; (3 weeks,+ 1 week washout)	n=10	Not provided	Numeric pain rating scale (NPRS)	6 subjects reported clinically significant reduction in pain (60%)

Study Type	Content; (Duration of treatment)	Sample	Gender, Age; Duration of Symptoms	Pain Outcome Instrument	Pre/Post Mean Difference ; Pre/Post Percentage of Change (%)
Keet et al 2007; placebo controlled trial	compared no tape with placebo tape and medial patelar tape, after maximal quadriceps contraction and step test; (one day)	n=15	Female and males 25 to 34 years; >5weeks	VAS	No difference in pain among the conditions
Crossley et al 2002; randomized control clinical trial	Compared (1): McConnell taping +quadriceps retraining + mobilization + home exercises; with (2): sham ultra-sound + placebo gel + placebo taping (6 weeks)	(1)n=33 (2)n=34	Male and females 12 to 40 years ≥1month	VAS worse and usual pain	(1)worse VAS: -40 (57%), (1)usual VAS: -35 (77.7%)
Alaca et al 2002; before and after group analysis	Effectiveness of an isokinetic program; (6 weeks)	n=22	Females and males, 14 to 45 years; >12days	VAS	-30.8 (49.3%)
Ng et al 2002; per/post design	Effects of patellar taping during a semi-squat; (one day)	n=15	Males and females, 15 to 45 years; Not reported	VAS	-11 (47.8%)
Sultive et al 2004, pre/post diagnostic study	Effects of orthoses and activity modification and investigation of a clinical prediction rule; (3 weeks)	n=35	Female and male; 18 to 40 years, chronic	VAS	-29.3 (60.5%) 60% got better
Iverson et al 2008, prospective cohort / predictive validity study	Effect of lumbopelvic manipulation in 3 funtional tests ; (one day, before and after)	n=49	Female and males, 18 to 50 years, >1week	NPRS	-3.5 (39.7%) 42% got better

Study Type	Content; (Duration of treatment)	Sample	Gender, Age; Duration of Symptoms	Pain Outcome Instrument	Pre/Post Mean Difference ; Pre/Post Percentage of Change (%)
Fukuda et al 2010; randomized control clinical trial	Compared (1) conventional knee musculature with (2) hip and knee musculature strengthening and (3) control; tested pain during ascending and descending stairs; (4 weeks)	(1)n=20 (2)n=21 (3)n=23	Females 20 to 40 years; ≥3months	NPRS	(1)Asc -1.5 (30.6%) (1)Desc -1 (22.2%) (2)Asc -2.2 (42.3%) (2)Desc -2.6 (53%)
Powers et al 2004; before /after	Effect of bracing during knee extensions; (one day)	n=15	Females 18 to 45 years; not reported	VAS	-20mm (43.4%)
Mascal et al 2003; case report	2 case reports targeting hip and trunk muscles; (14 weeks)	n=2	Females 20 and 37 years old; >2years	VAS	Case A: -50 (100%) Case B: -80 (80%)
Earl et al 2010; Case Series	Effects of a proximal strengthening program (hip and core) for 8 weeks	n=19	Females 16 to 40 years; >4weeks	VAS	-35mm (87.5%)
Way MC 1999; SSD	Effect of the addition of foot orthoses during treatment; (10 weeks)	n=1	Female 19 years old; Acute	VAS	-90mm (90%)

Table 26. Summary of the studies investigating treatment effectiveness for PFPS. The table presents study title, type, content, duration of treatment, sample sizes, subjects characteristics (age, gender, duration of symptoms), the outcome instrument used, results (pain change in mm if VAS, points if NPRS, and percentage of change).

5.2.2   Feasibility: Compliance, Performance and Limiting Factors

The deeps squats protocol used in the present study was very demanding. As part of the objectives, the feasibility of the protocol was examined. Compliance to the protocol, number of the protocol repetitions performed and reported limiting factors were examined to assess feasibility. All 11 subjects were considered compliers (because they all did squats in 20 or more days of the protocol), 6 subjects performed ≥ 80% of the protocol, 1 subject performed 72%, 1 performed 60% and 3 performed ≤ 32% of the protocol.

