# Clinical Trial Protocol for pilot study

## Title: Is manual therapy for stiff knees using lessons learned from 4D motion analysis more effective than traditional manual therapy?

PosteroAnterior versus AnteroPosterior manual therapy mobilisation for stiff knees. A pilot study for a randomised controlled trial.

### Acronym: PAVAP.

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### Investigators

Principal Investigator:

Professor Jennie Scarvell

(Head of School of Health Sciences, Faculty of Health, University of Canberra)

Co-Investigators:

Yi-Ying Zeng B. Physiotherapy Honours Student, University of Canberra

Dr Diana Perriman Clinical Research Coordinator, Trauma and Orthopaedic Research,

Canberra Hospital

Mr Bjarne Kragh Principal, Southside Physiotherapy, Tuggeranong

Mr Peter Suffolk Clinical Educator, Faculty of Health Student Led Clinics. University of Canberra

Mrs Sally Jackson Clinical Educator, Faculty of Health Student Led Clinics. University of Canberra

### Clinical sites: University of Canberra

### Southside Physiotherapy

Collaborating institution: Trauma and Orthopaedic Research Unit, Canberra Hospital

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### 1. Synopsis

Knee stiffness is treated using exercise and manual therapy. Manual therapy techniques utilize accessory movements to increase the range of movement of joints. The accessory movements aim to replicate those that occur during the normal joint movement. In order to increase knee flexion, the accessory movement is a posterior glide achieved by applying pressure to the top of the tibia in an anterior to posterior direction. This is based on the concave/convex rule which is applied to all joints. However, recent in vivo kinematic modelling conducted by our group indicates that posterior to anterior pressures better replicate knee joint movement at the end of flexion.

The aim of this study is to compare the results of both techniques in patients presenting with stiff knees. The aim of this as a pilot study, is to explore the feasibility of running this study, as well as collect data on effect size, responsiveness to intervention, and information on dose-response to inform a later clinical trial. The primary outcome is change in knee flexion range and secondary outcomes include measures of pain and function. The clinical significance of this project is to change practice in physiotherapy to ensure the most effective manual therapy techniques will be used to restore movement and relieving pain.

### 2. Abbreviations and Acronyms

 AP AnteroPosterior

 PA PosteroAnterior

 4D 4-dimensional, where the 4th dimension is time.

### 3. Introduction/Background

Good knee function is important for mobility, social participation and quality of life. Knee stiffness is reported by patients to be important if it limits their ability to perform activities such as rising from a chair, squatting, kneeling and gardening (Weiss 2002, Noble 2012). Knee stiffness may be due to injury, trauma or degenerative changes such as osteoarthritis or meniscal damage. Stiffness is a late consequence of the normal inflammatory processes that lay down scar tissue, but can restrict full knee flexion and extension (Pujol 2015). In extreme cases, surgery may be indicated, but in the majority of cases physiotherapy is effective (Xu 2017). Manual therapy and a home program of knee strengthening and stretching exercises is a common prescription. However, it is not clear which manual therapy techniques are more effective (Deyle 2000, Deyle 2005, Abbott 2009).

The biomechanical concepts underpinning current manual therapy techniques may be incorrect. Recent advances in imaging technology and computer modelling have enabled more accurate and detailed joint motion imaging than ever before (Li 2008). Where previously, motion studies were carried out with skin markers or by examining cadaveric specimens, we can now image joints while participants carry out functional activities and ‘see inside the knee’. Manual therapy techniques were based on the theory that joints need to glide, as well as roll, to achieve full movement without exceeding the limit of the articular surface. The theory is that, if the moving surface is concave, there is a concomitant glide in the same direction of the movement; however, if the moving surface is convex, the glide is in the opposite direction (Kaltenborn 2002, Schomacher 2009). This is referred to as the ‘concave-convex rule’. However, our recent work involving image registration of knees during deep knee flexion has demonstrated that to increase knee flexion, the tibia needs to glide anteriorly rather than posteriorly as dictated by the ‘concave-convex rule’ (Scarvell 2017).

