BMJ Open

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041742
Article Type:	Protocol
Date Submitted by the Author:	24-Jun-2020
Complete List of Authors:	Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Johnston, Richard; La Trobe University - Bundoora Campus, La Trobe Sports and Exercise Medicine Research Centre Coburn, Sally; La Trobe University, La Trobe Sports and Exercise Medicine Research Centre Jones, Denise; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Schache, Anthony; La Trobe University, La Trobe Sports and Exercise Medicine Centre Mentiplay, Benjamin ; La Trobe University, King, Matthew; La Trobe University Scholes, Mark; La Trobe University De Oliveira Silva, Danilo; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Smith, Anne; Curtin University, School of Physiotherapy McPhail, Steven; Queensland University of Technology, Australian Centre for Health Service Innovation and School of Public Health & Social Work Crossley, Kay; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, SPORTS MEDICINE, REHABILITATION MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title page

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Joanne L Kemp,[1] Richard TR Johnston,[1] Sally L Coburn,[1] Denise M Jones,[1] Anthony G Schache,[1] Benjamin F Mentiplay,[1] Matthew G King,[1] Mark J Scholes,[1] Danilo de Oliveira Silva,[1] Anne J Smith,[2] Steven M McPhail,[3,4] Kay M Crossley.[1]

[1] La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Human Services and Sport, La Trobe University, Bundoora, Victoria, Australia.

[2] School of Physiotherapy and Exercise Science, Curtin University, Perth, Western Australia, Australia.

[3] School of Physiotherapy & Social Work and Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Queensland, Australia.

[4] Centre for Functioning and Health Research, Metro South Health, Brisbane, Queensland, Australia.

Correspondence to:

Dr Joanne L Kemp, La Trobe Sport and Exercise Medicine Research Centre, La Trobe University, Bundoora, Victoria 3086, Australia

j.kemp@latrobe.edu.au

Word count: 3604

ABSTRACT

Introduction: Femoroacetabular impingement (FAI) syndrome is a common cause of hip-related pain in young and middle-aged active adults (18-50 years of age). Physiotherapist-led interventions have potential as a first-line treatment, but efficacy is unknown. As such, this double-blind, randomised controlled trial (RCT) aims to compare the 6-month efficacy of a targeted physiotherapist-led intervention to a standardised physiotherapist-led intervention, on hip-related quality of life (QOL) in people with FAI syndrome. We hypothesise that at 6-months, the targeted physiotherapist-led intervention will be associated with greater improvements in hip-related QOL when compared to the standardised physiotherapist-led intervention.

Methods and analysis: We will recruit 164 participants with FAI syndrome who will be randomised into one of the two intervention groups, both receiving one-on-one treatment with the physiotherapist over 6-months. The targeted physiotherapist-led intervention group will receive a personalised exercise therapy and education programme. The standardised physiotherapist-led intervention group will receive a standardised stretching and education program. Primary outcome is change in hip-related QOL using International Hip Outcome Tool (iHOT-33)). Secondary outcomes include patient-perceived improvement, cost-effectiveness, muscle strength, range of motion, functional task performance, biomechanics, hip cartilage structure and physical activity levels. Statistical analyses will make comparisons between both treatment groups by intention-to-treat, with all randomised participants included in analyses, regardless of protocol adherence. Linear mixed models (with baseline value as a covariate and treatment condition as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at primary end-point (6-months).

Ethics and dissemination: The study protocol was approved (La Trobe University Human Ethics Committee (HEC17-080)) and prospectively registered with the Australian New Zealand Clinical Trials Registry. The findings of this RCT will be disseminated through peer reviewed scientific journals and conferences. Patients were involved in study development and will receive a short summary following the completion of the RCT.

Trial registration number: ACTRN12617001350314

Keywords: Hip joint, rehabilitation, exercise therapy, femoroacetabular impingement, physiotherapy

Strengths and limitations of this study

- This prospective, double-blind RCT is the first full-scale study to test the efficacy of a physiotherapist-led intervention for FAI syndrome.
- Patient-reported outcomes will be collected at clinically relevant time points and allows analysis of outcomes that are important to patients.
- Cost effectiveness analysis will inform clinical decision making.
- This physiotherapist-led RCT has the potential to reduce the burden of FAI syndrome and, if shown to be efficacious, may become the preferred first treatment choice for FAI syndrome.
- The blinding of participants and assessors provides the highest level of rigour to test the efficacy of the physiotherapist-led intervention.

INTRODUCTION

Musculoskeletal conditions, such as hip-related pain,[1] are leading causes of pain and disability in the community, and the second largest global contributor to years lived with a disability.[2] Femoroacetabular impingement (FAI) syndrome is a common cause of hip-related pain in adults,[3] and evident in 49% of young and middle-aged adults with hip-related pain.[4] It is diagnosed with a triad of imaging findings, patient reported hip-related symptoms, and clinical signs that are associated with excessive bone formation at the femoral head-neck junction (Figure 1). The most commonly reported altered bony shape is cam morphology, which describes excessive bone formation at the femoral head-neck junction.[5] Cam morphology may lead to aberrant joint forces during functional movements in the position of hip impingement (primarily involving flexion, rotation, and abduction or adduction), and subsequent damage to the articular cartilage of the hip joint.[6]

Figure 1. Diagrammatic representation of cam morphology at the femoral head-neck junction.[7]

Insert figure 1 here

While most studies focus on MSK pain affecting the elderly (e.g. osteoarthritis), there is compelling and increasing evidence that FAI syndrome in younger adults (e.g. aged 18-50 years) creates a substantial burden in society,[8 9] associated with persistent hip-related pain and symptoms,[10] impaired physical function,[11] reduced sports and physical activity participation, and impaired quality of life (QOL). The burden of FAI syndrome is amplified by the high daily physical demands (e.g. occupational, familial responsibilities, and recreational activities) encountered by younger adults.

Treatment options for FAI syndrome can be surgical or non-surgical.[12] Non-surgical approaches are recommended as the first line options for other MSK pain conditions (evident from clinical guidelines for osteoarthritis,[13 14] low back pain,[15] and chronic whiplash associated disorders[16]), due to the far greater costs and risks associated with surgery. However, rates of hip arthroscopy surgery have risen rapidly over the last 15 years.[17-20] Recently published RCTs comparing hip arthroscopic surgery to a physiotherapist-led intervention for FAI syndrome found small[21 22] to moderate[23] between-group differences favouring hip arthroscopy, with a greater cost and risk of adverse events associated with surgery.[21-23] The physiotherapist-led intervention used for comparison to hip arthroscopy consisted mostly of non-targeted, non-progressive exercises.[21 22 24 25] Thus, a physiotherapist-led intervention that reflects contemporary clinical practice should be developed and tested.[24 25]

A recent consensus meeting recommended exercise-based intervention as the first-line treatment for young adults with hip-related pain.[12] However, absence of a full-scale RCT evaluating the efficacy of an exercise-based, physiotherapist-led intervention for FAI syndrome[26-28] limited the strength of such recommendations. Therefore, the primary aim of this RCT is to compare the efficacy of a 6-month targeted physiotherapist-led intervention to a standardised physiotherapist-led intervention in 164 participants with FAI syndrome on hip-related QOL (International Hip Outcome Tool 33 (iHOT-33)). We hypothesise that, compared to standardised physiotherapist-led intervention, the targeted physiotherapist-led intervention will result in greater improvement in: (i) hip-related QOL. Secondary aims are to measure: (i) perceived improvement; (ii) the cost-effectiveness of the targeted physiotherapist-led intervention compared to the standardised physiotherapist-led intervention; (iii) the effects of targeted physiotherapist-led intervention on physical activity levels; (iv) the effects of targeted physiotherapist-led intervention on hip strength; and explore (v) the effects of targeted physiotherapist-led intervention on hip biomechanics; and (vi) the effects of targeted physiotherapist-led intervention on hip joint structure.

METHODS

Participants

This participant and assessor-blinded superiority RCT aligns with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.[29] We will recruit 164 participants from the general community in urban (greater Melbourne) and regional Victoria (Ballarat) (Australia) with a history of hip-related pain. The recruited cohort will be randomised into two parallel intervention groups. Block randomisation will be utilised with a 1:1 ratio, with the primary end-point of hip-related QOL after 6-months. This RCT study was prospectively registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12617001350314) and ethics approval obtained through the La Trobe University Human Ethics Committee (HEC 17-080).

Inclusion and Exclusion criteria

Eligibility for this RCT was based on clinical and radiographic features,[3] which were used in our previous pilot RCT for FAI syndrome.[6]

Inclusion criteria: (i) aged 18-50 years; (ii) hip-related (anterior hip or groin) pain which is aggravated by prolonged sitting or hip movements into positions of impingement;[3] (iii) hip-related pain ≥3/10 on numerical pain scale for ≥6 weeks; (iv) cam morphology (defined as radiographic alpha angle ≥60°),[30] as described below; and (v) a positive flexion–adduction–internal rotation (FADIR) test.

The alpha angle represents the sphericity of the femoral head and is used to identify and then quantify cam morphology if greater than 60° (Figure 2). To determine the presence of cam morphology, the potential participants will undergo a standing anteroposterior (AP) and Dunn 45° radiograph, following a standardised protocol.[3 30] Following previously described methods,[5] the alpha angle will be calculated by one examiner (JLK) using both the AP and the Dunn 45° radiographs, to quantify the asphericity of the femoral head.

Figure 2. Alpha angle measurement from AP radiograph.[30]

Insert figure 2 here

Exclusion criteria: (i) physiotherapy treatment for the hip in the past three months; (ii) previous hip or back surgery; (iii) planned lower limb surgery in the following year; (iv) radiographic hip osteoarthritis (Kellgren and Lawrence score ≥2,[31] representing moderate to severe hip osteoarthritis); (v) intra-articular hip-joint injection in the previous three months; (vi) neurological, other MSK, or systemic arthritis conditions; (vii) unable to perform testing procedures; (viii) unable to commit to a 6-month physiotherapy-led intervention or associated outcome assessments; (ix) contraindications to x-ray (including self-reported pregnancy and pregnancy during the study); or (x) inability to understand English language.

Procedures

The study procedure flow-chart is shown in Figure 3. Following clinical and radiographic screening to confirm study eligibility, participants will attend La Trobe University or Lake Health Group, Victoria, Australia to complete written and informed consent. Demographic characteristics will be recorded, and baseline patient reported outcome measures (PROMs) completed using an electronic data collection system (Promptus, Melbourne, Australia). Participants will undergo clinical and biomechanical assessment (where appropriate) of their hip by a blinded assessor at baseline and upon study follow-up (6-months). Magnetic resonance imaging will be completed at baseline and 12 months follow-up. Participants will be blinded to the randomisation procedure.

Figure 3. Study procedure flow-chart.

