Sheffield Hallam University

MA/MBA/MSc Dissertation Proposal Form for

Health and Social Care Subjects

FACULTY OF HEALTH AND WELLBEING

RESEARCH PROJECT

STUDENT NAME:	STUDENT NUMBER:
PFLÜGLER GEORG	**26020250**

Contents: Proposal

Risk assessment form

HERE provide a very brief (maximum 100 words) overview of study: Who/what is involved, data collection, data analysis methods and outcomes?
The aim of the study is to assess the immediate effects of passive hip joint mobilisation (in comparison to a sham mobilisation) on eccentric hip abductor/external rotator muscle strength on the basis of manual muscle testing with a hand-held-dynamometer within a cross-over study design. Patients with anterior knee pain and signs of impaired hip function will be recruited in Vienna and surrounding area, measurements/data collection will be conducted in a physiotherapy group practice in 1150 Vienna. Data will be analysed with the Stata/IC15.1 software using descriptive statistics prior to further inferential statistics (independent group t-tests). The values of the primary outcome measure (torque measurements) will be normalized by the body mass of each participant.

Sheffield Hallam University

MA/MBA/MSc Dissertation Proposal

Registration of Project

FACULTY OF HEALTH AND WELLBEING

Complete all sections as appropriate

STUDENT NAME:	Pflügler Georg	**STUDENT NUMBER:**	26020250
COURSE:	MSc Manual Therapy		
PROJECT TITLE:	The immediate effects of passive hip joint mobilization on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function		
PROPOSED START:	October 2018	**CREDIT POINTS:**	
PROPOSED COM-PLETION:	April 2019		
TYPE OF PROJECT:	RESEARCH		
ACADEMIC SUPERVISOR:	Sionnadh McLean		

Proposal dissertation

Principal Research Question

What are the immediate effects of passive hip joint mobilization on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function?

Null Hypothesis

There are no immediate effects of passive hip joint mobilization on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function.

Experimental Hypothesis:

There are immediate (positive) effects of passive hip joint mobilization on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function.

Justification for research project

Anterior knee pain (AKP) is one of the most frequent reasons for consultation in the context of knee conditions in young adults, especially when they participate in sports (Foss, Hornsby, Edwards, Myer, & Hewett, 2012). Boling et al. (2010) found an AKP prevalence of 15% in females and 12% in males, similarly, Nejati et al. (2011) found the prevalence rate to be 16.7%. Nevertheless, despite its high prevalence, the treatment of AKP is often not successful. Collins et al. (2012) analyzed 4 conservative intervention protocols, and they revealed that 40% of these patients had an unfavourable recovery at 12 months after the initial diagnosis. Moreover, AKP is rarely a self-limiting condition; it is recurrent or chronic in between 70% and 90% of the cases (Powers, Bolgla, Callaghan, Collins, & Sheehan, 2012). Since AKP frequently occurs in young working adults, it has an important societal impact due to work absences as well as due to the economic expense involved in the treatment of these patients (Tan et al.,

2010). Moreover, these AKP patients may also have an increased risk of developing patello-femoral osteoarthritis (K. M. Crossley, 2014). In summary, the high prevalence of AKP along with poor long-term prognosis and high disability levels, turns this clinical entity into an urgent research priority. In fact, the Chartered Society of Physiotherapy in the UK has ranked AKP as the third most important topic (out of 185) in their Musculoskeletal Research Priority Project (Rankin, Rushton, Olver, & Moore, 2012), which is a further indicator of its research importance.

The aetiology of AKP is typically multifactorial, involving local, proximal and distal factors. Hence, there is no single right treatment, the treatment approach has to be tailored to the individual patient (Sanchis-Alfonso, McConnell, Monllau, & Fulkerson, 2016). However, in recent years much attention has been paid to the relationship between hip function and AKP. It is proposed that greater hip adduction and internal rotation, especially during weight-bearing activities, may lead to altered knee and patellofemoral joint kinematics and therefore present a potential risk factor for AKP development. Recent prospective studies support this hypothesis (Boling et al., 2009; Noehren, Hamill, & Davis, 2013). These altered movement patterns may result from impaired gluteal hip muscle function. In fact, many studies have associated AKP with the weakness of hip abductors, external rotators and hip extensors (Niemuth, Johnson, Myers, & Thieman, 2005; Prins & Van Der Wurff, 2009; Rathleff, Rathleff, Crossley, & Barton, 2014). Further, reduced hip joint range of motion (ROM) has been associated with AKP as well (Hamstra-Wright, Earl-Boehm, Bolgla, Emery, & Ferber, 2017).

In line with this evidence (that impaired hip muscle function is associated with AKP), Santos et al. (2015) have explored the clinical effects of hip strengthening programmes in their recent systematic review. Their results showed that hip muscle strengthening has an important role in the treatment of AKP patients, since this intervention is effective in reducing pain intensity and improving function. However, findings regarding the treatments' ability to improve muscle strength were equivocal. One reason that may explain this result is the fact that neuromuscular activation deficits may be the underlying mechanism for the persistent muscle weakness, and

therefore hip strengthening programmes will be ineffective, as long as the activation deficit is not targeted first.

Pietrosimone, Hopkins and Ingersoll (2008) proposed a new rehabilitation paradigm that recommends the previously stated: targeting neuromuscular activation deficits with the aid of disinhibitory interventions prior to traditional strength training to enhance rehabilitation outcomes. They argue that if musculature is inhibited, for example due to arthrogenous muscle inhibition (AMI = a continued reflex inhibition of musculature caused by a pathological joint, where despite intended maximal muscle contraction even unimpaired muscles are not able to fully activate (Hopkins and Ingersoll, 2000)), without prior reengagement of the inhibited motor neurons, suboptimal motor recruitment patterns could lead to decreased level of performance, increased rate of fatigue, increased risk of subsequent injury and increased risk of chronic dysfunction.

In recent years, AMI has been primarily studied in the quadriceps muscles following acute knee joint injuries, operations or experimentally induced joint effusion (Freeman, Mascia, & McGill, 2013). However, Freeman et al. (2013) investigated and confirmed the existence of AMI in the hip joint as well, by showing that intra-articular injection of fluid causes diminished gluteal activation at functional hip extension tasks. Since patients with AKP show persistent gluteal hip weakness in common with reduced hip ROM and impaired hip kinematics, it may be hypothesized, that AMI of the hip joint may play a significant role in the treatment of these patients.