Interestingly, subjects with the poorest performance (i.e. ≤ 32% of the protocol completed) did not report knee pain as a main limiting factor. Their reason to perform poorly was due to non-pain related factors: fatigue, a busy schedule, sickness, small trips and distractions. Conversely, among the subjects with the higher performance, 3 reported no pain, 3 reported non-limiting pain, and 2 reported limiting pain (could not perform more squats due to pain). In other words, poor performance was primarily due to non-pain related factors, and within the higher performance group, pain did not seem to decrease performance. Based on this data, it seems likely that this protocol may be feasible and that knee pain, when monitored, is not a major limiting factor.

5.3   Change of Pain and Function over Time

Figures 13 and 14 present all data points of all subjects, for pain and function, before, during and immediately after the treatment. Visually observing Figure 13, it seems likely that most subjects who had a reduction in pain (significant or not) started to have the reduction after the third week of the protocol, which is contrary to the experience of the

physical therapists in British Columbia. However, the difference visually seems to be only one week, which could be considered small. Some possible speculations can be formed based on this observation. First, the deep squat protocol started with each subject performing several repetitions of deep squats every day for 2 weeks, perhaps not leading to changes in their perception of pain, since squats can be one of the pain-related activities in PFPS people (53). Second, as cartilage can deform relatively easily (39) in different areas (38) and the recovery time is long (37), perhaps the periods of rest had a role in the greater reduction of pain after the third week (squatting only 3 times per week).

When visually observing Figure 14, changes in function appear to not correlate with changes in pain. Most of the subjects seem to have had a more visible change in function during the first two weeks of treatment. Some possible speculations can be formed based on this observation. Firstly, there could have had a real improvement in function; due to possible physiological benefits of deep squats. Secondly, the subjects could have had a decrease in fear and/or avoidance of performing activities related to pain, such as squats, which could have increased their perceived function (53). Since they were supposed to squat every day for the first 2 weeks of the protocol, their perceived function could improve at the beginning of the treatment period.

The changes in pain and function scores throughout the treatment period visually seem to reach a plateau-like state during week five and six. This observation may suggest that 6weeks of deep squats is a good length of treatment. However, larger clinical trials are necessary to investigate this.

5.4   Exploratory Discussions

5.4.1   Possible reasons for the Four Outcomes

Subject 2 had a low performance and no improvement in outcomes, which could be expected. Subjects 1, 9, 5, 10, 3 and 11 performed a significant portion of the protocol and had relevant improvements in outcomes, which was the hoped for result. Therefore, from the 11 subjects participating in this study, 7 had the hoped for results.

Subjects 6 and 7 had high performances but no relevant improvement in outcomes. Subject 6 had only 1.8 cm decrease in pain (not clinically relevant). Since she reported pain relief after taping her knee, and there is evidence of taping increasing the contact area and decreasing pain (61,64,65), perhaps she had patellar malalignment, which would not improve with deep squats. Another possible explanation, which can also be applicable to S7, is that no treatment in isolation seems to be effective for all people with PFPS (23,28,55,58,60,66). Therefore, the deep squats protocol might not be expected to work for all subjects. Perhaps other treatments would have been more effective for these individuals.

Subjects 4 and 8 had low performances but improvement in outcomes. Subject 8 had a main complaint of knee pain during the night (had to sleep with pillows under knees), and at the end of the protocol, she reported no pain during sleep. Perhaps her improvement in outcomes was due to the fact that she was reporting only her main complaint in the self-reported scales (which was resolved). Subject 4 appeared not to be committed to the study and was always apologizing for not doing the protocol. Perhaps, his self-reported scores were confounded by desirability bias (62,63). Desirability bias or socially desirable responding is the tendency of subjects to present a positive and acceptable response whenever asked about themselves in self-reported scales (62). The subject may believe in the reported information, or may fake it in order to gain social approval or

avoid criticism (63). Even though this bias is frequent when involving socially sensitive topics, it may also confound data when self-reporting health status to a health care professional (63). Since the VAS is a self-reported pain scale, there is the possibility that the results were confounded due to desirability bias.

5.4.2 Influence of Function Scores at Baseline and Performance on Pain and Function

Since pain and function had similar results (from the 8 subjects who had a pain decrease, 6 had an improvement in function and 2 had a possible ceiling effect), it seem likely that pain and function are connected, and can be seen as one when trying to explore possible factors that influence outcomes. In order to satisfy one of the objectives of the present study (look at possible factors that could have influenced outcomes) the data from the 8 subjects who had a clinically relevant pain reduction and function improvement was examined. From these data, it was possible to identify two distinct groups of subjects: a) subjects who performed > 70% of the protocol (6 subjects) and b) subjects who performed ≤ 32% of the protocol (2 subjects).