Insert Figure 3 here

Randomisation

Following baseline assessment, participants will be randomised into one of two intervention groups. To ensure concealed intervention allocation, we will use the telephone-based interactive voice response randomisation services (National Health and Medical Research Council Clinical Trials Centre, University of Sydney, Sydney, Australia). The randomisation schedule (blocks of 8 to 12) will be revealed to the unblinded assessor (JK, RJ) after the baseline assessment, who will communicate intervention allocation to the participant's study physiotherapist.

Blinding

As the primary outcomes are self-reported, participants are considered assessors; therefore, participants (and thus assessors) will be blinded to previous scores during the testing time points. Participants will be blinded to the physiotherapist-led interventions and consent will involve limited disclosure.

Physiotherapist-led interventions

Study participants will receive one of two physiotherapist-led interventions (targeted physiotherapist-led intervention or standardised physiotherapist-led treatment) across four clinical sites within Victoria (Australia). Registered physiotherapists will lead the two-phase intervention (Table 2) that will be delivered over a 6-month period and has been described using the Template for Intervention Description and Replication (TIDieR) guidelines.[32]

Targeted Physiotherapist-led Treatment

A team of expert physiotherapists with extensive clinical experience in FAI syndrome management (all with >15 years of individual experience) designed both physiotherapist intervention programs.[33-37] The targeted physiotherapist-led intervention was developed based on knowledge of physical impairments observed in FAI syndrome,[26] and a previous pilot study.[6] The targeted physiotherapist-led intervention is personalised to the individual participant's impairments and goals and has seven key elements: (i) progressive hip muscle strengthening exercises; (ii) progressive trunk muscle strengthening exercises; (iii) progressive functional exercises; (iv) progressive plyometric exercises; (v) a progressive physical activity/return to sport program; (vi) a personalised education program; and (vii) tailored manual therapy. Videos of all exercises in the targeted physiotherapist-led intervention can be found at [insert hyperlink here when accepted]. The targeted progressive hip and trunk strengthening exercises were designed using strength and conditioning guidelines outlined by the American College of Sports Medicine.[38] Adherence to these guidelines aims to facilitate hip joint loading tolerance utilising exercise dosages, volume, and progressions that will increase muscular strength-hypertrophy and strength-endurance. Full details of the targeted physiotherapist-led

intervention program are contained in Supplementary File 1. An example of how a participant may be provided with progressive targeted hip adductor strengthening exercises are presented in Figure 4. The participants will use the Physitrack® application (Physitrack, Ltd, London, UK), a web-based application compatible with smartphones, tablets, and computers, which provides photos, videos, and instructions of prescribed exercises to be played in real time. Those unable to access the Physitrack® application will be provided with paper-based pictures for exercise instruction.

Standardised physiotherapist-led intervention

The standardised physiotherapist-led intervention consists of standardised health education, non-specific, standardised stretching, standardised manual therapy and a physical activity program. In order to control for the psychosocial effects of therapist contact inherent with physiotherapy intervention, this program will provide a credible alternative to physiotherapy exercises to reduce the possibility of resentful demoralisation. Stretching was chosen as it has not previously demonstrated a clinically meaningful effect on joint mobility and function[6] (Supplementary File 2).

Delivery of targeted and standardised physiotherapist-led interventions

Phase 1: 0-3 months (6 physiotherapist-led interventions (1 per fortnight); 12 supervised gym sessions (1 per week), with a further two unsupervised gym sessions encouraged per week).

Phase 2: 4-6 months. Both intervention groups will receive a 3-month gym membership to continue with the unsupervised exercises independently. They will receive additional physiotherapy visits at months 4, 5, and 6 (i.e. 3 in total), with the aim of increasing adherence to the unsupervised intervention All clinical-site physiotherapists will receive treatment manuals and undergo three group training sessions (theory and practical) in the delivery of both interventions. Treating physiotherapists will then deliver either intervention. Clinics will be audited annually for treatment fidelity.

Participant adherence to intervention, adverse events and concomitant care

Participants will choose to attend one of four physiotherapy clinics to minimise transport burden within Melbourne and regional Victoria. The lead researcher (JLK) will maintain regular contact with study participants via the online PROM system (via weekly questionnaires on treatment adherence) and the Physitrack® app to monitor adverse responses to treatment.[6] Any adverse events will be reported to the Human Research Ethics Committee. Participants will be asked to refrain from concomitant physiotherapist-led treatment, other musculoskeletal therapies (chiropractic care, osteopathy, myotherapy or similar), or exercise interventions for their hip pain during the study. Participants will be allowed to continue care for other unrelated pre-existing conditions. There are minimal known risks associated with the physioFIRST study interventions, as such the physioFIRST study will not have a formal data monitoring committee or plans for post-trial care, and does not require an interim analysis.

Table 1: Intervention delivery described using the TIDieR guidelines for both groups

Phase	What	Targeted physiotherapy	Minimal intervention control
Phase 1. Month 0-3	**Who**	Physiotherapists	
	How	Face-to-face individual sessions	
	Where	Physiotherapy clinics (& clinic gyms) in Melbourne/Regional Victoria	
	When & how much	Fortnightly: 30 mins physiotherapy; and weekly: 30 mins supervised gym sessions. Exercises progressed based on assessment at each session	
	Tailoring	Tailored selection and progression of hip, trunk and functional strength exercises & manual therapy techniques Progressive, tailored physical activity program	Standardised non-specific stretching exercises Standardised education and information on increasing physical activity
	How well	Treatment response in files and adherence recorded in mobile phone app	
Phase 2. Month 4-6	**What**	**Targeted physiotherapy**	**Minimal intervention control**
	Who	Physiotherapists and local gymnasium	
	How	Face-to-face individual sessions & Membership to gymnasium	
	Where	Physiotherapy clinics & gymnasiums Melbourne/Regional Victoria	
	When & how much	3x 30 minute "top-up" physio sessions at month 4, 5 and 6. 3-times weekly unsupervised gym attendance	
	Tailoring	Semi-standardised with selection of exercise targeted to assessment	Standardised / non-specific stretching exercises
	How well	Treatment response in files and adherence recorded in mobile phone app	

Figure 4. An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises.

Insert figure 4 here

Measures to be collected

Measures to be collected will include primary and secondary outcomes, descriptive measures of the population, treatment modifiers, and treatment mediators. These are listed with timepoints of collection in Table 2.

Descriptive measures of the population

Participant baseline demographic characteristics, such as age, sex, height, body mass leg length, and waist and hip circumference, will be recorded. In addition, response to pain provocation tests will be recorded (Supplementary File 3).

Patient reported outcome measures

Primary Outcome

Hip-related QOL will be measured using the iHOT-33. The iHOT-33 questionnaire consists of 33 individual questions scored on a visual analogue scale from zero (worst possible score) to 100 (best possible score). The iHOT-33 has acceptable psychometric properties and is recommended for use in active adults with hip-related pain.[39 40] It has a low standard error of measurement (6 points),[41] is responsive,[42] with reported minimal clinically important differences ranging from 6 to 10 points [42] and minimal detectable change (groups) of 2 points.[41]

Secondary Outcomes

Patient-perceived global improvement will be measured on a 7-point Likert scale ('much improved', 'improved', 'a little improved', 'no change', 'a little worse', 'worse', 'much worse'). This is a clinically relevant tool for evaluating an individual patient's perspective on meaningful improvement.[43]

The Copenhagen Hip and Groin Outcome Score (HAGOS)[44] is a self-reported questionnaire consisting of six subscales that evaluates dimensions of hip and/or groin pain including: pain, symptoms, physical function of daily living, physical function in sport and recreation, participation in physical activities, and hip-related QOL. The HAGOS subscales are each scored out of 100 points (100=best possible score) has acceptable reliability and validity in young people with hip and groin pain.[45]

Workplace Activity Limitations Scale (WALS) is a 12-item questionnaire that aims to identify arthritis related activity limitations specific to various employment related tasks. Responses are made using a 4-point Likert scale and a total score is measured out of 33 (higher scores=more impairment).[46]

EQ-5D-5L (Registration ID 34190_TOU) is a reliable and valid measure of QOL.[47] The EQ-5D-QL asks the participant to indicate their health state according to five dimensions that assess: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[47 48]

Treatment modifiers

Pain Detect Questionnaire (PD-Q) evaluates the presence and severity of seven qualitative characteristics of pain, including: burning sensation, hyperesthesia, allodynia, shock-like, thermal, numbness, and tenderness. Based on the participant's self-reported scores, the likelihood for pain to be attributable to neuropathic factors is then classified as: (a) likely; (b) unlikely (and thus the pain type is identified as nociceptive); or (c) ambiguous (indicating the pain type is unclear and identified as having a mixed pattern).[49 50] The PD-Q is a reliable screening questionnaire for pain types with ICC's for measurement of pain intensities varying between 0.81 (95% CI: 0.75-0.87) and 0.87 (955 CI: 0.82-0.91).[50]

Keele STartT MSK Tool, contains 10 items that ask the participant about their function and disability, pain and coping, comorbidity, and the impact of pain. Once scored, it places the patient into three categories based on their risk of a poor outcome (low, medium, high). This tool has moderate-to-good level predictive ability in the identification of patients who develop persistent disabling pain.[51]

Tampa scale for Kinesiophobia (TSK), consists of 17 statements which measure pain-related fear of movement in patients with chronic MSK pain.[52] Each statement is provided with a 4-point Likert scale, and total scores range from 17 to 51, with a higher score indicating more fear of movement. The TSK demonstrates moderate reliability and validity when tested on patients with acute and chronic MSK pain.[53 54]

Physical impairment and functional outcome measures

Hip muscle strength will be measured with previously described methods,[55 56] as a secondary outcome and as a treatment mediator. A full description of the hip muscle strength tests are contained in Supplementary File 3.

Range of motion tests and functional performance tests are secondary outcomes and will be measured using previously published standardised methods (Supplementary File 3).[37 57] These tests of physical impairment will be measured at baseline and 6-months (Table 1). The tests have excellent reliability (ICC=0.82-0.95)[55] and were selected as they are frequently used in clinical practice and are associated with functional capacity of the hip and lower limb.[6 58]

Imaging measures

Radiographic hip alpha angle[30], as described above, will be used to describe the population and to determine its effect as a treatment modifier.

Hip joint cartilage structure at baseline will be quantified using the Scoring Hip Osteoarthritis with MRI (SHOMRI) semi-quantitative scoring system on a subset of 50 participants (25 per group).[59] The SHOMRI classification quantifies cartilage features in 10 subregions.[59] The SHOMRI scoring system has excellent previously published intra- and inter-reader reliability (ICC = 0.91-0.97; κ: 0.55-0.79).[59] This measure will be a secondary outcome and will also be used as a treatment modifier.