In the literature (Gabler, Lepley, Uhl, & Mattacola, 2016; Rice & McNair, 2010), transcutaneous electrical nerve stimulation (TENS) and cryotherapy are recommended as the most promising facilitatory modalities. Manual therapy (passive joint mobilisation/manipulation) as possible falicitatory intervention on the other hand shows contradictory findings (Harkey, Gribble, & Pietrosimone, 2014; Pietrosimone et al., 2015). Reasons for this contradiction may be caused by the selected study designs, where the explored manual therapy techniques often do not seem to be the most appropriate (and clinically reasoned) choice for the respective patient

population. For example, Grindstaff et al. (2012) examined the effect of lumbopelvic manipulation on quadriceps activation capacity in patients with AKP (but without present lumbopelvic impairments) and found that there was no immediate effect. However, one rationale behind passive mobilisation as a disinhibitory intervention is the stimulation of sensory receptors in and around the joint in order to modulate altered joint afferent discharge and thereby disinhibiting the musculature surrounding this joint (Bialosky, Bishop, Price, Robinson, & George, 2009). Therefore, in patients with AKP, the examination of the effect of peripheral knee joint mobilisation on quadriceps activation may have been more meaningful, when the knee as source for the inhibition is suspected. However, currently there are no such studies examining the effect of passive knee joint mobilisation on quadriceps muscle strength. On the other hand, two studies (Makofsky et al., 2007; Yerys, Makofsky, Byrd, Pennachio, & Cinkay, 2002) have explored the effect of passive hip mobilisation on gluteal muscle strength in healthy subjects. They have shown a significant facilitatory effect, suggesting greater and clinically more relevant effect may be possible in patients with persistent muscle weakness. For this reason the proposed study will explore the effect of a hip joint mobilisation on its inhibited surrounding musculature (namely hip ABD/ER) in a patient population (AKP patients with impaired hip function) with present persistent weakness. I expect that findings from this study may be relevant for the prevention of chronification in AKP patients as well as in the development of treatment strategies for patients suffering from multiple lower extremity joint pathologies that exhibit neuromuscular deficits.

Research design:

The design of the proposed study at hand will be similar to the works of Yerys et al. (2002) and Makofsky et al. (2007). Both examined the immediate effect of hip mobilisation on gluteal muscle strength in the form of a 'Pre-Test Post-Test equivalent group design'. Beside some changes in procedure and equipment being used, the most crucial contrasts between this proposed study and the previously mentioned works will lie in a different study population

(patients instead of healthy subjects) and study design (this study will use a cross-over design). Since the patients in a crossover trial serve as their own control, an advantage of using this design is the requirement of lower sample sizes compared to parallel-group trials to meet the same criteria in terms of type I and type II error risks (Wellek & Blettner, 2012).

Methods

Subjects:

AKP is frequently defined as retropatellar or peripatellar pain, of more than three months duration, in the absence of intra-articular pathology, that is aggravated by activities that load a flexed knee joint (K. Crossley, Bennell, Green, & McConnell, 2001; Nunes, Stapait, Kirsten, de Noronha, & Santos, 2013), and inclusion criteria for AKP patients in the literature being used are most commonly based on this definition as well as on the exclusion of other pathologies. As these criteria are often vague and heterogenous, the recent systematic review of (Leibbrandt & Louw, 2017) proposed an evidence-based checklist for researchers based on subjective and objective findings (*Figure 1*). This checklist will be adopted for this study at hand to serve as inclusion/exclusion criteria for participants. Further, *Table 1* lists additional criteria (as well as their justification), which are specific to the underlying research question of this study.

INCLUSION/EXCLUSION CRITERIA	JUSTIFICATION
Checklist for diagnosis of anterior knee pain (*Appendix 1*)	Evidence-based clinical checklist proposed by (Leibbrandt & Louw, 2017) for the diagnosis of patients with anterior knee pain (AKP).
Additional Inclusion Criteria	
Age: 18-60	
Signs for hip impairment: • Manually weak tested hip abductors/external rotators in comparison to the other, unaffected side (at least 1 point less on	Impaired hip function will be evaluated by an experienced physiotherapist, who will examine the quality of hip kinematics during single leg squat (via visual observation), passive hip range of motion (via digital goniometer) and eccentric strength of hip abductors/external rotators (via manual muscle testing). These assessment methods may not meet the highest scientific standards

manual muscle rating scale 0-10) • Reduced passive hip joint mobility in comparison to the other, unaffected side (at least 10 degrees of limitation in at least one direction of movement) • Impaired hip kinematics during single leg squat.	regarding validity and reliability. However, as they do not serve as outcome measures (but only as inclusion criteria), they more than suffice, since it is primarily a question of external validity and the binary assessment of "is or is there not a hip impairment present?". Further, the minimal detectable change for assessment of hip motions (measured with a goniometer by the same person) lies between 4 and 11 degrees (Reese, Bandy 2016). Therefore, a side difference of more than 10 degrees should in fact be a true restriction (since recent works assessing the reliability of the digital goniometer "Easy Angle" showed even better results than using a conventional goniometer (Risberg, 2018)). Regarding manual muscle tests, a numerical scale does not allow for the fine objective gradations that can be done when measuring units of force. However, the rough classification to discriminate between strong and weak has shown to be a valid clinical tool (Conable & Rosner, 2011; Cuthbert & Goodheart, 2007).
Prescription for Physiotherapy (with the diagnosis AKP)	Austrian law says, that Physiotherapists are only allowed to treat patients if a doctor prescripted physiotherapy in advance.
Additional Exclusion Criteria	
Signs for other possible reasons for gluteal inhibition/deconditioning: • spinal disorders associated with low back pain, lumbar referred pain or nerve root irritation • Severe and or recurring ankle sprains in recent history (significant enough, that it required a period of immobilization)	The rationale behind this research is, that the muscle activation capacity of AKP patients with weak abductor/external rotator muscles may profit from passive hip mobilisation, especially when impaired hip function is present and other causes for gluteal inhibition/deconditioning are ruled out/less likely. Since the diagnosis of AKP is mainly an exclusion of other pathologies, the checklist (Appendix 1) stated above already excludes many other possible causes for gluteal inhibition. In addition to this list, patients with severe lumbar as well as ankle problems will be excluded, as both has been linked to significant impaired gluteal function (Bullock-Saxton, 1994; Cooper et al., 2016; Friel, McLean, Myers, & Caceres, 2006)
Pregnancy	Precautionary measure
other relevant conditions such as neurologic/rheumatologic/psychiatric diseases, osteoporosis and malign disorders.	