From the 6 subjects who performed > 70%, all had knee pain as reported limiting factor or no limiting factor, and 5 had a high function score at baseline (exception: S9). S9 had a low function score at baseline but a high performance. Since the function questionnaire (Kujala questionnaire) also measures pain (5 out of 13 questions) (46), and her baseline mean pain was high (Table 18), it is likely that she scored the pain-related questions in the function questionnaire fairly low, resulting in a low function score at baseline. The 2 subjects who performed ≤ 32%, reported mainly non-knee pain factors as limiting factors (busy schedule, fatigue, etc...) and had a low function score at baseline.

Therefore, it seems possible that high performance of the protocol, reported limiting factors, and high function scores ($\geq$ 80 points) at baseline could have influenced the outcomes (pain reduction and function improvement).

5.5   The Rationale behind Deep Squats

Several studies investigated the effects of loading on the articular cartilage (21,37-39,67-71). Eckstein et al., (1998) found a significant amount of deformation of patellar cartilage, after 50 squats, in healthy volunteers (72). Eckstein et al., (1999) found no difference in cartilage deformation between several sets of 50 squats and one set of 100 squats (range: from 2.4% to 8.5%, and 2.4% to 8.6% respectively). These authors concluded that the deformation was caused by fluid flow (displacement) (37); which is beneficial to the nutrition and biosynthesis of the cartilage (20,21).

Eckstein et al., (2000 and 2005) investigated the extent and pattern of cartilage deformation after different types of exercise. They found greater deformation on the patellofemoral joint contact areas after dynamic exercises (i.e. the greater contact area the greater was the deformation area) (38,39). Since PFPS symptoms can be caused by problems in different areas of the patellar cartilage (8,70,73), the greater patellofemoral contact area of an exercise treatment, the better. Deep squats promote full contact between patella and femur (33,73), which is the reason behind performing deep squats as treatment for PFPS.

5.6   Limitations

Limitations of the present study include:

1. In a Single Subject Design – multiple baseline study, the baseline period should not be established prior to the experimentation. However, for the present study, the investigator chose to use small periods of time as baselines, since PFPS is a chronic (usually long term condition), which does not resolve by itself within weeks (74).

2. The baseline period of the B7 group was likely not long enough; even though it met the requirements of a SSD methodology (3 data points). Seven days of baseline was too short to ensure stabilization of the pain scores (Figure 13), resulting in great variability at baseline. This variability seemed to be prejudicial for the statistical analysis (2-SD band).

3. The protocol was mainly unsupervised, which could have limited the performance of the protocol.

4. The Kujala questionnaire (function) appeared to not be discriminating enough to detect change in function (possible ceiling effects), since some of the questions appeared to not be relevant for the subjects in this sample (examples: limp, feeling instability, wasting of thigh muscles, loss of knee bend) (Appendix 10).

5. There was no follow up in the present study. It would be interesting to observe whether the protocol was helpful at short-term (up to a month) or at long-term (6 months or more) periods. Lack of time and funds were the reason for the absence of a follow-up period.

5.7   Strengths

To the author's knowledge, this is the first study that observed deep squats as treatment for patellofemoral pain syndrome.

1. A deep squat is an exploratory and somewhat controversial intervention since it is contradictory to what is commonly advocated in clinical practice and in the literature (which recommends avoiding great knee flexion angles, using treatment with squats around 90° of flexion) (23,33,36,48). However, as the cartilage of the patella receives its nutrition through fluid flow due to compression, compression in all parts of the patella may add to the health of the cartilage.

2. In this study only one treatment was used, which could allow reproducibility in another study. It was also clinically feasible, since the subjects could perform the protocol at home with no great monitoring. However, performance of the subjects was not optimal with only two subjects (S3 and S11) performing 100% of the protocol (both had good results).

3. The sample used in this study was representative of the majority of the PFPS population, since the subjects were mainly young females 20 to 29 years of age), who performed physical activity and had chronic symptoms.

4. Due to the fact that a multiple baseline design was chosen as this study's design, it was possible to observe: 1) the changes in pain and function under ongoing treatment, 2) when to expect the changes and 3) to analyze each subject individually.