To date, no study has investigated the relative effectiveness of the anterior tibial glide compared to the posterior tibial glide manual therapy technique to restore the range of knee flexion in people with stiff knees. The aim of this study is to compare the relative efficacy of PosteroAnterior glides (with medial rotation and distraction) to the current practice of AnteroPosterior glides (with medial rotation and distraction) for the treatment of stiff knees. The primary outcome will be change in knee flexion range and secondary outcomes will include measures of pain and function. The impact of this study will be significant. If our hypothesis is upheld, the current manual therapy techniques used for knees will be revised and treatment efficacy will be enhanced.

### 4. Objectives

1. Pilot Study Objectives;
	* test the feasibility of running this study,
	* quantify effect size and responsiveness to intervention
	* record information on dose-response to inform a later clinical trial.
2. Primary Objective: To determine whether an anteriorly directed tibial glide (PA glide) is more effective than a posteriorly directed glide (AP glide) at increasing range of flexion in stiff knees.
3. Secondary Objective: To determine whether PA glide is more effective than AP glide at reducing pain and improving function in people with stiff knees.

### 5. Hypothesis

* H1: PA glide, with medial rotation and distraction to the knee, improves flexion range by ≥7° compared to standard AP glide with medial rotation and distraction.
* H0: AP glide, with medial rotation and distraction to the knee, improves flexion range by <7° compared to standard PA glide with medial rotation and distraction.

### 6. Study Methodology

* Study Type: Interventional Clinical Trial
* Study Design: Pilot Parallel Randomized Controlled Trial
* Location/Setting: Southside Physiotherapy, University of Canberra Health Hub Musculoskeletal Physiotherapy Clinic
* Sample size calculation 40 (20 in each group)
* Study Intervention: PA glide with medial rotation and anterior distraction to the knee.
* Study Comparison: Standard practice is an AP glide.

### 7. Study population

Number of participants: 40

Inclusion Criteria:

* Individuals with restricted knee flexion ROM
* Aged >18
* Stiffness duration ≥ 7 days

Exclusion Criteria

* Knee pain > 8/10 on Numeric Rating Scale
* Chronic Regional Pain Syndrome (CRPS): Post-traumatic phenomenon characterized by localized disproportionate pain, vasomotor disturbance, oedema and delayed recovery (Brukner and Khan, 4th Ed)
* Anxiety related to manual therapy
* Total Knee Replacement on the affected side
* Inflammatory Arthritis
* Anterior or posterior cruciate ligament graft surgery.
* Knee reconstruction or previous ligament rupture on the affected side
* Acute locked meniscus
* Initiation of opioid analgaesia or corticosteroid injection within the past 7 days.

Source of participants: Community. Individuals with limited knee flexion who present to the investigation sites either as patients at the practice, or as participants responding to recruitment advertising.

The recruitment for the pilot study will take place between mid January 2018 and July 2018. Based on previous data, we anticipate that 5 patients per month with stiff knees will present naturally to each of the two clinics. We also anticipate that we will be able to recruit another 20 participants from the community via recruitment strategies.

### 8. Study procedure

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#### Recruitment

Participants will be recruited from the practices and by recruitment advertising. Routine referral to the FoH student led clinic, is that a patient referred to the clinic with a knee problem will be provided with a standard physiotherapy consultation. If the patient appears eligible for the study, then the patient will be informed about the study and recruited. If a patient presents to Southside physiotherapy, they may be provided information about the study prior to attending, by email. Written consent will be sought when the patient presents for their initial assessment.

People who respond to the advertising will be sent the study information and followed up by telephone. If they are interested in participating, they will be booked into the most convenient clinic and written consent will be sought when they present for their initial assessment.

#### Randomisation

Concealed envelopes which are held by a third party will be used to allocate the participants to groups. Permuted block randomisation will be used to ensure that equal numbers of patients from each sex are allocated to each group.