Table 1: Inclusion and exclusion criteria (and their justification) of the proposed study at hand

Checklist for diagnosis of anterior knee pain.

		YES	NO
SUBJECTIVE INFORMATION:			
Age (must be yes)			
14–50[1,2,3,4,5]			
Area (must be yes)			
Front of knee or retropatella[1,2,3,4,5]			
Chronicity			
Longer than three months[1,3,5]			
Aggravated by (must be yes for two or more of the following)			
Squatting[1,2,3,4,5]			
Prolonged sitting[1,2,3,4,5]			
Stairs (ascending or descending)[1,2,3,4,5]			
Kneeling[1,2,3,4,5]			
Excluded if any of the below is known			
Previous lower limb surgery[1,3,5]			
History of trauma[1,3,5]			
Rheumatological conditions[1,3,5]			
Known intra-articular pathology: ligament and osteoarthritis[1,2,3,4,5]			
Patellar instability[3,4]			
Knee effusion[1,3]			
Patella subluxation/dislocation[1,3]			
Fat pad impingement/bursitis[3,5]			
Osgood–Schlatter[1,3]			
OBJECTIVE TESTS:			
Symptom reproduction with (must be positive for at least one of the following activities)			
Squatting[1,2,3,4,5]			
Kneeling[1,2,3,4,5]			
Ascending or descending stairs[1,2,3,4,5]			
Positive for at least one of the following			
Patella compression test[1,4]			
Patella tilt test[1,4]			
OR			
(Minimum two out of three) positive for combination of			
Squatting[3]			
Isometric quads[3]			
Palpation of patella borders[3]			
Excluded if positive for			
Lachmen's test[6,7,8]	ACL		
Posterior drawer test[6,8]	PCL		
Valgus stress test[6,8]	MCL		
Varus stress test[6,8]	LCL		
McMurray's test[6,8]	MENISCUS		
Patellar ballottement test[3]	Effusion		

Figure 1: Checklist for diagnosis of anterior knee pain (Leibbrandt, Louw 2017)

Recruitment of subjects will occur in cooperation with doctors (primary care orthopaedics and general practitioners) and physiotherapists licensed in Vienna and surrounding area, who are specialized in treating musculoskeletal pathologies. *Appendix 2* shows a list of names and working addresses of all doctors and physiotherapists, who have agreed to support this research. Prior to data collection, I will meet each in person, brief them regarding the inclusion/exclusion criteria as well as procedure of the study and hand over a participant information sheet (*see attached document: "Patienteninformation*") for them to distribute to possible participants (and a list with the inclusion/exclusion criteria as a reminder for themselves). After a first screening of subjects by telephone (age, pain during which activities, history of any relevant trauma/medical condition) I will invite them to my clinic (a group practice with the address: Gablenzgasse 11, 1150 Vienna – Austria) for a further evaluation to determine inclusion and exclusion criteria. Participants will be warned about the low risk of soreness to the

hip and surrounding muscles, have the opportunity to ask questions about the study, and will be informed of their rights to withdraw from the study at any time. If they meet the inclusion criteria and agree to participate in the study they will be asked to sign a consent form (*see attached document: "Patienteninformation*").

Materials:

The following equipment will be used during the study:

- A digital goniometer ("Easy Angle") to determine hip range of motion of both sides.
- For torque measurements, a Hand-Held Dynamometer (HHD) will be used ("Micro-FET2"). Reasons for using an HHD, instead of the gold standard isokinetic dynamometer, are of practical and financial nature, but also in favor of external validity: Using a HHD corresponds much more to manual muscle strength testing commonly used by therapists and doctors in daily practice. Further, this instrument has been widely used and many studies have shown its excellent intra- and inter-rater reliability for measurement of hip strength (Brindle, Ebaugh, & Milner, 2017; S. Kim & Lee, 2015).

Outcome measures

Figure 2: CLAM-method for measurement of hip abductors/external rotators with HHD

The main outcome measure will be muscle strength data obtained from torque measurements of the hip abductor/external rotator muscles of participants before and after intervention (via manual muscle testing). For measurements the end-position of the popular, non-weight bearing gluteus medius exercise, called the "CLAM"-Exercise will be used (*Figure 2*). Almeida, das Neves Rodrigues et al. (2017) showed that this method of measurement had excellent reliability indices (ICC intra-rater=0.991 [CI 95%, 0.978-0.997] between first and second evaluation in patients with AKP) as well as good validity (compared to isolated tests for abduction, external rotation and extension with a Pearson's correlation coefficient equal to 0.65 ($P<0.01$)) and the ability to detect strength deficits between affected and unaffected limb in patients with AKP. Aramaki, Katoh et al. (2016) also examined this method to measure hip abduction/external rotation torque and found similar good values for their reliability and validity analysis. Hence, it is appropriate to use the CLAM-method to measure hip abductor/external rotator strength within this research. *Table 2* features the reasons that speak in favour of this method instead of the commonly used strategies of measuring hip abductor strength (often in sidelying), hip external rotator strength (often in sitting) and hip extensor strength (often in prone) separately (S. Kim & Lee, 2015; Lu et al., 2011).