5.8 Recommendations for Future Research

There are many possibilities of future studies arising from the observations and speculations of the present study. Some possible directions for future research include:

a. Investigating this protocol: (i) using a different function scale, (ii) having closer monitoring of the performance, (iii) measuring physical activity level, (iv) using subjects with different activity levels, (v) using larger clinical trials,

b. Investigating possible factors related to good performance of deep squats,

c. Investigating dose-response and length of the protocol,

d. Investigating the protocol with a longer follow up to see how long the improvement lasted and whether the majority of subjects would continue to improve,

e. Investigating the role of biomechanics and/or possible physiological effects of deep squats in the PF joint (e.g. joint stress/pressure, cartilage nutrition and fluid flow),

f. Investigating SSDs or other methodologies looking at different characteristics of subjects with PFPS and how they respond to different treatments (one being deep squats).

CHAPTER 6.   **SUMMARY AND CONCLUSION**

6.1   Summary

The present study was an exploratory observation of a new exercise protocol as treatment for subjects with PFPS. Eleven subjects with chronic PFPS participated in this multiple baseline SSD study. The protocol was 25 days of deep squats over 6 weeks, with number of sets and repetitions suggested for each day. All subjects were considered compliers (since they performed squats in 20 or more days of the protocol), but the amount of squats performed varied. Most of subjects who performed more than 80% of the protocol had a pain reduction (85%), however 60% of subjects who performed less than 80% also had a pain reduction. Possible factors that could have influenced outcomes were observed, such as: function at baseline, reported limiting factors and performance.. Also, pain and function scores visually appeared to have a greater change around the second and third week of the protocol, respectively. From the observations of the present study, it seems that deep squats can be promising to treat subjects with PFPS, however further studies are necessary.

6.2   Conclusion

Based on the observations of the present study, it appears that:

- The protocol of deep squats may be feasible and promising as treatment for subjects with PFPS,

- Greater knee flexion angles are not harmful for subjects with PFPS,

- Positive changes in pain and function can be expected within 3 weeks of the protocol in most subjects,

- Performance of 70% or more of the protocol seems to be sufficient to promote good results,

- The protocol seems to work for some people with PFPS but not others,

- Low performance may still promote improvement in outcomes.

However, larger controlled trials are needed to support the results of this SSD study.

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APPENDIX 1

Ethics Approval

Ethics Application has been Approved

ID: Pro00014699

Title: The effect of deep leg squats on patellofemoral pain syndrome - a single subject design

Study Investigator: David Magee

Description: This is to inform you that the above study has been approved.

Click on the link(s) above to navigate to the HERO workspace.

Please do not reply to this message. This is a system-generated email that cannot receive replies.

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Advertisement

"THE EFFECTS OF DEEP LEG SQUAT ON PATELLOFEMORAL PAIN

Are you between 18 & 40 years old?

Are you having STRONG PAIN under or around your KNEE CAP?

Has the pain been present for 3 months or longer?

Did the pain come on for no apparent reason?

If you answered "YES" to the questions above, we invite you to participate in our study. We are evaluating if an exercise protocol of deep squats is effective in treating Patellofemoral Pain. This study involves a knee assessment, and 6 weeks of exercise treatment. The knee assessment will take about 1 hour, at Corbett Hall at the University of Alberta; and if you meet the inclusion criteria and agree to participate, the treatment will be a 6-week home exercise program.

For more information, please contact:

Larissa Costa, by email: lcosta@ualberta.ca ; or phone: (780) 492-4824

Knee pain Study Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	lcosta@ualberta.ca Larissa Costa – (780) 492-4824	lcosta@ualberta.ca Larissa Costa – (780) 492-4824	lcosta@ualberta.ca Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	Knee pain Study Larissa Costa – (780) 492-4824	lcosta@ualberta.ca Larissa Costa – (780) 492-4824

APPENDIX 3

Phone/Email Screening

Inclusion Criteria (all answers should be "Y")

Are you between 18 and 40 years of age?	Y N
Do you have pain behind or around your knee cap (patella)?	Y N
Is the duration of your symptoms greater than 3 months?	Y N
Did the pain come on for no apparent reason?	Y N

Exclusion Criteria (all answers should be "N")