#### Personnel

Physiotherapists and physiotherapy students from the University of Canberra who have been specifically trained to perform the techniques and assess the outcomes.

#### Blinding

Patients will be blind to whether they are receiving the intervention or the comparison treatment.

The therapists cannot be blinded but the measurements will be done by another therapist who is not involved in the treatment of that patient. In the case of the questionnaire instrument the patient will be asked to complete the questions without therapist involvement.

#### Intervention

Study Intervention:

In the clinic - two (2) treatments per week for a total of 4 treatments.

PA glide with medial rotation and anterior distraction to the knee performed with

30 oscillations, repeated 4 times, if comfortable

(or if preferred by therapist 6 repetitions of a sustained mobilization with 5-10 sec holds.)

Grade and holds modified to individual patient needs and tolerance. This intervention is delivered with the patient lying in supine with their treatment knee bent (Figure X).



Figure 1: Study Intervention- PosteroAnterior joint glide to the knee

Home Program - daily X2 day

Self administered mobilisation using strap and a broom handle, in the direction of the intervention.

3 x 6 repetitions. Diary Record.

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#### Study Comparison:

In the clinic - X2 per week for 2 weeks

Standard practice i.e. AP glides to the knee

30 oscillations, repeated 4 times, if comfortable

(or if preferred by therapist 6 repetitions of a sustained mobilization with 5-10 sec holds.)

Grade and holds modified to individual patient needs and tolerance. This intervention is delivered with the patient lying in supine with their treatment knee bent.



Figure 2; Study comparison - AnteroPosterior joint glide to the knee

Home Program - daily X2 day

Self administered mobilisation using strap, in the direction of the intervention.

3 x 6 repetitions . Diary record.

Medication: Some participants will be using medication for pain. We will record what they are taking and the frequency of their use. Patients will be encouraged to continue with their current regimen OR to report any deviation.

#### Outcome Measures

**Primary:**

**Knee flexion** is important for function in the knee and is highly correlated with patient satisfaction. The minimal clinically important difference is 5 degrees (Jacobs 2005 Cochrane review). Range will be measured using a digital goniometer (Dualler IQ, JTech medical, Utah). The measurements will be made in supine. The participant will have a mark placed 5 cm above the patella with the knee extended and another on the tibial tuberosity. The dualler will be positioned according to these marks (Figure X) and the participants will be asked to flex their knee by bringing their heel as close to their bottom as possible. The measurements will be repeated three times (Figure X) and the maximum will be entered as their knee flexion range. These measurements will be taken prior to and following the intervention in each clinic session.

**Secondary:**

**Pain** - Participants will be asked to rate their pain using a 0-10 Numerical Rating Scale (NRS) where 0 is no pain and 10 is the worst pain imaginable. The minimal clinically important difference is 12mm (Chapman 2011, Hjemstadt 2011). These measurements will be taken prior to, and following the manual therapy treatment in each clinic session.

**Knee Injury and Osteoarthritis Outcome Scale (KOOS)**

This instrument will be administered prior to treatment commencing and at the conclusion of the study.

The KOOS is a 42 item self-administered questionnaire which covers knee-related quality of life, activities of daily living, sport and recreation function, symptoms, and pain. Each item is scored on a 0-4 scale where 0 is indicative of no problems and 4 of extreme problems. The KOOS has been validated for use in knee injury, osteoarthritis and total joint replacement populations. The minimal detectable change is 12 points for pain, 8 points for symptoms and 10 points for ADL (Roos 2003). This instrument will be administered prior to treatment commencing and at the conclusion of the study.