Hip biomechanics

Hip biomechanics will be secondary outcomes. Using three-dimensional motion analysis according to our previously described protocol,[56] participants biomechanics during walking, running, the single leg squat, and the y-balance test will be examined in a subset of 50 participants (25 per group) at baseline and at 6-months. Changes in hip biomechanics during these tasks will be measured. Details of the biomechanics testing procedures are contained in Supplementary File 4.

Physical activity

Physical activity (average daily step count over 14 days) is a secondary outcome and will be measured using the Fitbit Surge™ on a subset of 40 participants. The Fitbit Surge™ is a lightweight wrist worn device that tracks physical activity and has demonstrated reliability in people aged 18-50 years.[60]

Long term follow-up

Participants will be invited to complete the patient-reported outcome measures listed in Table 1 at annual intervals to 5-years, and then again at 10-years to enable the assessment of long-term predictors of outcome, and progression to hip surgery, including hip arthroscopy and hip arthroplasty.

Table 2. Trial measures to be collected and their purpose.

PhysioFIRST TIMELINE														
MEASURE	**PURPOSE**	**TIME POINTS (MONTHS) COLLECTED**												
		0	**1**	**2**	**3**	**4**	**5**	**6#**	**7**	**8**	**9**	**10**	**11**	**12**
DESCRIPTIVE MEASURES														
Age (years)	Describe population, treatment modifier	X												
Sex	Describe population, treatment modifier	X												
Height (m)	Describe population	X												
Body mass (kg)	Describe population	X												
Leg length (cm)	Describe population	X												
Waist and hip circumference (cm)	Describe population	X												
PAIN PROVOCATION TESTS														
Hip Internal Rotation Test	Describe population	X						X						
Flexion/Adduction/Internal Rotation Test (FADIR)	Describe population	X						X						
Bent Knee Fall Out (BKFO)	Describe population	X						X						
PATIENT REPORTED OUTCOME MEASURES (PROMS)														
International Hip Outcome Tool (IHOT-33)	Primary outcome	X			X			X			X			X
Patient-perceived global improvement	Secondary outcome				X			X			X			X
The Copenhagen Hip and Groin Outcome Score (HAGOS)	Secondary outcome	X			X			X			X			X
Workplace Activity Limitations Scale (WALS)	Secondary outcome	X			X			X			X			X
EQ-5D-5L	Secondary outcome	X			X			X			X			X
Pain Detect Questionnaire	Secondary outcome, treatment modifier	X			X			X			X			X
Keele STartT MSK Tool	Secondary outcome, treatment modifier	X			X			X			X			X
Tampa Scale for Kinesophobia	Secondary outcome, treatment mediator	X			X			X			X			X
HIP STRENGTH TESTS														
Hip Abduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Adduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Extension (prone)	Secondary outcome, treatment mediator	X						X						
Hip External Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Internal Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Flexion (sitting)	Secondary outcome, treatment mediator	X						X						
FUNCTIONAL TESTS														
Trunk Muscle Endurance (side lying)	Secondary outcome, treatment mediator	X						X						

One Leg Rise	Secondary outcome, treatment mediator	X						X						
Star excursion Balance Test	Secondary outcome	X						X						
Hop for Distance	Secondary outcome	X						X						
Single leg squat (video analysis)	Secondary outcome	X						X						
RANGE OF MOTION (Degrees)														
Hip Flexion	Secondary outcome	X						X						
Hip External Rotation	Secondary outcome	X						X						
Hip Internal Rotation	Secondary outcome	X						X						
IMAGING														
Hip MRI cartilage	Secondary outcome, treatment modifier	X												X
Hip alpha angle	Describe population, treatment modifier	X												
BIOMECHANICS TESTS														
Walking	Secondary outcome	X						X						
Y-Balance	Secondary outcome	X						X						
Single Leg Squat	Secondary outcome	X						X						
Running	Secondary outcome	X						X						
ACTIVITY MONITORING														
Fitbit Activity Monitoring (2 Week Block)	Secondary outcome	X			X			X						X
COST EFFECTIVENESS														
Incremental cost per Quality Adjusted Life Year	Secondary outcome							X						

[#] = primary end-point; m=meters; kg=kilograms; MRI = magnetic resonance imaging

Data management

Data quality will be ensured via practitioner training, assessing procedural quality, and random checks of protocol adherence, data completeness, and accuracy. Intervention adherence will be defined as completing ≥80% of the physiotherapist-led treatments and supervised gym sessions and will be tracked by the clinical site booking system and weekly questionnaires or the Physitrack® app. All participants will be included in the intention to treat analyses, including participants adhering to <80% of treatment and those participants who withdraw from the study.[61]

Sample size

A power calculation was conducted for this RCT based on data from our previous pilot study that utilised and compared a similar tailored intervention to a standardised intervention.[6] The power calculation was based on the observed baseline standard deviation (SD) and the between-group differences in the scores of our primary outcome measure of hip-related QOL (iHOT-33) (baseline SD = 25 points; mean difference 15 points out of 100).[6 57] In our pilot study, we observed a standardised mean difference (SMD) of 0.68 for the iHOT-33. However, this SMD is likely to be variable due to the small sample (n=24) in the pilot study. In addition, we need to account for the difference in the expertise of treating physiotherapists in a full-scale study. Therefore, the proposed SMD was reduced to 0.50 (80% power, α=0.05), resulting in a sample size estimate of 130 participants. A SMD of 0.50 has been previously reported for exercise programs in people with osteoarthritis, and is likely to be clinically meaningful in this RCT.[62] To account for an estimated 20% study drop-out (greater than the 17% recorded in our previous pilot study,[6] but likely due to the longer study duration), a recommended sample size of 164 participants (82 in each group) will be recruited in this RCT.

Statistical analyses

Data will be analysed using intention to treat (ITT), with all randomised participants included in analyses, regardless of protocol adherence. An experienced biostatistician (ASMAJS) will perform blinded analyses of primary and secondary outcomes. Linear mixed models (with baseline value as a covariate and treatment condition as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at 3 and 6 months. Models will be adjusted for age and sex. In addition to the primary ITT analysis, sensitivity analyses for missing outcome data will be performed on multiple imputed datasets, and Complier Average Causal Effects (CACE) methods will be used to estimate the treatment effect at full and partial levels of participation in addition to the primary ITT analysis.

Exploratory moderation analysis will be conducted to determine the strength of evidence provided by the study that treatment effects are moderated by the factors outlined as potential moderators in Table 1, by incorporating an interaction term between the potential moderator and the treatment group indicator in the linear mixed models for the ITT sample for the primary outcomes. Investigation of the mediation of the treatment effect for the primary outcomes for the ITT sample by the potential mediator variables outlined in Table 1 will also be conducted. Standardised estimates of the mediated treatment effect with bootstrapped 95% confidence intervals will be presented.

Cost-effectiveness (Incremental cost per Quality Adjusted Life Year)

The economic evaluation will estimate the incremental cost (healthcare system perspective) per quality adjusted life year (QALY) from the EQ-5D-QL assessment. Healthcare resource utilisation, including co-interventions for hip-related pain (e.g. medicines, complementary treatments, and details of hospital presentations) will be collected from several sources to facilitate data analysis, reporting, and corroboration. Data sources will include the Medicare and Pharmaceutical Benefits Scheme (MBS and PBS) databases (includes rebated, private health insurance, and out-of-pocket costs). Resources used to deliver the trial interventions for each respective trial arm will also inform the economic evaluation.

Trial status

Recruitment commenced in February 2018 and it is anticipated that this will be completed by September 2020. In March 2020, adjustments were made to the study protocol due to COVID-19, these are described in Supplementary File 5.

Conclusion

This RCT aims to determine the efficacy of a physiotherapist-led intervention for FAI syndrome on hip-related QOL. It may provide an evidence-based framework for physiotherapists to implement the first line of care for the treatment of FAI syndrome.

Patient and public involvement

Patients were involved in the planning stages of this project. Patients provided input via questionnaires and interviews.

Patients' priorities gathered during the questionnaires and interviews informed the development of the research question.

Patients and clinicians provided input into the development of the interventions, the frequency of treatment, and their treatment goals.

Patients were not involved in the recruitment and conduct of the study.

Patients were asked to assess the burden of the intervention and time required to participate in the study during the planning stages of the study.

Patients and clinicians will provide input into the dissemination of study results by assisting with the decision on what information to share and in what format.

Acknowledgements

The authors acknowledge the staff of Lake Health Group, Ballarat, Australia; Lake Imaging, Ballarat, Australia; Imaging at Olympic Park, Melbourne, Australia; Clifton Hill Physiotherapy, Melbourne, Australia; Mill Park Physiotherapy, South Morang, Melbourne, Australia; and Complete Sports Care, Hawthorn, Melbourne, Australia.

Data statement

Dataset will be publicly available after publication of study findings at Figshare (add url on publication)

Author contributions

JLK and KMC conceived the study design. JLK and RTJ prepared the manuscript. SLC, DMJ, AGS, BFM, MGK, MJS, DOS, AJS, SMM, and KMC all contributed to the drafting of the manuscript and approved the final version.

Competing interests

The authors declare that they have no competing interests.

Patient consent

Obtained.

Ethics Approval

Ethical approval was obtained from the La Trobe University Human Ethics Committee registration number HEC 17-080.

Funding

Dr J L Kemp is funded by the National Health and Medical Research Council of Australia (NHMRC ECF GNT:1119971).

Provenance and peer review

Not commissioned; externally peer reviewed.