Do you have any other knee problems? (meniscus, ligaments…)	Y N
Have you ever had knee surgery?	Y N
Has your knee cap (patella) ever subluxed or dislocated?	Y N
Do you have any of the following: a) Cancer? b) Cognitive impairment? c) Cardiac problems? d) Low back/hip/foot/ankle pain?	Y N Y N Y N Y N
Do you have flat feet?	Y N
Are you pregnant?	Y N

APPENDIX 4

Inclusion and Exclusion Criteria

Inclusion

Are you 18-40 years old?	Y	N
Do you have pain behind or around your knee cap?	Y	N
Is the duration of your symptom greater then 3 months?	Y	N
Is your pain not related to injury or trauma?	Y	N

Do you have pain in any of the following:
   a) Squatting
   b) Stair climbing
   c) Kneeling
   d) Prolonged sitting
	
	Y
	Y
	Y
	Y
		
		N
		N
		N
		N

What is your usual pain level? (VAS>3?)	Y	N

Do you have pain in any of the following:
   a) Manual compression of the patella against the femur at rest or while performing quadriceps contraction with extended knee
   b) Palpation of the borders of the patella
	
	Y
	
	Y
		
		N
		
		N

Exclusion

Do you have a concomitant injury or knee pathology? (problems in your ACL/PCL/MCL/LCL, menisci, pes anserinus, patellar tendon, iliotibial band)	Y	N

Have you had one of the following:
   a) Knee surgery
   b) Patellar dislocation/suluxation
	
	Y
	Y
		
		N
		N

Do you have any of the following:
   a) Sinding-Larsen-Johansson Syndrome
   b) Osgood-Schlatter
   c) Cancer
   d) Cognition impairment
   e) Cardiac problems
   f) Low back/hip/foot/ankle pain
	
	Y
	Y
	Y
	Y
	Y
	Y
		
		N
		N
		N
		N
		N
		N

Are you pregnant?	Y	N
Do you wear foot orthoses?	Y	N

Assessment:
   a) Knee effusion
   b) NDT > 10mm
   c) Forefoot heel not aligned?
	
	Y
	Y
	Y
		
		N
		N
		N

HEIGHT: WEIGHT: DURATION OF SYMPTOMS: GENDER:

APPENDIX 5

Information Letter

Study: "The Effects of Deep Leg Squats on Patellofemoral Pain Syndrome – a Single Subject Design"

Principal Investigator: Dr. David Magee, PhD. Faculty of Rehabilitation Medicine

Sub-Investigator: Larissa Costa, MScRS. Faculty of Rehabilitation Medicine

Contact Information: Dr. David Magee at (780) 492-5765, Larissa Costa at (780) 492-6707; or lcosta@ualberta.ca

Background:

Patellofemoral Pain is a very common knee problem. There are different treatment options for this problem, however none have demonstrated great results. A new exercise protocol has been proposed to treat patellofemoral pain, and clinically it seems to be effective. The purpose of this study is to determine the effectiveness of this protocol.

Purpose:

You are being asked to participate in this research study to compare your knee condition before, after and during this new exercise protocol. The investigators are interested in measuring your knee pain and knee function, in order to see if this protocol is a good treatment for Patellofemoral Pain.

Procedure: *Participating in this study will involve:*

a) 4 appointments at the Sports Therapy Research Lab (University of Alberta). The first appointment will take approximately one hour, and the other 3 approximately half hour each.

b) Knee and foot assessments by a physical therapist to determine inclusion and exclusion criteria.

c) Different amounts of time involved in the study. You will have equal chances of participating in this study for 49, 55, or 61 days. The treatment will be the same, and it will take 42 days (6 weeks). However, the number of days you will wait for the treatment will depend on chance. There will be three possibilities: 7, 13 or 19 days of waiting before the treatment starts. You will find which group you are in when you open a sealed envelope (which will contain one of these numbers).

d) Measuring your knee function and knee pain every 3 days. You will report function and pain using one scale and one questionnaire provided by the investigator.

e) Answering a perception scale. On the last day of study, you will be asked to compare your knee condition before and after the treatment.

f) Performing the treatment protocol. The treatment is a 6-week exercise protocol of deep squats, performed daily for weeks 1 and 2, three times per week for weeks 3 and 4, and twice per week for weeks 5 and 6.

g) Writing down the number of squat repetitions. You will be asked to write on a diary sheet the number of squats you did every exercise day.

h) Receiving calls from the investigator. To check on your symptoms, the investigator will call daily during the first week of treatment, and weekly for the remaining 5 weeks.