**Patient Specific Functional Scale (PSFS)**

The Patient Specific Functional Scale (PSFS) is a patient-specific questionnaire which assesses functional ability in patient-specific activities. It utilizes an 11-point scale on which patients rate their current ability to complete specified activities or tasks. 0 constitutes inability to perform the task and 10 indicates the ability to complete the task at a premorbid level. This outcome measure has been validated for use in various populations including those with chronic pain, low back pain, neck dysfunction, and knee dysfunction. The minimal detectable change in a knee dysfunction population is considered to be 1.5 points (Chatman et al, 1997). The PSFS has been demonstrated to have excellent test-retest reliability in a knee dysfunction population. However, it has been observed to have a floor effect in knee dysfunction patients as activities unable to be completed scored a 0, leaving no room to record and account for further deterioration in function. This instrument will be administered prior to treatment commencing and at the conclusion of the study.

**Demographic Data**

Patient history will be taken as per usual practice. Data from this process will be extracted for the study including:

Age, sex, height and weight, duration of symptoms, affected knee, comorbidities, previous therapy.

Table 1: Data Collection Schedule

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Recruitment call | Visit 1 | Visit 2 | Visit 3 | Final Visit  |
| Screening | X |  |  |  |  |
| Consent |  | X |  |  |  |
| Demographic questionnaire |  | X |  |  |  |
| Flexion ROM |  | XX | XX | XX | XX |
| Pain |  | XX | XX | XX | XX |
| KOOS |  | X |  |  | X |
| PSFS |  | X |  |  | X |
| Medication questions | X | X | X | X | X |

Table 2: Study timelines:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Milestones | Nov | Dec | Jan | Feb | Mar | Apr | May | Jun | Jul | Aug | Sep | Oct |
| Protocol developed |   |   |   |   |   |   |   |   |   |   |  |  |
| Ethics submission | 7  |   |   |   |   |   |   |   |   |   |  |  |
| Ethics approval |   |   |   |   |   |   |   |   |   |   |  |  |
| Reliability and validity verification |   |   |   |   |   |   |   |   |   |   |  |  |
| Recruitment |   |   |   |   |   |   |   |   |   |   |  |  |
| Data collection |   |   |   |   |   |   |   |   |   |   |  |  |
| Analyse data |   |   |   |   |   |   |   |   |   |   |  |  |
| Write up  |   |   |   |   |   |   |   |   |   |   |  |  |
| Present at APA ACT seminar |   |   |   |   |   |   |   |   |   |   | 11 Sep |  |
|  Present at UC Honours seminar |   |   |   |   |   |   |   |   |   |   |  | 16 Oct |
| Submit finished report |  |  |  |  |  |  |  |  |  |  |  | 25 Oct |

#### Participant withdrawal

Participants may be withdrawn from the study if they have an adverse event, precluding them from continuing.

If a participant wishes to withdraw consent, they are able to do so at any time, for any reason of their own, according to the ethical principles and consent.

Withdrawing from the project will not affect their access to Physiotherapy services provided at the clinical trial sites.

**How will patient information be managed if they withdraw from the study?**

If a participant withdraws prior to randomisation, their clinical and research information will be archived according to record keeping protocols. The participant data is counted in the participant flow diagram, but not included in analysis. All information is retained for the prescribed period.

If a participant withdraws after randomisation, their clinical and research information will be included in the study analysis according to intention to treat principles. The ‘Last observation carried forward’ principle is used for intention to treat analysis. All records and materials will be maintained. The participant is counted in the participant flow diagram, and included in analysis. All information is retained for the prescribed period. (see patient information sheet).

**Protocols for follow up of participants**

If contact is lost with a participant

* they miss an appointment,
* They fail to return documents
* They lose contact with the clinical site team

Follow up attempts will be made according to this protocol. Polite and friendly reminders will be sent Limits: 1 each of these media: phone call, email, letter in post (phone - landline not answered is not included in count, mobile phone not answered is included since ‘missed call’ number will be listed; a voice message counts as a phone call.

### 9. Data Management

· Where and how is data going to be stored?

All paper files and electronic files will be kept at the clinical site during data collection phase and copies to the research folder in the UC main archive. All electronic data, participant files and data sets will be stored at UC. Folders and databases will have password protection. All papers will be kept in a locked filing cabinet

· Will there be any attempts to de-identify data?