REASONS	JUSTIFICATION
Favourable gluteal-to-TFL activation ratio	As described in the introduction, AKP patients show significant weakness in hip abduction, external rotation and extension (which complies with the function of gluteus medius and superior part of gluteus maximus (Neumann, 2010)). The tensor fascia latae (TFL) on the other hand, in addition to being an abductor, is an internal rotator of the hip and can also exert a lateral force on the patella via connections to the iliotibial band (Merican, Amis 2009). Both, excessive hip internal rotation and lateral patellar displacement, have been linked to AKP (Powers 2010). Therefore, a measurement method to detect gluteal weakness in patients with AKP should promote gluteal activation as well as minimize TFL recruitment. Selkowitz, Beneck and Powers (2013) examined eleven different exercises on the basis of electromyographic signals using fine-wire electrodes and found, that the CLAM exercise had by far

	the most favourable gluteal-to-TFL activation ratio. In contrast, side-lying hip abduction showed no such favourable activation ratio.
Better Conrollability of possible compensatory movements	The commonly used (Widler et al., 2009) manual muscle strength test of hip abductors in side-lying (with the tested leg up in hip abduction, extension and slight external rotation (knee joint in extension)) is hard to reach, especially for patients with expected weaknesses. Typical compensations would be hip flexion and/or dorsal rotation of the pelvis, both movements facilitating the tensor fascia latae muscle (Kendall et al., 2005). A test position which is hard to reach for subjects and hard to control for examiners does not seem appropriate to get meaningful results. With the CLAM-method on the other side, the pelvic of the patient can be far better stabilized/controlled.
Functionality and Practicability	This method was developed to allow a three-dimensional evaluation of gluteal muscle strength, which makes it more functional when compared to the uniplanar assessment of the hip muscles (Almeida, das Neves Rodrigues, Helena Larissa, De Freitas, & de Paula Lima, Pedro Olavo, 2017). Further, in clinical practice, separately testing requires repetitive training, testing, rest periods, and positioning adjustments for the tests (Piva, Teixeira et al. 2011), which is tiring for the patient and time consuming for the therapist, whereas the CLAM-method is a quick and easy alternative.

Table 2: Reasons for using the CLAM-methode for measuring hip abductor/external rotator strength

Different from the previously mentioned studies measuring with the CLAM-method, this study will use a “break test” instead of a “make test” and therefore measure eccentric rather than concentric muscle strength. Both methods in general show similar reliability (Conable & Rosner, 2011), but eccentric hip torque especially has been associated with functional capacity and pain levels in patients with AKP (de Marche Baldon et al., 2012; Nakagawa, de Marche Baldon, Muniz, & Serrão, 2011), and as the break test measures a complex proprioceptive response to changing pressure (rather than solely an isometric peak force), it seems to be a more valid method to measure functional impairments. Of course, even more meaningful would be strategies, that measure timing, activity level and capability to control movements of agonists and antagonists during different functional tasks, however, such methods would go beyond the scope of this dissertation.

Procedure:

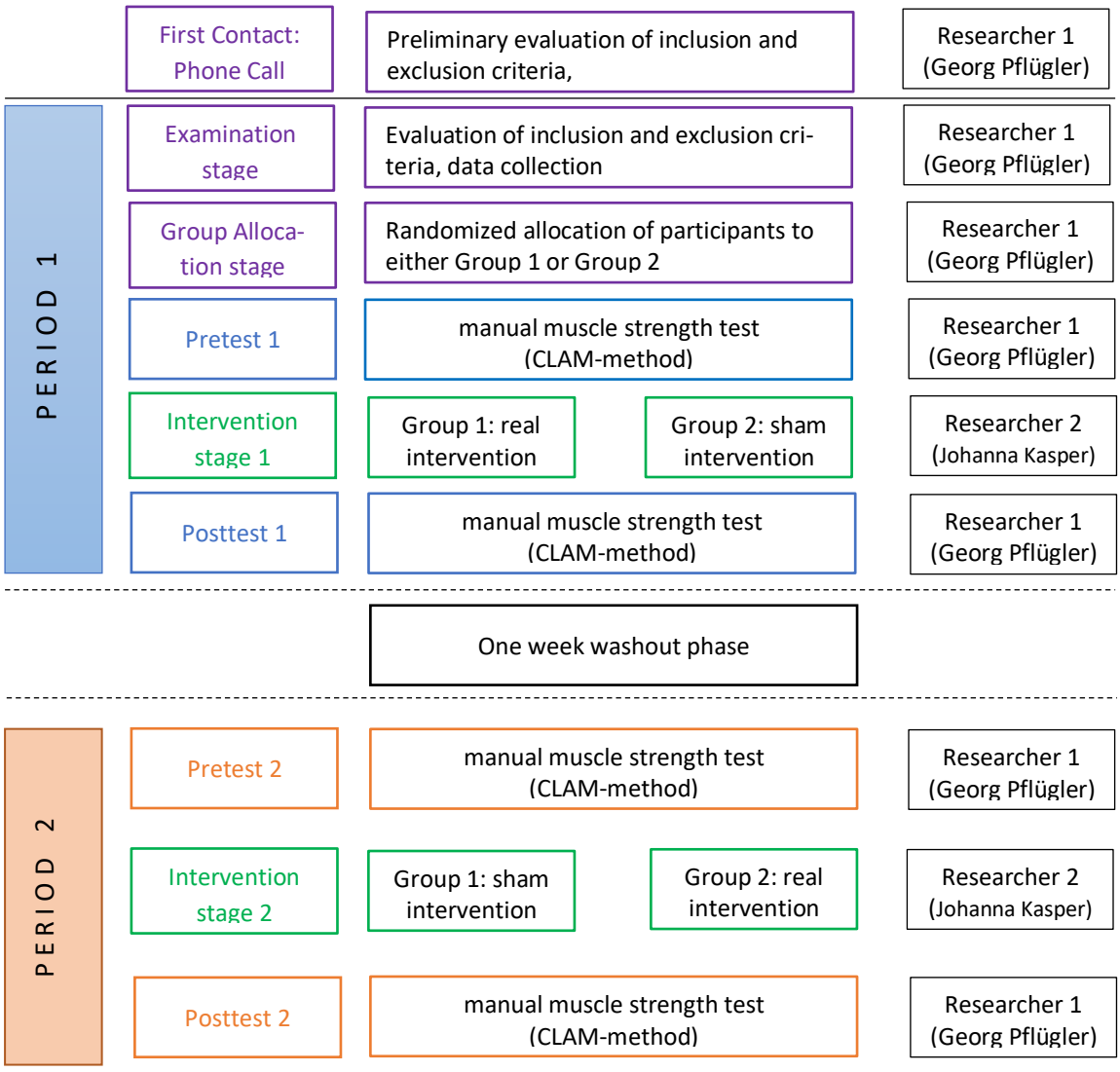

Figure 2: Stage of study | Short description of stage | Collector of data

Figure 2 illustrates the procedure of the proposed study. Researcher 1 (a physiotherapist trained in manual therapy, with seven years of clinical experience) will perform examination procedures and data collection (*Appendix 5*). If subjects agree to participate and meet inclusion criteria, they will be randomly assigned to either Group 1 or Group 2. Group 1 will receive the real intervention during the first period of measurement and a control/sham intervention one week later. Group 2 vice versa. Hence, each participant will serve as his/her own control group. As a simple randomization method is not recommended for a sample size of less than 100 (J. Kim & Shin, 2014), randomization sequence will be created using an online application called “Sealed Envelope” (Sealed Envelope Ltd, 2017) with random block