Benefits/Risks:

Since squats are widely performed and have often been recommended as a form of treatment, and because this treatment has already been used clinically with positive results, the investigators believe that there are several possible benefits in participating in this study, such as: decrease of your knee pain, improvement of 1) your health, 2) your leg-muscle strength, 3) your endurance, 4) your self-esteem, and 4) your knee function. There are only two potential risks: the possibility of increasing your knee pain, or no change in your pain level. However, this possibility is very low, since the squats will be performed without increasing your previous pain level, and the investigator will keep checking with you to ensure your symptoms are not getting worse.

Confidentiality:

Personal health records relating to this study will be kept confidential in a safe, secure area. Any research data collected about you during this study will not identify you by name, only by your initials and a number. Your name will not be disclosed outside the research clinic except where a code of ethics or the law requires. Any report published as a result of this study will not identify you by name. The data gathered for this study may be looked at again in the future to help us answer other study questions. If so, an ethics board will first review the study to ensure that the data are used ethically.

Voluntary Participation:

Your participation is completely voluntary. If, at any time, you decided to withdraw, you are free to do so without consequences.

In Case of Injury:

If your knee becomes more painful with the exercise protocol than it was before, you will receive contact information for the Corbett Hall Student Physiotherapy Clinic which provides free physical therapy treatment.

In Case of Emotional Distress

If you feel emotionally stressed about anything related to the study, please contact the investigators right away. If you feel it is an issue that you do not want to speak to the investigators about, please contact Dr Joanne Volden, Associate Dean – Research, in the Faculty of Rehabilitation Medicine (780 – 492 – 0651). If the issue deals with any issue other than the research process, please contact the Peer Support Centre at 780 492-HELP or to book an appointment by phoning the administration line at 780-492-4268.

In Case of Research Participant's Rights

For questions related to one's rights as a research participant, please contact the University of Alberta Health Research Ethics Board at 780-492-0302.

APPENDIX 6

Informed Consent Form

SAMPLE CONSENT FORM

Part 1 (to be completed by the Principal Investigator):

Title of Project: The Effects of Deep Leg Squat on Patellofemoral Pain Syndrome – a Single Subject Design

Principal Investigator(s): Dr. David Magee, PhD, Associate Dean   Phone Number(s): 780 492-5765

Co-Investigator(s): Larissa Costa   Phone Number(s):780 492-6707

_____

Part 2 (to be completed by the research subject):

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to your research results?	☐	☐
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If so, give his/her name _____	☐	☐

Who explained this study to you? _____

I agree to take part in this study: YES   ☐   NO   ☐

Signature of Research Subject _____

        (Printed Name) _____

Date:_____

Signature of Witness _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee   _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT

APPENDIX 7

Assessment of Foot Pronation

Foot pronation was assessed prior to enrolment in the study by performing two tests for foot alignment: navicular drop test (NDT) and forefoot alignment (31,66,75). These tests have been shown to be good predictors of improvement in outcomes when patients use orthoses (31). The NDT is a common clinical method used to quantify foot pronation with a moderate intrarater reliability (ICC=0.78, SEM=1.68) and positive likelihood ratio (+LR=2.4, 95%CI) (31,76). It has been used in another PFPS study (31), and values above 10mm are considered abnormal (foot pronation) (75). Forefoot valgus alignment was shown to have a high positive likelihood ratio in predicting treatment success using orthoses (+LR=4.0, 95%CI) when the angle between the metatarsal heads and the calcaneal line is $\geq 2°$ valgus; and, a high specificity (97%) (31). In this study, participants were considered as having foot pronation when: NDT $\geq$ 10mm, and the forefoot alignment was not perpendicular (metatarsal heads and calcaneal line did not form a perpendicular angle) (31,75,77).

APPENDIX 8

Exercise Protocol – Deep Squats

Body position:
1-feet shoulder width apart
2-heels raised 2-4cm (only for the 2 first weeks)
3-feet may be slightly in toe out
4-upper body in neutral spine position
5-contract the core to maintain posture
6-let your knees go over your toes

Squatting:
1-Knee tracking over second toe as you squat
2- Movement is similar to pick up a ball off the floor between your feet
3-Your range of motion should be pain controlled (no extra knee pain)
4-Progress the depth of the squat according to your pain and balance
5- Use the heel lift if you have difficulties going all the way down; but alternate its use with no use (in order to discontinue the heel lift after the second week)
6-Stop if: your knee "gives away because of pain"; "pain is so great that it stops you"; feeling low back pain; when feeling sufficient weakness in the legs that you cannot do a squat; feeling a painful stretch in the calf muscles, and/or the heels lift off the floor or pad.