References

1. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2020:bjsports-2019-101453. doi: 10.1136/bjsports-2019-101453
2. Vos T, Flaxman AD, Naghavi M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet (London, England)* 2012;380(9859):2163-96. doi: 10.1016/s0140-6736(12)61729-2 [published Online First: 2012/12/19]
3. Griffin DR, Dickenson EJ, O'Donnell J, et al. The Warwick Agreement on femoroacetabular impingement syndrome (FAI syndrome): an international consensus statement. *Br J Sports Med* 2016;50(19):1169-76. doi: 10.1136/bjsports-2016-096743 [published Online First: 2016/09/16]
4. Mascarenhas VV, Rego P, Dantas P, et al. Imaging prevalence of femoroacetabular impingement in symptomatic patients, athletes, and asymptomatic individuals: A systematic review. *European journal of radiology* 2016;85(1):73-95. doi: 10.1016/j.ejrad.2015.10.016 [published Online First: 2016/01/03]
5. Agricola R, Waarsing JH, Thomas GE, et al. Cam impingement: defining the presence of a cam deformity by the alpha angle: Data from the CHECK cohort and Chingford cohort. *Osteoarthritis and Cartilage* 2014;22(2):218-25. doi: https://doi.org/10.1016/j.joca.2013.11.007
6. Kemp JL, Coburn SL, Jones DM, et al. The Physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A Pilot Randomized Controlled Trial. *J Orthop Sports Phys Ther* 2018;48(4):307-15. doi: 10.2519/jospt.2018.7941 [published Online First: 2018/04/03]
7. Brukner P, Khan K. Brukner & Khan's Clinical Sports Medicine: Injuries, Fifth Edition: McGraw-Hill Education (Australia) 2016.
8. Byrd JWT. Femoroacetabular impingement in athletes, part 1: cause and assessment. *Sports health* 2010;2(4):321-33. doi: 10.1177/1941738110368392
9. Byrd JWT, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-46. doi: 10.1007/s11999-008-0659-8 [published Online First: 12/19]

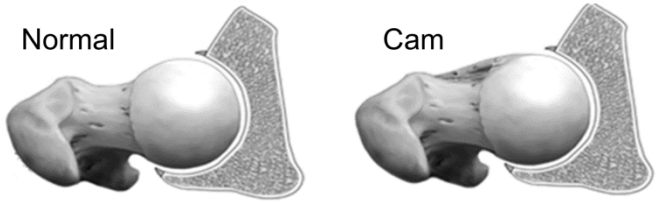
10. Weir A, Brukner P, Delahunt E, et al. Doha agreement meeting on terminology and definitions in groin pain in athletes. *Br J Sports Med* 2015;49(12):768-74. doi: 10.1136/bjsports-2015-094869 [published Online First: 2015/06/03]
11. Kemp JL, Beasley I. 2016 international consensus on femoroacetabular impingement syndrome: the Warwick Agreement-why does it matter? *Br J Sports Med* 2016;50(19):1162-3. doi: 10.1136/bjsports-2016-096831 [published Online First: 2016/09/16]
12. Kemp JL, Risberg MA, Mosler A, et al. Physiotherapist-led treatment for young to middle-aged active adults with hip-related pain: consensus recommendations from the International Hip-related Pain Research Network, Zurich 2018. 2019:bjsports-2019-101458. doi: 10.1136/bjsports-2019-101458 %J British Journal of Sports Medicine
13. Fernandes L, Hagen KB, Bijlsma JWJ, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Annals of the Rheumatic Diseases* 2013;72(7):1125. doi: 10.1136/annrheumdis-2012-202745
14. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage* 2014;22(3):363-88. doi: 10.1016/j.joca.2014.01.003 [published Online First: 2014/01/28]
15. Koes BW, van Tulder M, Lin C-WC, et al. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *Eur Spine J* 2010;19(12):2075-94. doi: 10.1007/s00586-010-1502-y [published Online First: 07/03]
16. TRACsa. Clinical guidelines for best practice management of acute and chronic whiplash associated disorders: Clinical resource guide. . Trauma Injury and Recovery, Adelaide, South Australia.2008.
17. Cvetanovich GL, Chalmers PN, Levy DM, et al. Hip Arthroscopy Surgical Volume Trends and 30-Day Postoperative Complications. *Arthroscopy* 2016;32(7):1286-92. doi: 10.1016/j.arthro.2016.01.042 [published Online First: 2016/04/14]
18. Montgomery SR, Ngo SS, Hobson T, et al. Trends and demographics in hip arthroscopy in the United States. *Arthroscopy* 2013;29(4):661-5. doi: 10.1016/j.arthro.2012.11.005 [published Online First: 2013/02/05]
19. Maradit Kremers H, Schilz SR, Van Houten HK, et al. Trends in Utilization and Outcomes of Hip Arthroscopy in the United States Between 2005 and 2013. *J Arthroplasty* 2017;32(3):750-55. doi: 10.1016/j.arth.2016.09.004 [published Online First: 2016/10/30]
20. Davies O, Grammatopoulos G, Pollard TCB, et al. Factors increasing risk of failure following hip arthroscopy: a case control study. *Journal of hip preservation surgery* 2018;5(3):240-46. doi: 10.1093/jhps/hny020 %J Journal of Hip Preservation Surgery
21. Griffin DR, Dickenson EJ, Wall PDH, et al. Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial. *The Lancet* 2018;391(10136):2225-35. doi: 10.1016/S0140-6736(18)31202-9
22. Mansell NS, Rhon DI, Meyer J, et al. Arthroscopic surgery or physical therapy for patients with femoroacetabular impingement syndrome: a randomized controlled trial with 2-year follow-up. *Am J Sports Med* 2018:363546517751912. doi: 10.1177/0363546517751912 [published Online First: 2018/02/15]
23. Palmer AJR, Ayyar Gupta V, Fernquest S, et al. Arthroscopic hip surgery compared with physiotherapy and activity modification for the treatment of symptomatic femoroacetabular impingement: multicentre randomised controlled trial. *BMJ* 2019;364:l185. doi: 10.1136/bmj.l185

24. Kemp JL, Mosler AB, Hart H, et al. Improving function in people with hip-related pain: a systematic review and meta-analysis of physiotherapist-led interventions for hip-related pain. 2020:bjsports-2019-101690. doi: 10.1136/bjsports-2019-101690 %J British Journal of Sports Medicine
25. Kemp JL, King MG, Barton C, et al. Is exercise therapy for femoroacetabular impingement in or out of FASHIoN? We need to talk about current best practice for the non-surgical management of FAI syndrome. *British Journal of Sports Medicine* 2019:bjsports-2018-100173. doi: 10.1136/bjsports-2018-100173
26. Freke MD, Kemp J, Svege I, et al. Physical impairments in symptomatic femoroacetabular impingement: a systematic review of the evidence. *Br J Sports Med* 2016;50(19):1180. doi: 10.1136/bjsports-2016-096152 [published Online First: 2016/06/16]
27. Kemp JL, Collins NJ, Makdissi M, et al. Hip arthroscopy for intra-articular pathology: a systematic review of outcomes with and without femoral osteoplasty. *Br J Sports Med* 2012;46(9):632-43. doi: 10.1136/bjsports-2011-090428 [published Online First: 2011/12/24]
28. Reiman MP, Thorborg K, Holmich P. Femoroacetabular Impingement Surgery Is on the Rise-But What Is the Next Step? *J Orthop Sports Phys Ther* 2016;46(6):406-8. doi: 10.2519/jospt.2016.0605 [published Online First: 2016/06/02]
29. Chan AW, Tetzlaff JM, Gotzsche P, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346(e7586)
30. Agricola R, Heijboer MP, Bierma-Zeinstra SMA, et al. Cam impingement causes osteoarthritis of the hip: A nationwide prospective cohort study (CHECK). *Annals of the Rheumatic Diseases* 2013;72(6):918-23.
31. Kellgren JH, Lawrence JS. Radiological Assessment of Osteoarthrosis. *Ann Rheum Dis* 1957;16:494-502.
32. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical Journal* 2014;348 doi: 10.1136/bmj.g1687
33. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
34. Crossley K, Grimaldi A, Kemp J. Grieve's Modern Musculoskeletal Physiotjerapy. Hip Related Pain. 4th ed. London2015.
35. JL Kemp, KM Crossley, AG Schache, et al. Hip-related pain. In: PD B, Khan KM, KM C, et al., eds. Brukner and Khan's Clinical Sports Medicine. Sydney: McGraw Hill 2017.
36. Kemp JL, Moore K, Fransen M, et al. A phase II trial for the efficacy of physiotherapy intervention for early-onset hip osteoarthritis: study protocol for a randomised controlled trial. *Trials* 2015;16:26. doi: 10.1186/s13063-014-0543-7 [published Online First: 2015/01/28]
37. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
38. Medicine ACoS. ACSM's guidelines for exercise testing and prescription. 10th ed. Philadelphia, PA.: Wolters Kluwer/Lippincott Williams & Wilkins 2017.
39. Mohtadi NG, Griffin DR, Pedersen ME, et al. The Development and validation of a self-administered quality-of-life outcome measure for young, active patients with

symptomatic hip disease: the International Hip Outcome Tool (iHOT-33). *Arthroscopy* 2012;28(5):595-605; quiz 06-10.e1. doi: 10.1016/j.arthro.2012.03.013 [published Online First: 2012/05/01]

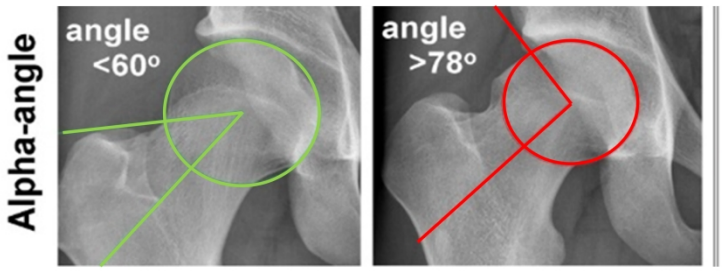
40. Impellizzeri FM, Jones DM, Griffin D, et al. Patient-reported outcome measures for hip-related pain: a review of the available evidence and a consensus statement from the International Hip-related Pain Research Network, Zurich 2018. 2020:bjsports-2019-101456. doi: 10.1136/bjsports-2019-101456 %J British Journal of Sports Medicine
41. Kemp JL, Collins NJ, Roos EM, et al. Psychometric properties of patient-reported outcome measures for hip arthroscopy. *American Journal of Sports Medicine* 2013;41:2065-73. doi: http://dx.doi.org/10.1016/j.joca.2013.02.582
42. Mohtadi NGH, Griffin DR, Pedersen ME, et al. The Development and Validation of a Self-Administered Quality-of-Life Outcome Measure for Young, Active Patients With Symptomatic Hip Disease: The International Hip Outcome Tool (iHOT-33). *Arthroscopy: The Journal of Arthroscopic & Related Surgery* 2012;28(5):595-610.e1. doi: http://dx.doi.org/10.1016/j.arthro.2012.03.013
43. ten Klooster PM, Drossaers–Bakker KW, Taal E, et al. Patient-perceived satisfactory improvement (PPSI): Interpreting meaningful change in pain from the patient's perspective. *Pain* 2006;121(1–2):151-57. doi: http://dx.doi.org/10.1016/j.pain.2005.12.021
44. Thorborg K, Hölmich P, Christensen R, et al. The Copenhagen Hip and Groin Outcome Score (HAGOS): development and validation according to the COSMIN checklist. *British Journal of Sports Medicine* 2011;45(6):478. doi: 10.1136/bjsm.2010.080937
45. Thorborg K, Branci S, Stensbirk F, et al. Copenhagen hip and groin outcome score (HAGOS) in male soccer: reference values for hip and groin injury-free players. *British Journal of Sports Medicine* 2014;48(7):557. doi: 10.1136/bjsports-2013-092607
46. Beaton DE, Tang K, Gignac MA, et al. Reliability, validity, and responsiveness of five at-work productivity measures in patients with rheumatoid arthritis or osteoarthritis. *Arthritis Care Res (Hoboken)* 2010;62(1):28-37. doi: 10.1002/acr.20011 [published Online First: 2010/03/02]
47. Conner-Spady BL, Marshall DA, Bohm E, et al. Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. *Quality of Life Research* 2015;24(7):1775-84. doi: 10.1007/s11136-014-0910-6
48. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
49. Nakawaki M, Fukushima K, Inoue G, et al. Use of the painDETECT questionnaire to differentiate the nature of hip pain associated with a labrum tear. *Asia-Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology* 2018;11:1-5. doi: https://doi.org/10.1016/j.asmart.2017.10.002
50. Tampin B, Bohne T, Callan M, et al. Reliability of the English version of the painDETECT questionnaire. *Current Medical Research and Opinion* 2017;33(4):741-48. doi: 10.1080/03007995.2017.1278682
51. Campbell P, Hill JC, Protheroe J, et al. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *Journal of pain research* 2016;9:807-18. doi: 10.2147/jpr.s116614 [published Online First: 2016/10/30]