sizes of 4 and 6. This study will be double-blinded in the sense that both, subjects and the assessor of hip strength will be blinded to group assignment, whereas the therapist (Researcher 2), who carries out the interventions, will be the group allocator and not be blinded to group assignment.

Torque measurement (Pre-Test) will be obtained by Researcher 1 (a physiotherapist trained in the use of a HHD; seven years of clinical experience) using the Clam-method (*Figure 1*). See *Appendix 5* for a detailed protocol. To maintain blinding, the subsequent interventions will be performed by Researcher 2, who will make sure that Researcher 1 has left the room. According to the respective group assignment, participants will either receive a hip joint mobilization or a sham intervention (see *Table 3* for a detailed description). All subjects will be re-tested (Post-Test) from Researcher 1 by using the same method as pre-intervention to establish post-intervention muscle strength immediately afterwards. In addition, Researcher 1 will use a scale to determine the subjective felt change in strength of participants and will assess the passive range of movement of the respective motions, which were restricted before the intervention, by using a digital goniometer.

One week later, the participants will be put through the same procedure again. Only this time, Group 2 will receive the real intervention, whereas Group 1 will get the placebo intervention.

INTERVENTION	JUSTIFICATION
Intervention	
<u>Passive hip joint mobilization:</u> passive accessory movement on femur in anterior/posterior direction, grade III for four minutes and passive physiological movement of the most restricted hip joint movement, grade III for one minute (without pain).	The selection of this method of mobilization is not based on a theory of peripherally acting and specific biomechanical mechanisms. As Bialosky, Beneciuk et al. (2018) argue in their proposed model on mechanisms of manual therapy (MT), the literature does not support such a traditional mechanical theory. Their recent model rather suggests that a mechanical stimulus initiates a number of potential neurophysiological effects which produce the clinical outcomes associated with MT; the choice of technique does not seem to matter as much as identifying an individual likely to respond. That is why the inclusion criteria of this study are signs of hip impairment as well as no signs of other possible causes for gluteal inhibition/deconditioning

	(therefore individuals seem more likely to profit from hip joint mobilization). The rationale behind the possible effect of MT on muscle strength is the stimulating of sensory receptors in and around the joint in order to modulate altered joint afferent discharge and thereby disinhibiting/facilitating the musculature surrounding this joint. As the direction of the mobilisation may not be as relevant, other factors such as intensity, duration and location, on the other hand I believe is. But why using the described method then (ap mobilisation, grade III)? – It is a relaxing position for the patient (supine with a knee roll), where the therapist may easily accomplish a mechanical stimulus specifically directed to the hip joint (which shows impairments), comfortably and without pain. Further, the subsequent passive physiological mobilisation addresses an individual impairment of the patient too. And lastly, because I have had good results with this method in my personal clinical experience.
Control Intervention	
Sham hip joint mobilization: grade I, very small amplitude without encountering any tissue resistance for five minutes. Hence, effectively just a laying on of hands.	In studies it is ethically acceptable to use placebo/sham interventions where no current proven intervention exists and when their use does not expose research participants to excessive risk of any serious or irreversible harm (Fregni et al., 2010) and both is the case for the proposed study. As it is recommended that there should be as little variability in interventions as possible in between both the real and the placebo groups (Fregni et al., 2010), the control group will receive a sham hip joint mobilisation with the same duration, same setting, same therapist and similar verbal education of underlying effect mechanisms, but different intensity/mechanical stimulus. Reason for using a Placebo Intervention: Although any benefit seen from MT likely arises from a complex interplay between neurophysiological effects, placebo, patient expectation, and therapeutic alliance (Bialosky, Beneciuk et al. 2018), this study will try to highlight, that these possible confounding variables alone are not as effective (in this case regarding muscle strength) as combined with an appropriate mechanical stimulus.

Table 3: Description and justification of the used Interventions of the proposed study

Sample size Calculation

To calculate the proper sample size required for the study, a power calculation was undertaken, based on the alpha value, statistical power and the estimated effect size and the measurement variance expected to occur if the measurement procedure would be repeated a large number of times in the same patient under identical conditions (Wellek & Blettner, 2012). As conventionally done, alpha level was set at 0,05 and statistical power at 0,8 (Ellis, 2010). The

results of the work of Yerys and coworkers (2002) have been used as reference to estimate the effect size for this study: applying a calculation method appropriate for cross-over designs (Wellek & Blettner, 2012) their results lead to an expected effect size of 1,34. The expected measurement variance is 2,1 (kgf) and has been determined with the aid of a small pilot study. Therefore, on the bases of these values and with the aid of an unpaired t-test (Wellek & Blettner, 2012), the appropriate sample size for this study has been calculated to be 16 (8 per group). Allowing for drop-outs and to make sure that this study will be adequately powered, the total sample size will 20.

Pilot study

A pilot study has been conducted prior to the carrying out of the main study, with the aim to establish the time required to examine and measure each participant, to familiarise the researchers with the experimental procedures and to determine the expected measurement variance for the sample size calculations. Four healthy and voluntary participants have been recruited. All has been conducted under the same test conditions as those highlighted in the proposed main study. The data recorded in the course of the pilot study will not be included in the final analysis.

Data Collection

See *Appendix 6* for a list of all variables that are going to be collected in the course of this study. This list highlights their level of measurement, domain or coding, during which stage of the measurements they will be collected, who will collect them and why they are going to be collected.