Protocol:
Phase I – week 1 and 2
Ice around the knee for 10-20 minutes after squats (if needed)
Daily exercises: 5 sets of 10 to 50 repetitions
The goal is to reach 5 sets of 50 repetitions by the end of week 2.
Exercises must be performed 7 times per week, with 30s to 1min rest between sets
Phase II – week 3 and 4
Three times per week: 4 sets of 60 to 80 repetitions
The goal is to reach 4 sets of 80 by the end of week 4.
Exercises must be performed 3 times per week, with 30s to 1min rest between sets
Phase III – week 5 and 6
Week 5: three times; 3 sets of 80 to 90 repetitions
Week 6: two times; 2 sets of 95 to 100 repetitions
The goal is to reach 2 sets of 100 repetitions by the end of week 6.

APPENDIX 9

Visual Analogue Scale for Worst Pain (VAS –W)

Please indicate with a vertical mark, in the line bellow, what was your level of pain during the WORST PAIN felt LAST three days:

_____

No pain   Worst pain

imaginable

Kujala Questionnaire – Knee Function

Name: Knee: L / R   Date:

For each question, circle the latest choice (letter) which corresponds to the problems you have in your knee NOW.

1. Limp

(a) None (5)

(b) Slight or periodical (3)

(c) Constant (0)

2. Taking weight on your leg

(a) Full support without pain (5)

(b) Painful (3)

(c) Weight bearing impossible (0)

3. Walking

(a) Unlimited (5)

(b) More than 2 km (3)

(c) 1-2 km (2)

(d) Unable (0)

4. Stairs

(a) No difficulty (10)

(b) Slight pain when descending (8)

(c) Pain both when descending and ascending(5)

(d) Unable (0)

5. Squatting

(a) No difficulty (5)

(b) Repeated squatting painful (4)

(c) Painful each time (3)

(d) Possible with partial weight beating (2)

(e) Unable (0)

6. Running

(a) No difficulty (10)

(b) Pain after more than 2 km (8)

(c) Slight pain from start (6)

(d) Severe pain (3)

(e) Unable (0)

7. Jumping

(a) No difficulty (10)

(b) Slight difficulty (7)

(c) Constant pain (2)

(d)Unable(0)

8. Prolonged sitting with the knees bend

(a) No difficulty (10)

(b) Pain after exercise (8)

(c) Constant pain (6)

(d) Pain forces to extend knees temporarily(4)

(e) Unable (0)

9. Pain

(a) None (I0)

(b) Slight and occasional (8)

(c) Interferes with sleep (6)

(d) Occasionally severe (3)

(e) Constant and severe (0)

10. Swelling

(a) None (10)

(b) After severe exertion (8)

(c) After daily activities (6)

(d) Every evening (4)

(e) Constant (0)

11. Feeling instability, giving way in the kneecap

(a) None (10)

(b) Occasionally in sports activities (6)

(c) Occasionally in daily activities (4)

(d) At least one documented dislocation (2)

(e) More than two dislocations (0)

12. Wasting of thigh muscles

(a) None (5)

(b) Slight (3)

(c) Severe (0)

13. Loss of knee bend

(a) None (5)

(b) Slight (3)

(c) Severe (0)

Note: 1Km = 0.62 miles

APPENDIX 11

Exercise Protocol Diary Sheet

Please write down how many sets and how many repetitions of deep squats you did, at every time you did the exercise protocol. Please use the format: "3x20" (for 3 sets of 20 repetitions, for example).

Name: _____

WEEK 1						
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7

WEEK 2						
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7

WEEK 3		
Day 1	Day 2	Day 3

WEEK 4		
Day 1	Day 2	Day 3

WEEK 5		
Day 1	Day 2	Day 3

WEEK 6	
Day 1	Day 2

APPENDIX 12

Reminder Calendar

Days to fill out the Kujala questionnaire and the pain scale (VAS).

Please, check the respective box after filling out the function and pain forms:

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
MM/DD	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*
DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
MM/DD	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*
DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21
MM/DD	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*	*MM/DD*