**Participant information:** materials on consent, contact details and other communications will be kept in a participants’ folder, password protected on the clinical site and backed up at UC.

**Research data** will be de-identified, but re-identifiable from the participant sheet if required. Research data will not identify any individual. Research reports will not identify any individual.

#### Privacy and Confidentiality

Privacy and confidentiality on clinical sites will comply with the Australian National Privacy Act 1988.

### 10. Adverse Event Reporting

Adverse events

We anticipate very rare adverse events associated with the treatment to be administered. In a recent systematic review (Xu, 2017) of 14 studies of manual therapy (including traditional chinese therapies) only one study reported that one participant felt increased discomfort and refused to complete the assessment. Seven studies (53.8%) did not report whether they had AEs or not. The remaining 6 studies (46.2%) stated that no AEs occurred.

Adverse events may include:

- increase in knee pain requiring use of medication, medical consultation or hospital admission.

- Bruising requiring first aid, ice, bandage or other intervention

- Structural or internal derangement of the knee, causing pain, instability, or swelling

- Accidents or injuries while attending the clinic, related or unrelated to the treatment, for example falls, faints, or other

Adverse events will be managed immediately and followed up until resolved. Adverse events will be reported within 24 hours to the chief investigators. Serious adverse events (requiring medical or pharmaceutical intervention or hospital admission) will be reported within 24 hours to the UC HREC as per TGA Good Clinical Practice procedures.

### 11. Statistical Analysis

· **Analysis plan**

o Details on how the primary and secondary outcomes will be analysed.

o Statistical methods to be used - ANOVA. Linear mixed model. Repeated measure ANOVA

o Who is going to carry out the analysis?

Advice will be sought from the University of Canberra consulting biostatistician. Analysis will be conducted by the honours student, under the guidance of the supervisor.

The baseline data for the participants in the study will be explored and described by descriptive statistics. To examine for any differences between the two interventions groups prior to intervention, the gender ratio between groups will be analysed using Chi-square statistics and age distribution analysed with a t-test. Outcomes measures at baseline (Pain, KOOS, PSFS) will be explored by descriptive statistics (mean and standard deviation) and t-test.

The effect of intervention on primary outcome measures of flexion and pain will be examined for within and between group effects using a linear mixed model analysis of variance. Fixed factors include the group, visit number, and sex. Random factors included the participant identification number. Outcomes will be described by estimated marginal means and variance by standard error. Confidence intervals of 95% will be reported.

Differences will be considered significant at p > or = 0.05, and confidence intervals set at 95%.

In this study, intention to treat analysis will be completed using imputation of the last observation carried forward. In this method, no participant who is randomized is omitted.

In this pilot study there will be no interim analysis conducted.

### 12. Quality assurance, monitoring & safety

UC Human Research Ethics committee will scrutinise this study. Oversight is provided by the Honours supervision team in the Discipline of Physiotherapy at University of Canberra. There is no external body to whom the research team report.

The research team is made up of Registered and experienced Physiotherapists from three areas, Canberra Hospital, Southside Physiotherapy and University of Canberra. This team provides a breadth of practice experience and a depth of research experience. Each of these supervisors has 15+ years of clinical physiotherapy experience, 2 hold a PhD and substantial research track record.

#### Stopping rules

The treatment of knee flexion stiffness using manual physiotherapy techniques is not a high risk intervention. Adverse events are unlikely. Serious adverse events are considered to be very rare. Knee reconstruction and inflammatory arthritis are exclusion criteria due to the potential vulnerability of the inflamed soft tissues and graft to load. Knee replacement is an exclusion criterion due to the joint not being an anatomical joint and therefore having non-physiological movement potentially.

The most likely reason to stop the plot study is delayed recruitment. If recruitment to the study is slow, advertising is planned by UC communications and media team, to increase awareness of the study.

If any team members are unable to continue in the research team, the other team members will substitute for them and the project continue.

### 13. Ethical Issues

#### Consent

There will be no coercion to participate in this study

There is no inducement or advantage offered to participants.