52. Miller RP KS, Todd D. "The Tampa Scale: A Measure of Kinisophobia.". *The Clinical Journal of Pain* 1991;7(1):51-52.
53. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85(3):317-32. [published Online First: 2000/04/27]
54. Kvist J, Ek A, Sporrstedt K, et al. Fear of re-injury: a hindrance for returning to sports after anterior cruciate ligament reconstruction. *Knee Surgery, Sports Traumatology, Arthroscopy* 2005;13(5):393-97. doi: 10.1007/s00167-004-0591-8
55. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16:292-96.
56. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]
57. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
58. Culvenor AG, Collins NJ, Vicenzino B, et al. Predictors and effects of patellofemoral pain following hamstring-tendon ACL reconstruction. *Journal of Science and Medicine in Sport* 2016;19(7):518-23. doi: https://doi.org/10.1016/j.jsams.2015.07.008
59. Lee S, Nardo L, Kumar D, et al. Scoring Hip Osteoarthritis with MRI (SHOMRI): a Novel Whole Joint Osteoarthritis Evaluation System. *Journal of Magnetic Resonance Imaging* 2014;under review
60. Jones D, Crossley K, Dascombe B, et al. VALIDITY AND RELIABILITY OF THE FITBIT FLEX™ AND ACTIGRAPH GT3X+ AT JOGGING AND RUNNING SPEEDS. *International journal of sports physical therapy* 2018;13(5):860-70.
61. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ : British Medical Journal* 2013;346:e7586. doi: 10.1136/bmj.e7586
62. Bennell KL, Egerton T, Wrigley TV, et al. Comparison of neuromuscular and quadriceps strengthening exercise in the treatment of varus malaligned knees with medial knee osteoarthritis: a randomised controlled trial protocol. *BMC Musculoskelet Disord* 2011;12:276. doi: 10.1186/1471-2474-12-276 [published Online First: 2011/12/07]



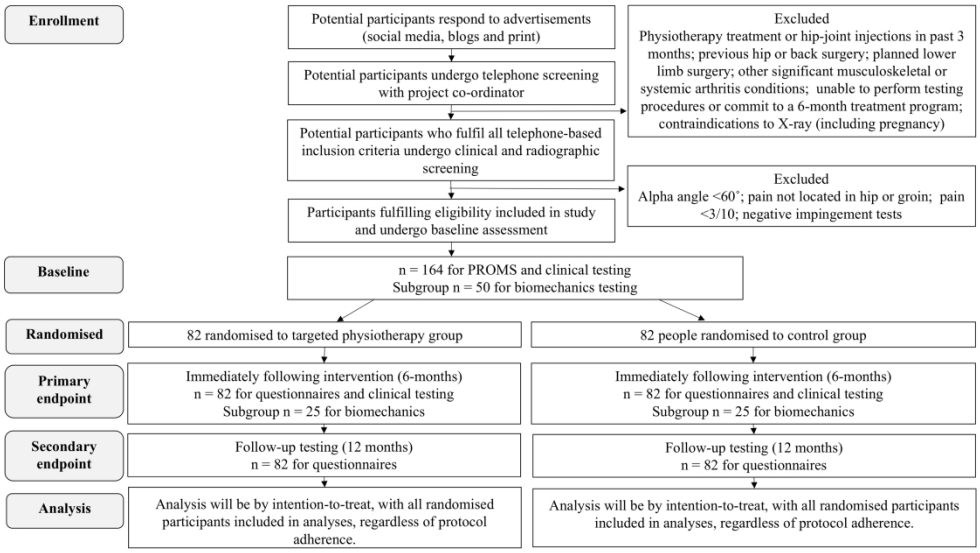
Diagrammatic representation of cam morphology at the femoral head-neck junction

338x190mm (300 x 300 DPI)



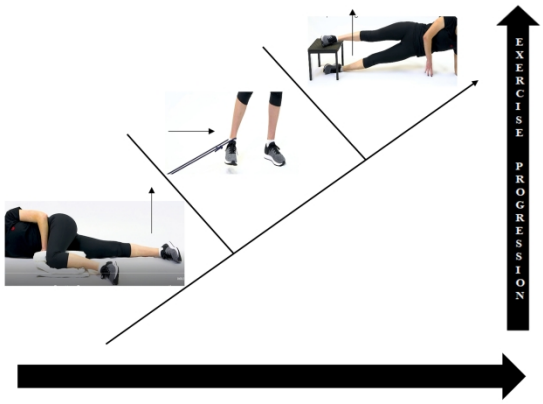
Alpha angle measurement from AP radiograph

338x190mm (300 x 300 DPI)



Study procedure flow-chart

338x190mm (300 x 300 DPI)



An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises

338x190mm (300 x 300 DPI)

Supplementary File 1: Targeted Physiotherapist-led treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Lion group refers to the progressive, semi-standardised rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The six components of the rehabilitation program were selected based on current knowledge of the highest level of evidence for physical impairments in FAI, and from the results of our recent pilot study.

The six key components targeted in this program include:

1. **ROM (flexion)**
2. **Hip muscle strength (Extension, Abduction, Adduction)**
3. **Trunk strength/endurance**
4. **Functional task performance (strength and plyometric)**
5. **Cardiovascular training/load management**
6. **Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Review of exercise program and progression of program as appropriate, for each of the targeted elements (hip adductor, abductor, extensor strength, trunk strength, functional strength and plyometric). ***Note: each patient should always be doing one exercise from each targeted element.*** See Tables 2-7 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
5. Review of cardiovascular fitness program as appropriate. See Table 8 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
6. Tailored education based on patient preference, three patient-focussed goals, and other topics raised by patient during treatment. Answers to common questions outlined below in Table 9.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, the 3 patient-focussed goals, and ensure patient appointments are booked into the system.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current exercises in hip strength (adduction, abduction, extension), trunk strength and functional strength exercises, including full sets and reps.
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app
3. Progression of exercises for each of the targeted elements where appropriate
4. Continuation of tailored education program

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Hip extension strength program

Extension			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging Gluteal squeeze and lift up into bridge hold and lower	3x10 reps 5 sec hold Weight = 10RM (10kg max)

2		Single leg Bridging Gluteal squeeze and lift up into bridge position, extend one leg, hold, extend other leg, hold, lower	3x10 reps 5 sec holds Weight = 10RM (10kg max)
3		Prone Hold Hip Extension - knees From knees move affected leg into hip extension, hold and lower leg, Cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
4		Prone Hold Hip Extension - toes From toes move affected leg into hip extension, hold and lower leg, cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
5		Standing single leg arabesque, weight in opposite hand	3x10 reps 5 sec ecc, 5 sec conc Weight = 10RM (10kg max)
6		Standing single leg arabesque, weight in opposite hand	3x20 reps 5 sec ecc, 5 sec conc Weight = 20RM (10kg max)

Table 3: Hip abduction strength program

Abduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging with band Bridge with band around knees, gently abduct against light band.	1x20 reps 5kg on pelvis 5 sec hold Band = 20RM
2		Bridging with band Bridge with band around knees, gently abduct against light band.	3x10 reps 5 kg on pelvis 5 sec hold Band = 10RM
3		Bridging with band Bridge with band around knees, gently abduct against heavy band.	3x10 reps 10 kg on pelvis 5 sec hold Band = 10 RM
4		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both feet on ground.	3x10 reps 5kg on pelvis 5 sec hold Band = 10RM

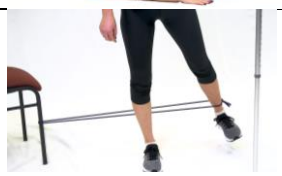
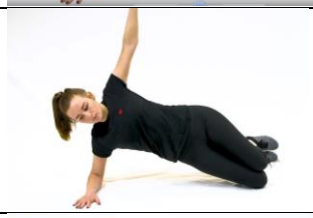
5		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both legs on ground.	3x10 reps 10kg on pelvis 5 sec hold Band = 10RM
6		Standing abduction with band or pulley, abduction to 30-45˚	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
7		Side lie abduction with band	3x10 reps 3 sec conc 3 sec ecc Band = 10RM

Table 4: Hip adduction strength program

Adduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	1x30 reps 5 sec hold 5 kg on hips
2		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	2x30 reps 5 sec hold 5 kg on hips
3		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	2x8 reps 5 sec hold
4		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x8 reps 5 sec hold
5		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold
6		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold Cuff weight = 10RM, 5kg max

7		Standing adduction with band or pulley	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
8		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower	3x10 reps 5 sec hold
9		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower. Cuff weight on ankle	3x10reps 5 sec hold Cuff weight = 10RM

Table 5: Trunk strength and endurance program

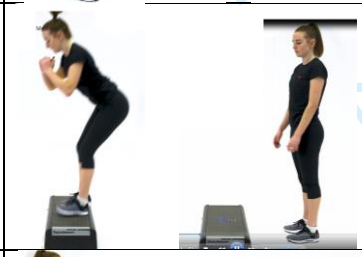
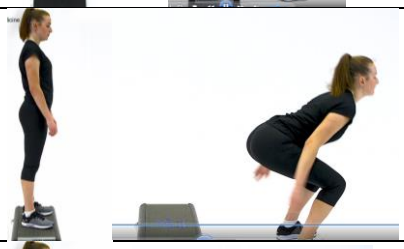
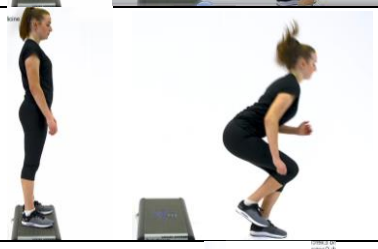
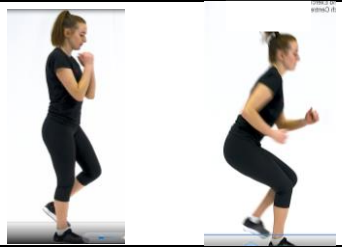
Trunk muscle strength (both sides in all patients)			
Phase	**Exercise**	**Description**	**Dosage**
1		Side bridge knees	30 secs hold 5 reps each side
2		Side bridge knees with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
3		Side bridge toes	30 secs hold 5 reps each side
4		Side bridge toes with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
5		Side bridge toes with arm rotations, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