During the evaluation of inclusion/exclusion criteria, the data of the physical examination procedure and some personal data (gender, age, height, weight) will be required by all

participants. Any data obtained from participants who do not meet inclusion criteria will be deleted immediately. Any data obtained from participants who do meet the criteria will be recorded by Researcher 1 for all participants. No participant will be identifiable from the data collected. Researcher 2 will be the group allocator and only person, to know the group assignment.

Each participant will be given a unique study ID. Patient details and study ID will be kept purely for administrative reasons and will be contained in a password protected file which only members of the research team will have access to. Data files will use only study ID numbers to ensure that participants cannot be recognized. Following the measurements, all data will be kept confidential in a research file, which will be stored in a locked cupboard. See *Appendix 9* for the actual Data Sheets being used in the course of this study. All electronic data will be stored on a password secured lap-top.

Statistical Analysis:

The data will be analyzed using the Stata/IC15.1 software. At first, raw data will be analyzed using descriptive statistcs (mean and standard deviation of anthropometric and clinical characteristics and the outcome variables) and screened for any evident anomalies, which, if present, will be explored in the discussion following the investigation. Prior to further inferential statistical analysis, the Post-test differences of both groups (the differences between treatment effects) of the dependent variable (torque measurements) will be checked for normal distribution using the Shapiro-Wilk test, which is appropriate for small sample sizes (Schäfer & Schöttker-Königer, 2015) and a box and whisker plot will be prepared to eyeball the distribution of data. The values of the torque measurements are scaled metrically (muscle strength data will be normalized by the body mass of each participant: strength[kgf]/bmi[kg]).

Researchers analyzing the data of crossover trials often proceed as though they were performing a simple pre/post comparison by using a paired t-test or any other procedure for paired samples, which presents a methodologically flawed analysis (Wellek & Blettner, 2012). This error will not happen within this research. Two things have to be analyzed within the crossover design: Firstly, the assumption of negligible carryover effects between the two periods (with the help of an unpaired t-test with the sums of the Post-test-values). If this test does not yield a significant result, then the assessment of the difference between treatment effects (intervention versus control) is indicated: Again with the help of an unpaired t-test, but this time on the bases of the within-subject differences of the Post-test-values.

If the data is not normally distributed, non-parametric methods such as the Wilcoxon test or the Mann Whitney test will be applied. P-values of less than 0.05 will be considered significant (Schäfer & Schöttker-Königer, 2015).

Ethical Considerations

The primary consideration of any research involving human subjects has to be the safety, health, dignity, right to self-determination, privacy and confidentiality of personal information of the participants, as stated in the Declaration of Helsinki (World Medical Association, 2013). Certainly, these considerations will be carefully implemented in the proposed study.

Prior to participating each participant will receive an information sheet and a consent form. Time will be allocated for each participant to read the information sheet, sign the consent form and ask further questions. Participants will be free to withdraw from the study at any time without giving reasons (Guraya, London, & Guraya, 2014).

In studies it is ethically acceptable to use placebo/sham interventions where no current proven intervention exists and when their use does not expose research participants to excessive risk of any serious or irreversible harm (Fregni et al., 2010). As both is the case in this proposed

study, and because of the fact that participants will only have to spend two single additional session of approximately 30 minutes (therefore there will be no delay in ordinary treatment for anyone), it is ethical to use a placebo group in this case.

A risk assessment form is shown in *Appendix 8.* Prior to the submission to the Ethic Committee of the Medical University of Vienna, the proposed study has been submitted to the Sheffield Hallam University Ethics Committee and has gain approval. However, no testing will commence until ethical approval from Vienna has been granted.

Reporting

Upon completion of this study, a report will be prepared for potential publication. The aim is to publish in a recognised, peer reviewed Physiotherapy specific journal. If desired, findings will also be disseminated to all participants that were involved in the study.

Funding

The two researchers involved will work for this project without payment. There will be no costs expected to complete this study, excluding the already purchased hand held dynamometer, which is now private propriety of the first researcher. Other equipment and environment needed for the carrying out of the study will be provided by the group practice, the two involved researchers are part of. This clinic conforms to the Austrian guidelines that are required for working with patients in a physiotherapeutic setting.

There will be no conflict of interest.

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Appendix 1

Preliminary Inclusion/Exclusion Criteria:

Preliminary Inclusion and Exclusion Criteria	
Inclusion Criteria	Exclusion Criteria
peripatellar or retropatellar pain	History of trauma
pain aggravated by activities that load a flexed knee joint	Previous lower limb surgery
weak tested hip abductors/external rotators (CLAM-method)	intra-articular pathology (knee joint)

Vorläufige Ein- und Ausschlusskriterien:

Vorläufige Ein- und Ausschlusskriterien	
Einschlusskriterien	Ausschlusskriterien
voderer Knieschmerz	Vorangegangenes Trauma
Schmerzverstärkung bei Aktivitäten, welche das Kniegelenk in einer gebeugten Stellung belasten	Vorangegangene Operation an der unteren Extremität
schwach getestete Hüftabduktoren/Außenrotatoren (CLAM-Methode)	Intra-artikuläre Pathologie des Kniegelenks

Appendix 2

The following list shows the names and working addresses of all doctors and physiotherapists, who have agreed to support this research:

NAME	PROFESSION	ADDRESS
Manfred Neumaier	Orthopaedist	Wienerstr. 2/2/3, 2340 Mödling
Ursula Leitner	General practioner	Hartlgasse 15, 2486 Pottendorf
Herbert Prohaska	Orthopaedist	Kreuzgasse 37/2, 1180 Wien
Johanna Kasper	Physiotherapist	Kreuzgasse 37/2, 1180 Wien Gablenzgasse 11, 1150 Wien
Evelyne Tratter	Physiotherapist	Gablenzgasse 11, 1150 Wien
Jakob Mauracher	Physiotherapist	
Antonia Navratil-Schmidt	Physiotherapist	
Friederike Kreuzer-Rath	Physiotherapist	
Stephanie Huber	Physiotherapist	
Julian Gullner	Physiotherapist	
Andrea Höller	Physiotherapist	
Katja Friedmann	Physiotherapist	
Elmari du Preez	Physiotherapist	
Sophia Billet	Physiotherapist	
Heinz Aigner	Physiotherapist	
Laszlo Roth	Physiotherapist	Kreuzgasse 37/2, 1180 Wien
Sabine Weissmann	Physiotherapist	
Seraph Buttinger	Physiotherapist	
Barbara Pavlis	Physiotherapist	
Jakob Eschwé	Physiotherapist	
Sandra Brunner	Physiotherapist	
Katrin Köhler	Physiotherapist	
Florian Raderbauer	Physiotherapist	
Patrick Gomez	Physiotherapist	Huttengasse 37/15, 1160 Wien