There is no advantage to students or staff of the university

#### Ethics Review

Application will be submitted to University of Canberra Human Research Ethics Committee. Recruitment will not commence until approval is obtained.

#### Regulatory Compliance

This pilot study will comply with the ICH Good Clinical Practice, the TGA Clinical Trials Handbook and the University of Canberra Policies on the conduct of ethical research.

Each member of the team has completed GCP training.

Peer Review

Oversight and peer review are provided by the Honours supervision team in the Discipline of Physiotherapy at University of Canberra. There is no external body to whom the research team report.

What goes beyond standard practice? The interventions in this study do not extend beyond scope of standard practice. Only the procedure of randomisation is not standard. Usually a manual therapy technique would be chosen by the clinical reasoning decision of the physiotherapist.

The relationship between the therapist/student therapist and the patient may be perceived to be unequal. However, the relationship is always one of trust and respect. The therapists/student therapists who will be recruiting patients for this study will be trained in research ethics and will know that in no circumstances should a patient be coerced to participate in the study.

### 14. Finance and resource use

#### Sponsors:

University of Canberra

Trauma and Orthopaedic Research Unit at Canberra Hospital

Southside Physiotherapy

#### Budget including direct and indirect costs

Personnel Research to be carried out by students and staff of UC.

Equipment Purchase of a dualler electrogoniometer by UC

 Use of current dualler owned by TORU

Consumables, printing provided by UC

Data storage provided by UC

Infrastructure support provided by UC

Costs of advertising. provided by UC, media team.

### 15. Dissemination of Results and Publication policy

This pilot study is to fulfil the requirements of an honours thesis in Physiotherapy at UC. The primary publication will be the development of the thesis.

Publications to arise from this pilot study will be submitted for presentation to

Australian Physiotherapy Association ACT Branch symposium Sept 2017.

Australian Physiotherapy Association National meeting Oct 2019

IFOMPT 2020 Melbourne 6-8 October 2020

Publications to arise from this pilot study will be submitted for publication to

Journal of Physiotherapy

[Musculoskeletal Science and Practice](https://www.journals.elsevier.com/musculoskeletal-science-and-practice)

Participants in this study will be provided with a report of the results of the study by

* communiqué (abstract in lay language, poster or infographic)
* Thank you

Any publications must be approved by each and every member of the research team, including conference abstracts, media releases or scientific journal publications (YYZ, BK, DP, JS). This team may include a representative of the FoH Clinics.

### 16. References

**Manual Therapy Interventions.**

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Deyle, G. D., S. C. Allison, R. L. Matekel, M. G. Ryder, J. M. Stang, D. D. Gohdes, J. P. Hutton, N. E. Henderson and M. B. Garber (2005). Physical therapy treatment effectiveness for osteoarthritis of the knee: a randomized comparison of supervised clinical exercise and manual therapy procedures versus a home exercise program. Phys Ther 85.

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Noble, P. C., G. R. Scuderi, A. C. Brekke, A. Sikorskii, J. B. Benjamin, J. H. Lonner, P. Chadha, D. A. Daylamani, W. N. Scott and R. B. Bourne (2012). Development of a new knee society scoring system. Clinical Orthopaedics and Related Research 470(1): 20-32.

Pujol, N., P. Boisrenoult and P. Beaufils (2015). Post-traumatic knee stiffness: Surgical techniques. Orthopaedics & Traumatology: Surgery & Research 101(1, Supplement): S179-S186.

Scarvell, J., N. Hribar, C. Galvin, M. Pickering, D. Perriman and P. Smith (2017). If you could see inside the knee, what would you see in kneeling? Visualisation of 4-dimensional arthrokinematics in deep flexion. . World Congress of Physiotherapy, Cape Town.

Schomacher, J. (2009). The convex–concave rule and the lever law. Manual Therapy 14: 579-582.