6		Side plank with stability ball	30 secs hold 5 reps each side
7		Side plank with stability ball, with arm lifts. Can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

Table 6: Functional strengthening program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1	Box/chair squats.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing	3x10 reps 5 secs conc, 5 secs ecc
2	Box/chair squats with weight.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
3	Backwards lunges.	Step back and drop back knee towards ground, then stand up. Ensure good alignment	3x10 reps each side 5 secs conc, 5 secs ecc
4	Backwards lunges with weight.	Step back and drop back knee towards ground, then stand up. Ensure good alignment. Hold weight plate to chest	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
5	Repeater Step Ups	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor.	3x10 reps 5 secs conc, 5 secs ecc
6	Repeater Step Ups with weight	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
7	Single Leg Squats	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing	3x10 reps 5 secs conc, 5 secs ecc
8	Single Leg Squats with weight	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)

Table 7: Functional plyometric program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1		Jump forwards as far as possible – double leg take-off and landing	20 reps
2		Jump forwards as far as possible – double leg take off, single leg landing	20 reps each leg
3		Jump up onto box/step double leg take-off and landing	20 reps
4		Jump down off box/step/bosu double leg take-off and landing	20 reps
5		Jump down off box/step/bosu double leg take off, single leg landing	20 reps each side
6		Single leg hop forwards	20 reps each leg

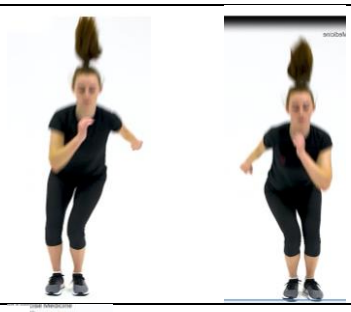
7		Multidirectional jump double leg	20 reps
8		Multidirectional hop single leg	20 reps each leg

Table 8: Cardiovascular fitness progressive program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	10 minutes every second day
2	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	20 minutes every second day
3	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes every second day
4	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes total, including 5x60 seconds high intensity every second day
5	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic	30 minutes including up to 10x60secs or 5x2 minutes

		activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	high intensity every second day
6	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	45 minutes including up to 15 minutes total high intensity every second day
7	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	15 mins every second day (can be combined with 30 mins level 1 activity)
8	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	20 mins every second day (can be combined with 25 mins level 1 activity)
9	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	30 mins every second day (can be combined with 20 mins level 1 activity)
10	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	45 mins every second day, including 10 mins higher intensity (can be combined with 15 mins level 1 activity)
11	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	50 mins every second day, including 20 minutes high intensity (can be combined with 10 mins level 1 activity).
12	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	Up to 1 hour, 3 time/week, full load

Table 9. Key education components

1.	Weight maintenance with recommended weight loss if BMI ≥ 25. This may require referral to dietician or GP. Generally, evidence suggests that a 3kg weight loss can result in 25% reduction in symptoms in people with OA.
2.	Patients' expectations of treatments. Hip pain due to FAI is not "curable" but can be well managed with appropriate treatment. Flares of pain are common and usually settle well with appropriate physiotherapy treatment. Small increases in pain (up to 3/10) can occur when starting or increasing exercises. This is nothing to be afraid of, and will settle as the body adapts to the new activity. It is of paramount importance to not completely rest, as this reduces this body's capacity to cope with normal day-to-day loads.
3.	Patients' specific goals of treatment, based on baseline assessment. Important to discuss with patient whether these are appropriate, and then plan to most appropriately achieve these.

4.	Patients' expectations of returning to sport, and whether this is possible. This may require a modification of expectations. To date there is no evidence to indicate that running sports, and kicking sports are likely to lead to short-term and long-term problems in people with FAI, and in most patients, it is possible to return to these types of activity in a sensible and gradually progressive way.

Supplementary File 2: Standardised treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Tiger group refers to the usual care, control group rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The four components of the rehabilitation program were selected to represent what could be "usual care" for hip pain, and has been tested in our pilot study

The four key components of the control program include:

1. **ROM (flexion)**
2. **Standardised stretching**
3. **Standardised cardiovascular training/load management advice**
4. **Standardised Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Provision of standardised stretching program. See Table 2 for each weekly set of exercises
5. Provision of standardised cardiovascular fitness program. This should be handed out in first treatment and patient asked to progress self through program. See Table 3 for details below.
6. Standardised education Table 4.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, and ensure patient appointments are booked into the system.

Please note, if patients complain of increasing pain during treatment that is concerning them or you, please contact Joanne Kemp to discuss. Do not allow the patient to continue to deteriorate without discussion.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current stretching exercises
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Weekly stretching program

Week 1								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip Flexor stretch off plinth.	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Thoracic rotation in supine	5 x 5sec holds to each side
	b) Short adductor stretch	30 sec hold, repeat x3,					b) Trunk rotation in Supine	5 x 5sec holds to each side.
	c) Hamstring stretch	Symptomatic leg 30 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 2								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Trunk rotation in Supine	5 x 5sec holds to each side.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in Supine	5 x 5sec holds to each side.
	b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 40 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 3								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Short adductor stretch	60 sec hold, repeat x2.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) ITB stretch	Symptomatic leg 60 sec hold, repeat x2.						

Week 4								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 40 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 60 sec hold, repeat x2.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		c) Tib Ant stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hold/relax Hamstring stretch (Therapist assisted)	At movement barrier, 20% contraction x 3.						
	d) Gluteal stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 5								
Hip			**Lower leg**			**Trunk**		
Exercise	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 60 sec hold, repeat x2.		a) Calf roller stretch	Symptomatic leg 40 sec x 2.		a) Trunk rotation in standing	5 x 5sec holds to each side
	b) Adductor stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		c) Tib Ant stretch in kneeling	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	40 sec hold x 2
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) Gluteal stretch	Symptomatic leg 40 sec hold, repeat x3.						

Week 6								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	60 sec hold x 2
	c) Hamstring foam roller in sitting	Bilateral, 40 sec x 2.					c) Elbow prop lumbar extension in prone	
	d) Gluteal stretch on wall	Symptomatic leg 30 sec hold, repeat x3.						

Week 7								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 40 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 60 sec hold, repeat x2.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) Gluteal stretch on wall	Symptomatic leg 40 sec hold, repeat x3.					c) Elbow prop lumbar extension in prone	5 x 5sec holds.
	d) Gluteal foam roller	Symptomatic leg 40 sec x 2.						

Week 8								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) LL calf stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 3 to each side.
	b) Hamstring- stretch standing	Symptomatic leg 30 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Salute to the sun	3 x 5sec holds at end of range extension and flexion
	d) ITB standing with side trunk flexion	Symptomatic leg 30 sec x 3.						

Week 9								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) calf stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Hamstring- hold/relax (therapist assisted)	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Extension in lying	5 x 5 second holds
	d) ITB standing	Symptomatic leg 30 sec x 3.						

Week 10								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 5 to each side.
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) calf stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) Gluteal foam roller	Symptomatic leg 60-120 sec.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 11								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 12								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 60 sec hold, repeat x2.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Table 3: Cardiovascular fitness standardised program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breastroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	As much as hip pain will allow. Progress to Level 2 when patient feels ready
2	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	As much as hip pain will allow

Table 4. Key education components

1.	Weight maintenance with recommended weight loss if BMI ≥ 25. Patients are encouraged to seek their own guidance for weight loss. Specific patient questions can be answered.
2.	Patients' expectations of treatment and activity. Patients are encouraged to do as much activity as their hip pain allows. No specific guidance is offered around activity modification, but patient-specific questions can be answered.

Supplementary File 3
PhysioFIRST Clinical testing procedures

Descriptive measures

Height (m)

Body mass (kg)

Leg length (cm): Distal greater trochanter to lateral knee joint line (centre) and distal greater trochanter to distal tip lateral malleolus

Waist circumference (cm): Measured at navel level

Hip circumference (cm): Measured at widest point of greater trochanter

Pain provocation tests

Hip Internal Rotation Pain[1-3]:

Participant Position: Supine

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90° (zero-degree position). Examiner internally rotates hip to point of resistance, keeping thigh in neutral position (i.e., avoiding abduction, adduction and pelvic tilt). Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Flexion 90°/Adduction/Internal Rotation (FADIR) Pain[1-3]:

Participant Position:

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90°. Examiner adducts hip to endpoint (while avoiding movement of the pelvis) and then

internally rotates hip, maintaining flexion and adduction components. Examiner asks participant if they “feel pain or discomfort in the inner thigh, upper thigh, hip or groin area”.

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Bent Knee Fall Out (BKFO)[1]*:*

Participant position:

Participant is lying supine with knee of test leg bent so that foot touches contralateral knee.

Method:

Participant externally rotates hip of test leg, so that the bent knee lowers toward exam table. Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh, hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Hip strength tests

All strength tests done with Power track II (Commander). Each strength test will be performed 3 times, 2 seconds to generate maximum force and then 3 seconds as hard as possible. Rest time will be allowed of 5 seconds between each repetition, 30 seconds minimum between each test. Therapist matches participants force (make test).

Supine

Abduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate 5 cm above lateral malleolus.

Participant instructed to *“keep trunk stable and opposite leg still, keep your heel on the bed, toes pointing to the ceiling and push leg out to side against force plate as hard as possible”.*

"go ahead: push-push-push-push-relax"

Adduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate for long lever 5 cm above medial malleolus,

Participant instructed to "*keep trunk stable and opposite leg still, keep heel on the bed, toes pointing towards ceiling and pull leg in to centre against force plate as hard as possible"*

"go ahead: push-push-push-push-relax"

Prone

Extension strength[4 5]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant prone, with test leg knee bent to 90° and positioned off the edge of the foot of the lowered exam table, chin resting on hands.

Force plate attached to Velcro of seatbelt and placed over centre of patient's heel, patient instructed to *"push foot straight up to ceiling"*.

Therapist matches force by placing foot in lower loop of seatbelt using bodyweight as counter resistance.

"Go ahead: push-push-push-push-relax"

External rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to medial malleolus of ankle, therapist on same side of bed, close to lower leg, with two hands on HHD.

Participant instructed to *"keep your trunk and opposite leg still and turn shin inwards towards the centre as hard as possible"*

"go ahead: push-push-push-push-relax"

Internal rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to lateral malleolus of ankle, therapist standing on same side of bed close to lower leg, with two hands on HHD laterally.