Appendix 5

Protocol of outcome measurement:

Figure 1: CLAM-method for measurement of hip abductors/external rotators with HHD

Prior to measurement, a mark will be placed five centimeters proximal to the middle of the knee joint line (along the body's longitudinal axis), to provide a consistent landmark for dynamometer placement. The CLAM-method will be performed with the participant in side-lying, with both legs positioned at 45° of hip flexion and 90° of knee flexion, with the limb to be tested superior (Figure 1). The participant will be instructed to lift the knee of the superior leg as far as possible while keeping the heels in contact, without allowing any compensatory movements. Following a warm-up consisting of one submaximal and one maximal practice trial, participants will perform three measurements with isometric contraction at their maximum exertion (with a 30 seconds rest between each trial). The instructions for the break test will be "Push as hard as you can; now don't let me move your leg." Consistent verbal encouragement will be provided during the slow increase of the applied force, until the resistance of the participant gets broken. Mean values will be calculated for each participant. If compensation movements are present, values will be discarded and a new measurement will be done after 30 seconds. No feedback (regarding their torque measure) will be provided to the subjects during the testing period.

Appendix 6

Variable list of the proposed study:

Nr	Abbrevation	Variable	Level of Measure-ment	Domain/Coding	Stage of measurement and Collector of data	Reason for measure-ment
1	id	Identification number of participant	nominal	0-20	Group Allocation stage. Researcher 2	Statistical analysis
2	group	Group affiliation of partici-pant	nominal	1 = first session intervention, second session placebo 2 = vice versa		Methodology of study
3	female	Gender of participant	nominal	0 = male 1 = female	Examination stage. Researcher 1	Description of sample
4	age	Age of participant	metric	Integral Numbers		Description of sample
	right	affected side	nominal	0 = left 1 = right		
5	weight	Weight of participant	metric	Integral Numbers (in kg)		Normalization of Out-come measure
6	height	Height of participant	metric	Integral Numbers (in cm)		Normalization of Out-come measure
7	checklist	checklist for diagnosis of AKP	nominal	0 = fulfils checklist 1 = does not fulfil checklist		assessment of inclu-sion/exclusion criteria
8	slsq	Quality of single leg squat	nominal	0 = normal 1 = impaired		assessment of inclusion criteria
9	strength	Strength of hip abd/er	nominal	0 = normal 1 = weak		assessment of inclusion criteria
10	flex_l	ROM hip flexion, L	metric	Integral Numbers (in degree)		
11	flex_r	ROM hip flexion, R	metric	Integral Numbers (in degree)		
12	er90_l	ROM hip ER/90, L	metric	Integral Numbers (in degree)		
13	er90_r	ROM hip ER/90, R	metric	Integral Numbers (in degree)		
14	ir90_l	ROM hip IR/90, L	metric	Integral Numbers (in degree)		

15	ir90_r	ROM hip IR/90, R	metric	Integral Numbers (in degree)		assessment of inclusion criteria
16	abd_l	ROM hip abd, L	metric	Integral Numbers (in degree)		
17	abd_r	ROM hip abd, R	metric	Integral Numbers (in degree)		
18	add_l	ROM hip add, L	metric	Integral Numbers (in degree)		
19	add_r	ROM hip add, R	metric	Integral Numbers (in degree)		
20	ext_l	ROM hip ext, L	metric	Integral Numbers (in degree)		
21	ext_r	ROM hip ext, R	metric	Integral Numbers (in degree)		
22	er0_l	ROM hip ER/0, L	metric	Integral Numbers (in degree)		
23	er0_r	ROM hip ER/0, R	metric	Integral Numbers (in degree)		
	ir0_l	ROM hip IR/0, L	metric	Integral Numbers (in degree)		
	ir0_r	ROM hip IR/0, R	metric	Integral Numbers (in degree)	Pretest 1. Researcher 1	
24	pretest_1_mean	mean of strength tests of hip abd/er of affected side (first period)	metric	0.4 to 135 (in kilograms force with 0.1 increments)		determing torque values before intervention
	pret-test_1_i					
	pret-test_1_ii					
	pret-test_1_iii					
25	pretest_1_pain	reportment of pain during pretest (first period)	nominal	0 = no pain 1 = pain		for interpretation of results (later in the discussion section of this study)
26	posttest_1_mean	strengthtest after intervention (first period)	metric	0.4 to 135 (in kilograms force with 0.1 increments)	Posttest 1. Researcher 1	determing torque values after intervention
	post-test_1_i					
	post-test_1_ii					
	post-test_1_iii					
27	posttest_1_pain	reportment of pain during posttest (first period)	nominal	0 = no pain 1 = pain		for interpretation of results
	subj_change_1					
	p_rom_change_1_*					
	p_rom_change_1_*					
	p_rom_change_1_*					

28	pretest_2_mean	strength of hip abd/er with hhd of affected side (second period)	metric	0.4 to 135 (in kilograms force with 0.1 increments)	Pretest 2. Researcher 2	determing torque values before intervention
	pret-test_2_i					
	pret-test_2_ii					
	pret-test_2_iii					
29	pretest_2_pain	reportment of pain during pretest (second period)	nominal	0 = no pain 1 = pain		for interpretation of results
30	posttest_2_mean	strengthtest after intervention (second period)	metric	0.4 to 135 (in kilograms force with 0.1 increments)	Posttest 2. Researcher 2	determing torque values after intervention
	post-test_2_i					
	post-test_2_ii					
	post-test_2_iii					
31	posttest_2_pain	reportment of pain during posttest (second period)	nominal	0 = no pain 1 = pain		for interpretation of results
	subj_change_2					
	p_rom_change_2_*					
	p_rom_change_2_*					
	p_rom_change_2_*					