Weiss, J. M., P. C. Noble, M. A. Conditt, H. W. Kohl, S. Roberts, K. F. Cook, M. J. Gordon and K. B. Mathis (2002). What functional activities are important to patients with knee replacements? Clinical Orthopaedics And Related Research(404): 172-188.

Xu, Q., B. Chen, Y. Wang, X. Wang, D. Han, D. Ding, Y. Zheng, Y. Cao, H. Zhan and Y. Zhou (2017). The effectiveness of manual therapy for relieving pain, stiffness, and dysfunction in knee osteoarthritis: A systematic review and meta-analysis. Pain Physician 20(4): 229-243.

**Outcomes measures:**

**Knee Flexion**

Jacobs WCH, Clement DJ, Wumenga AB. (2005) Retention versus removal of the posterior cruciate ligament in total knee replacement: A systematic literature review within the Cochrane framework. Acta Orthopaedica 76: 757-768

iCAHE Outcomes Calculator Musculoskeletal Version User Manual. Monitoring patient status over time using common pain and musculoskeletal outcome measures Updated August 2013 Prepared by The Research Team International Centre for Allied Health Evidence . University of South Australia.

**KOOS**

Goncalvesyz RS, Cabriy J, Pinheirox JP, Ferreirak PL, Gilz J (2010): Reliability, validity and responsiveness of the Portuguese version of the Knee injury and Osteoarthritis Outcome Score e Physical Function Short-form (KOOS-PS). Osteoarthritis and Cartilage 18:372- 376.

Monticone M, Ferrante M, Salvaderi S, Rocca B, Totti V, Foti C, Roi GS (2012): Development of the Italian version of the knee injury and osteoarthritis outcome score for patients with knee injuries: cross-cultural adaptation, dimensionality, reliability, and validity. Osteoarthritis and Cartilage 20: 330-335.

 Roos EM, Roos PH, Lohmander LS et al: Knee injury and Osteoarthritis Outcome Score (KOOS): Development of a self-administered outcome measure. Journal of Orthopaedic and Sports Physical Therapy 78(2): 88-96, 1998

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Salavati M, Akhbari B, Mohammadi F, Mazaheri M , Khorrami M (2011): Knee injury and Osteoarthritis Outcome Score (KOOS); reliability and validity in competitive athletes after anterior cruciate ligament reconstruction. Osteoarthritis and Cartilage 19: 406- 410.

### 17. Appendices – Useful web links for resources.

KOOS

http://www.unisa.edu.au/Global/Health/Sansom/Documents/iCAHE/Outcomes%20Calculator/iCAHE\_OC\_Muscskel\_User\_Manual\_2014.pdf

<http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=1011>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC280702/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1471783/>

<http://www.jospt.org/doi/abs/10.2519/jospt.1998.28.2.88>

<https://hqlo.biomedcentral.com/articles/10.1186/1477-7525-1-64>

Patient Specific Function Scale

<https://academic.oup.com/ptj/article/77/8/820/2633201/The-Patient-Specific-Functional-Scale-Measurement>

<http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=890>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3036014/>

<http://www.utpjournals.press/doi/abs/10.3138/ptc.47.4.258>

<https://www.ncbi.nlm.nih.gov/pubmed/22324057>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1084357/>

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Visual Analog Scale, and Verbal Rating Scale (Chapman et al., 2011; Hawker et al., 2011; Hjermstad et al., 2011; Mannion et al., 2007).

 NPRS and VAS require less time to administer as compared to other measures reported in the literature (Chapman et al., 2011; Hawker et al., 2011; Hjermstad et al., 2011; Mannion et al., 2007). However NPRS is more convenient to use and it can be administer both in writing and verbally. (Hawker et al., 2011; Hjermstad et al., 2011)

In clinical practice and research, the 11 point numeric pain rating scale (NPRS) for pain reported for the previous 24 hours is commonly used, whereby a score of 0 is considered no pain and 10 is considered the worst pain imaginable. This outcome measure has been found to be valid, reliable, and responsive to change (Chapman et al., 2011; Hjermstad et al., 2011).

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