Participant instructed to *"keep trunk and opposite leg still and turn shin outwards as hard as possible, keeping both knees together"*

"go ahead: push-push-push-push-relax"

Sitting (on end of plinth)

Flexion strength[4]

Moment arm measured greater trochanter to lateral joint line knee

Both legs in resting position (hip 90º flexion), belt across contra-lateral thigh (placed firmly over middle of thigh)

Force plate 5 cm proximal to superior pole patella

Ensure participant is sitting in upright sitting position

Ensure that the contralateral leg is in 90° knee flexion and not being used to stabilise against the underneath of the bed.

Be aware that if you position someone in EOR hip flexion pain will potentially limit the force they can produce. Ensure that the testing leg is raised 1cm off the bed in a comfortable range

Participant instructed to *"sit with arms folded, chest up, not to lean backwards and pull knee up towards chest against force plate"*

"go ahead: push-push-push-push-relax"

Participant instructed to "*keep arms folded, chest up, thigh and knee flat on the bed and turn shin outward, as far as possible, keeping knees together*"

Functional tests

Trunk Muscle Endurance Test[6]

The patients will be positioned in side lying on a plinth/bench or a mat on the floor, with one leg resting directly on top of the other.

Participant instruction will be: "*lift your hips off the bed, supporting your weight through your feet and forearm and hold the position for as long as possible. If you get to 3 min we will stop*"

Encouragement will be given at 30 second intervals throughout the test. The time (seconds) will be recorded from the start of the test until the participant's hips touches the plinth, which represents the end of the test.

One leg rise test[6]

Subject seated on side of plinth, foot placed in position on floor measured 10cm forward from a plumb line at the edge of the plinth, other leg held straight out in front of body, arms at rest by sides

Height of plinth adjusted so knee angle is 90º

Subject instructed to "*keep back of heel on marker, stand as many times as possible on one leg keeping arms by your side, in time with my counting. If you get to 50 we will stop.*

Star Excursion Balance test[7]

We will use the procedures described by Hertel et al (2000), where three test directions are measured; anterior, posteromedial and posterolateral. In addition, we will measure balance in the anterolateral direction. From a centre point identified as a cross, 4 tape measures will be attached to the floor in the anterior, anterolateral, posteromedial and posterolateral directions (see Figure).

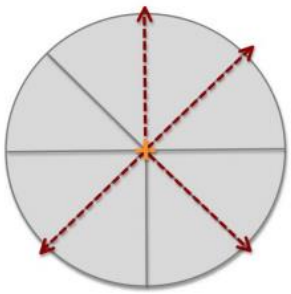


Figure. The test directions of the Star Excursion Balance Test for left leg stance

The test will be performed without shoes, starting with the uninvolved leg as the stance leg and the involved leg as the test leg. The starting position is a single-leg stance in the centre of the cross, with the most distal aspect of the great toe at the starting line and hands on hips.

While maintaining single-leg stance, the patient will be asked to reach with the free limb to touch the tip of their big toe as far as possible in all 4 directions, starting from anterior direction and moving around clockwise. The test leader will mark the reach distance in all four directions. The trial will be judged invalid if the patient i) fails to maintain unilateral stance, ii) lifts or moves the stance foot from the starting point, iii) touches down with the reach foot, or iv) fails to return the reach foot back to the starting position.

The patients will be allowed 1 practice trial in all 4 directions on both legs. Each of the four directions will be recorded on each stance leg, then the same process repeated. Two measures will be recorded for 4 directions on each stance leg, with the best reach for each direction recorded online.

Participant instruction will be: "*Keep your stance foot flat on the floor and hands on hips. Make a reach with your other leg as far as you can and lightly touch the tip of your big toe on the measuring tape, without stepping on it. Without pushing off the ground with your reaching leg, return it back to the centre of the testing grid next to stance foot. You move as much as you like to keep your balance as long as your stance foot is flat and hands are on your hips, otherwise we will repeat test, eg if you slide your foot, miss the tape, lift your heel, move hand off hips or can't return foot to start position.*"

Hop for distance test[6]

Subjects stand on starting line on one foot in bare feet hands held behind back

Instructed to "*hop as far forward as possible landing on the same foot*"

Distance recorded from the back of the landing foot with an inflexible tape measure

Subjects will be given 1 practice and then 3 trials each leg, with the greatest distance for each leg recorded.

Subjects must keep their balance on landing but can put the other foot down to record the distance of the landing foot.

Single Leg Squat[8]

The order of limb testing will be right followed by left to reduce order effects.

Single-leg squat recording:

Performance will be recorded with a digital video camera (HDR-XR150, Sony, Tokyo, Japan) fixed to a tripod. The camera will be positioned at a height of 37 cm, perpendicular to the frontal plane, 3 m in front of the participant.

The participant's unique code will be filmed prior to single-leg squat performance to allow later identification.

Single leg squat set-up:

Bilateral surface landmarks will be marked with black ink over the anterior superior iliac spine, the midpoint between the lateral and medial femoral condyles anteriorly, and the midpoint between the lateral and medial ankle malleoli anteriorly.

Participants will stand in front of standard height stool 65cm from floor to seat, with their foot position standardized on a template whereby the medial edge of the first metatarsophalangeal joint and the center of the posterior aspect of the heel were lined up on parallel lines 12 cm apart, and heel 10 cm from point where a vertical line at edge of stool touches the floor.

Single leg squat performance:

Participants will stand on their right leg with the trunk upright and contralateral leg in approximately 20° of hip flexion, with the knee extended and toes off the floor (Figure I).

Participant instruction will be “Hold this starting position for 3 seconds, then lower pelvis down until the buttocks lightly touch the stool (Figure II) and return to the starting position, taking 4 seconds in total.

Five consecutive squats will be performed, and the procedure repeated on the left leg.

Range of motion tests

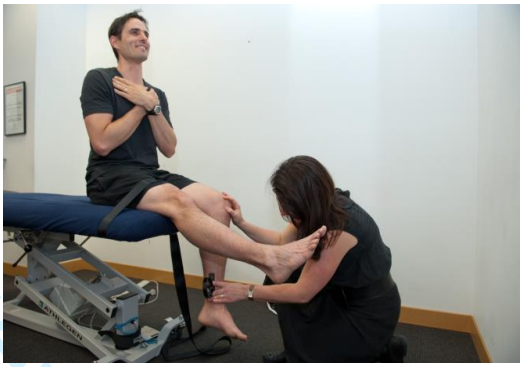
Flexion range of motion[9]

Both legs extended at rest, contra-lateral leg restrained with seat belt (placed firmly over middle of thigh), arms crossed over chest

Centre of inclinometer triangle placed on testing thigh 5cm above superior pole of patella, starting angle noted.

Participant instructed to *"keep arms folded and bend knee towards chest as far as possible"*.

Active external rotation range of motion



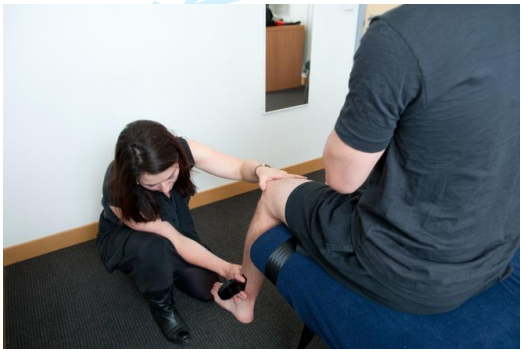
Sitting on the end of the plinth, belt over contra-lateral thigh

Centre of inclinometer triangle held to inside of shin 5 cm proximal to medial malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright position

Participant instructed "*keep arms folded, chest up and turn shin inward as far as possible, keeping thigh and knee flat and keeping other knee extended to allow clearance*"

Active internal rotation range of motion



Sitting on end of plinth, belt over contra-lateral thigh (placed firmly over middle of thigh)

Centre of Inclinometer triangle held to inside of shin 5 cm above lateral malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright sitting position

Participant instructed "*keep arms folded, chest up and turn shin outward as far as possible, keeping thigh and knee flat and buttocks flat on the bed*"

References for Supplementary File 3.

1. Reiman MP. Orthopedic Clinical Examination 1ed. USA: Human Kinetics Publishers 2016.
2. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2019;Online first doi: doi: 10.1136/bjsports-2019-101453
3. Reiman MP, Goode AP, Cook CE, et al. Diagnostic accuracy of clinical tests for the diagnosis of hip femoroacetabular impingement/labral tear: a systematic review with meta-analysis. *British Journal of Sports Medicine* 2015;49(12):811-11. doi: 10.1136/bjsports-2014-094302
4. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
5. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]
6. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
7. Risberg MA, Ageberg E, Nilstad A, et al. Arthroscopic Surgical Procedures Versus Sham Surgery for Patients With Femoroacetabular Impingement and/or Labral Tears: Study Protocol for a Randomized Controlled Trial (HIPARTI) and a Prospective Cohort Study (HARP). *J Orthop Sports Phys Ther* 2018;48(4):325-35. doi: 10.2519/jospt.2018.7931 [published Online First: 2018/04/03]
8. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
9. Hatton AL, Kemp JL, Brauer SG, et al. Dynamic single-leg balance performance is impaired in individuals with hip chondropathy. *Arthritis care & research* 2014;66(5):709-16.

Supplementary File 4: PhysioFIRST hip biomechanics assessment and calculation.

As outlined, hip biomechanics will be a secondary outcome of the study. Forty participants (20 per group) will undergo a baseline (pre-intervention) and 6-month follow-up (post-intervention) biomechanical assessment at the La Trobe University Gait Laboratory.

Experimental data collection: Participants will be required to change into a pair of running shorts, running singlet, and a pair of Teva Original-Universal sandals (Deckers Brands, Goleta, CA) to allow adequate exposure of bony landmarks for accurate marker placement. Forty-nine small (14 mm) spherical reflective markers (B & L Engineering, Albion, Australia) will be placed on the participant's body utilising a previously published protocol [1]. In summary, for the upper body and trunk, marker locations are on the C7 spinous process, acromioclavicular joints, lateral epicondyle of the humerus, and the posterior joint line of the wrists. A thermoplastic plate with four markers is affixed to the pelvis of the participant using a belt at the height of the posterior superior iliac spine, with two additional markers placed on the anterior superior iliac spines. For the lower limbs and feet, markers will be placed on the medial and lateral femoral condyles, medial and lateral malleoli, 5th and 1st metatarsal heads, and the great toes. Four additional segment tracking markers are placed on each thigh (two anterior, two lateral), three on the shank (two anterior, one lateral), and two on the midfoot (one superior, one lateral) [1]. Such marker locations are consistent with previously published biomechanics studies in hip pain [2-4].