Appendix 7

Data Management Plan

1. What data will you collect or create?

see appendix 6

2. How will your data be documented and described?

see appendix 6

3. How will you deal with any ethical and copyright issues?

see “Ethical Considerations” (proposal)

4. How will your data be structured, stored, and backed up?

see “Data Collection” (proposal)

5. What are your plans for the long-term preservation of data supporting your research?

see “Data Collection” (proposal)	

6. What are your plans for data sharing after submission of your thesis?

see “Reporting” (proposal)

Appendix 8

Sheffield Hallam University

MA/MBA/MSc Dissertation Proposal

FACULTY OF HEALTH AND WELLBEING

PROJECT SAFETY PLAN: Risk Assessment Form

TITLE:	The immediate effects of passive hip joint mobilization on hip abductor/external rotator muscle strength in patients with anterior knee pain and impaired hip function	**LOCATION:**	Gablenzgasse 11, 1150 Vienna
PEOPLE AFFECTED:	Patients with anterior knee pain who meet inclusion criteria and agree to participate		
ASSESSMENT CARRIED OUT BY:	Pflügler Georg (Physiotherapist) and Kasper Johanna (Physiotherapist)		
PROJECT SAFETY OFFICER:			
SUPERVISOR:	Sionnadh McLean		
SIGNATURE OF SUPERVISOR		**DATE:**	

ACTIVITY	**HAZARD ASSOCIATED WITH THE ACTIVITY**	**HAZARD RATING** **(High, Medium or Low)**	**CONTROL MEASURES TO BE TAKEN**

Physical Examination procedure	Potential irritation/pain provocation/tissue damage of patient being examined	Low	The procedure will be conducted by an experienced physiotherapist in a clinical setting (physiotherapy practice) that conforms to the Austrian guidelines that are required for working with patients in a physiotherapeutic setting. If any signs of potential harm are present, the examiner will not perform any further tests and exclude the potential participant.
Manual muscle strength Test	Potential damage/physical overload due to maximal isometric contraction	Low	Patients with any relevant pathology (systemic diseases, severe osteoporosis, fractures..) or pregnancy will be excluded prior to the measurement. As the examiner is trained in the use of a HHD, there is no additional risk in using this apparatus within the strength test (other than it could be inconvenient for the patient on his/her skin, which will be checked with the patient). To ensure that the movement will be done correctly, two practice trials will be performed under the supervision of the researcher.
Passive hip joint mobilization	Potential irritation/pain provocation/tissue damage of patient being treated	Low	Again, performed by an experienced physiotherapist within a clinical setting. The intensity of the mobilisation will be moderate and without pain provocation. Patients will be encouraged beforehand to tell if anything is inconvenient for them. The screening/testing procedures and the interventions within this research project involve standard tests/techniques that any physiotherapist may conduct in the course of a clinical examination

Please keep this form in your Site File (Section 3 - Ethics) and update as appropriate.

Project Files and Site Files

All studies require a file with the administrative details such as letters and consent forms. If it is a non-NHS project then these are called 'project files', if an NHS project they are called 'site files'. They contain more or less the same things - for details see in the ethics folder on the BlackBoard site.

Appendix 9

First Contact/Examination Data sheet:

Variable	Data
id	
right	
female	
age	
weight	
height	
checklist_subj	
lumb_p	
ank_p	
pregn	
rel_dis	

Variable	Data
checklist_obj	
slsq	
strength	

p_rom	left (_l)	right (_r)
flex		
er90		
ir90		
abd		
add		
ext		
er0		
ir0		

Checklist for diagnosis of anterior knee pain.

SUBJECTIVE INFORMATION:

Age (must be yes)	YES	NO
14–50[1,2,3,4,5]		

Area (must be yes)		
Front of knee or retropatella[1,2,3,4,5]		

Chronicity		
Longer than three months[1,3,5]		

Aggravated by (must be yes for two or more of the following)		
Squatting[1,2,3,4,5]		
Prolonged sitting[1,2,3,4,5]		
Stairs (ascending or descending)[1,2,3,4,5]		
Kneeling[1,2,3,4,5]		

Excluded if any of the below is known		
Previous lower limb surgery[1,3,5]		
History of trauma[1,3,5]		
Rheumatological conditions[1,3,5]		
Known intra-articular pathology: ligament and osteoarthritis[1,2,3,4,5]		
Patellar instability[1,4]		
Knee effusion[1,5]		
Patella subluxation/dislocation[1,5]		
Fat pad impingement/bursitis[3,5]		
Osgood–Sclatter[1,3]		

OBJECTIVE TESTS:

Symptom reproduction with (must be positive for at least one of the following activities)		
Squatting[1,2,3,4,5]		
Kneeling[1,2,3,4,5]		
Ascending or descending stairs[1,2,3,4,5]		

Positive for at least one of the following		
Patella compression test[1,4]		
Patella tilt test[1,4]		

OR

(Minimum two out of three) positive for combination of		
Squatting[3]		
Isometric quads[3]		
Palpation of patella borders[3]		

Excluded if positive for			
Lachmen's test[6,7,8]	ACL		
Posterior drawer test[6,8]	PCL		
Valgus stress test[6,8]	MCL		
Varus stress test[6,8]	LCL		
McMurray's test[6,8]	MENISCUS		
Patellar ballottement test[5]	Effusion		

Figure 1: Checklist for diagnosis of anterior knee pain (Leibbrandt, Louw 2017)

Post-Test Data sheet:

Variable	Data
pretest_1_i	
pretest_1_ii	
pretest_1_iii	
pretest_1_pain	
posttest_1_i	
posttest_1_ii	
posttest_1_iii	
posttest_1_pain	
subj_change_1	
p_rom_change_1_*	
p_rom_change_1_*	
p_rom_change_1_*	
pretest_2_i	
pretest_2_ii	
pretest_2_iii	
pretest_2_pain	
posttest_2_i	
posttest_2_ii	
posttest_2_iii	
posttest_2_pain	
subj_change_2	
p_rom_change_2_*	
p_rom_change_2_*	
p_rom_change_2_*	