Marker trajectories will be collected using a ten camera opto-reflective motion capture system (Vicon Motion Systems Ltd, Oxford, UK) sampling at 100 Hz. Ground reaction force (GRF) data will be collected using two 600mm*400mm force plates in series (Advanced Mechanical Technology, Watertown, MA) and one 1200mm*600mm force plate (for running only) (Advanced Mechanical Technology, Watertown, MA) mounted in the laboratory floor. GRF data will be sampled at 1000 Hz. Marker trajectories and GRF data will be recorded concurrently using Vicon Nexsus version 2.8 (Vicon Motion Systems Ltd, Oxford, UK).

Functional task data collection: Prior to data collection of the functional tasks, a static calibration trial will be captured, with the participant standing in an upright neutral posture, with their arms out to the side, to calculate anthropometric properties and lower limb joint centres. Following this, participants will complete four functional tasks for biomechanical data collection; walking, single-leg squats, the Y-balance test, and running.

- Walking: participants will be instructed to walk along a 10-metre walkway through the capture volume of the cameras at a comfortable self-selected speed.
- Single-leg squat: Participants will complete 10 (5 each leg) single-leg squats on the force plates in time with a metronome at 60 beats per minute. Participants will be instructed to maintain a stationary single-leg stance for two beats, descend for two beats, ascend for two beats and maintain a stationary single-leg stance for a final two beats. A maximal depth indicator will be located 10 cm behind the participant and set to a height whereby the end of the descent phase corresponds to 60 degrees knee flexion (calculated via the use of a hydraulic plinth and goniometer during participant setup).
- Y-balance test: participants will complete six y-balance tests (three each limb) within the capture volume of the cameras as per standard protocol [5].
- Running: participants will be instructed to run along a 20-metre walkway through the capture volume of the cameras (utilising the larger force plate) at speed between 3 and 3.5 m/s (calculated using timing gates placed 5 m apart inside the capture volume). Verbal

feedback will be given to the participants to speed up or slow down after each trial until the prescribed speed is obtained.

Hip joint kinematics and kinetics: A seven-segment (pelvis, left/right thigh, left/right shank, left/right foot) customised biomechanical model will be generated in Vicon BodyBuilder 3.6.4 (Vicon Motion Systems Ltd, Oxford, UK). This model will utilise previously defined anatomical co-ordinate systems by Schache and Baker [6]. The hip joint centre will be defined according to Harrington, Zavatsky, Lawson, Yuan, & Theologis [7] and a dynamic optimisation approach will be used to determine the knee flexion and extension axis [8]. Pelvis angles will be calculated in reference to the lab (global) co-ordinate system utilising the Cardan sequence recommended by Baker [9]. Hip joint angles will be calculated using a joint co-ordinate system convention [10], with a standard inverse dynamic method used to calculate external joint moments [6]. External joint moments will be reported in the same non-orthogonal joint co-ordinate system as the calculated hip, knee, and ankle angles [6]. Joint moments will be normalised to body mass and reported as Newton metres per kilogram (Nm/kg) for analysis.

References

1. Crossley, K.M., et al., *Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study.* J Physiother, 2018. **64**(1): p. 55.
2. King, M.G., et al., *Lower limb biomechanics during low- and high-impact functional tasks differ between men and women with hip-related groin pain.* Clin Biomech (Bristol, Avon), 2019. **68**: p. 96-103.
3. King, M.G., et al., *Sub-elite Football Players With Hip-Related Groin Pain and a Positive Flexion, Adduction, and Internal Rotation Test Exhibit Distinct Biomechanical Differences Compared With the Asymptomatic Side.* J Orthop Sports Phys Ther, 2018. **48**(7): p. 584-593.
4. King, M.G., et al., *Lower-Limb Biomechanics in Football Players with and without Hip-related Pain.* Med Sci Sports Exerc, 2020.
5. Shaffer, S.W., et al., *Y-balance test: a reliability study involving multiple raters.* Mil Med, 2013. **178**(11): p. 1264-70.
6. Schache, A.G. and R. Baker, *On the expression of joint moments during gait.* Gait Posture, 2007. **25**(3): p. 440-52.
7. Harrington, M.E., et al., *Prediction of the hip joint centre in adults, children, and patients with cerebral palsy based on magnetic resonance imaging.* J Biomech, 2007. **40**(3): p. 595-602.
8. Schache, A.G., R. Baker, and L.W. Lamoreux, *Defining the knee joint flexion-extension axis for purposes of quantitative gait analysis: an evaluation of methods.* Gait Posture, 2006. **24**(1): p. 100-9.
9. Baker, R., *Pelvic angles: a mathematically rigorous definition which is consistent with a conventional clinical understanding of the terms.* Gait Posture, 2001. **13**(1): p. 1-6.
10. Grood, E.S. and W.J. Suntay, *A joint coordinate system for the clinical description of three-dimensional motions: application to the knee.* J Biomech Eng, 1983. **105**(2): p. 136-44.

Supplementary file 5: COVID-19 Project changes implemented April 2020

Changes made	Reason for the changes
Suspension of Phase 1 of study (n=22 participants).	Normally, phase 1 of the study is provided through weekly face to face sessions over 12 weeks administered by study physiotherapists. Due to COVID-19 restrictions we were no longer able to undertake this phase of the study. We explored telehealth options but decided the validity of the treatment would be significantly impacted without face to face contact. Therefore, we decided to suspend this phase of the study until face to face treatment was able to be used again. Participants were offered the opportunity to withdraw or recommence treatment once it is safe. All participants chose to remain in the study until it recommenced. The chief investigator (JLK) maintained fortnightly contact with these participants over this time to check on their wellbeing and answer any questions.
Provision of telehealth treatment sessions (n=23 participants) in Phase 2 of study	Normally, phase 2 of the study is provided through once-monthly face to face sessions administered by study physiotherapists. We decided to use telehealth appointments to undertake these treatment sessions during the COVID-19 shutdown. This enabled this phase of the study to continue and also protect the health of investigators and study participants.
Postpone the time point of follow-up clinical and biomechanics (secondary outcome) assessment from 6 months post randomization to as soon as is safe following COVID-19 closure.	As it was no longer safe or legally possible for participants to attend the laboratory at La Trobe University, we postponed all face to face follow-up testing until it was safe to do so. The primary outcome of the study, collected via online questionnaires, is not impacted by this postponement.

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page number in manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	20
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, Supp files 1 and 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15, Table 1, Supp 3 and 4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig 3 and 4, 9-12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18-19

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	10
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	LTU
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19-20
	31b	Authorship eligibility guidelines and any intended use of professional writers	20
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	LTU
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041742.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Dec-2020
Complete List of Authors:	Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Johnston, Richard; La Trobe University - Bundoora Campus, La Trobe Sports and Exercise Medicine Research Centre Coburn, Sally; La Trobe University, La Trobe Sports and Exercise Medicine Research Centre Jones, Denise; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Schache, Anthony; La Trobe University, La Trobe Sports and Exercise Medicine Centre Mentiplay, Benjamin ; La Trobe University, King, Matthew; La Trobe University Scholes, Mark; La Trobe University De Oliveira Silva, Danilo; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Smith, Anne; Curtin University, School of Physiotherapy McPhail, Steven; Queensland University of Technology, Australian Centre for Health Service Innovation and School of Public Health & Social Work Crossley, Kay; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, SPORTS MEDICINE, REHABILITATION MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title page

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Joanne L Kemp,[1] Richard TR Johnston,[1] Sally L Coburn,[1] Denise M Jones,[1] Anthony G Schache,[1] Benjamin F Mentiplay,[1] Matthew G King,[1] Mark J Scholes,[1] Danilo de Oliveira Silva,[1] Anne J Smith,[2] Steven M McPhail,[3,4] Kay M Crossley.[1]

[1] La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Human Services and Sport, La Trobe University, Bundoora, Victoria, Australia.

[2] School of Physiotherapy and Exercise Science, Curtin University, Perth, Western Australia, Australia.

[3] School of Physiotherapy & Social Work and Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Queensland, Australia.

[4] Centre for Functioning and Health Research, Metro South Health, Brisbane, Queensland, Australia.

Correspondence to:

Dr Joanne L Kemp, La Trobe Sport and Exercise Medicine Research Centre, La Trobe University, Bundoora, Victoria 3086, Australia

j.kemp@latrobe.edu.au

Word count: 3604

ABSTRACT

Introduction: This double-blind, randomised controlled trial (RCT) aims to compare the effectiveness of a physiotherapist-led intervention with targeted strengthening to a physiotherapist-led intervention with standardised stretching, on hip-related quality of life (QOL) and perceived improvement at 6-months in people with femoroacetabular impingement (FAI) syndrome. We hypothesise that at 6-months, targeted strengthening physiotherapist-led treatment will be associated with greater improvements in hip-related QOL and greater patient-perceived global improvement when compared to standardised stretching physiotherapist-led treatment.

Methods and analysis: We will recruit 164 participants with FAI syndrome who will be randomised into one of the two intervention groups, both receiving one-on-one treatment with the physiotherapist over 6-months. The targeted strengthening physiotherapist-led treatment group will receive a personalised exercise therapy and education programme. The standardised stretching physiotherapist-led treatment group will receive standardised stretching and personalised education program. Primary outcomes are change in hip-related QOL using International Hip Outcome Tool (iHOT-33)) and patient-perceived global improvement. Secondary outcomes include cost-effectiveness, muscle strength, range of motion, functional task performance, biomechanics, hip cartilage structure and physical activity levels. Statistical analyses will make comparisons between both treatment groups by intention-to-treat, with all randomised participants included in analyses, regardless of protocol adherence. Linear mixed models (with baseline value as a covariate and treatment condition as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at primary end-point (6-months).

Ethics and dissemination: The study protocol was approved (La Trobe University Human Ethics Committee (HEC17-080)) and prospectively registered with the Australian New Zealand Clinical Trials Registry. The findings of this RCT will be disseminated through peer reviewed scientific journals and conferences. Patients were involved in study development and will receive a short summary following the completion of the RCT.

Trial registration number: ACTRN12617001350314

Keywords: Hip joint, rehabilitation, exercise therapy, femoroacetabular impingement, physiotherapy

Strengths and limitations of this study

- This prospective, double-blind RCT is the first full-scale study to test a head-to-head comparison of two exercise-based physiotherapist-led interventions for FAI syndrome.
- Patient-reported outcomes will be collected at clinically relevant time points and allows analysis of outcomes that are important to patients.
- Cost effectiveness analysis will inform clinical decision making.
- This physiotherapist-led RCT has the potential to reduce the burden of FAI syndrome and, if shown to be efficacious, may become the preferred first treatment choice for FAI syndrome.
- The blinding of participants and assessors provides the highest level of rigour to test the efficacy of the physiotherapist-led intervention.

INTRODUCTION

Musculoskeletal conditions, such as hip-related pain,[1] are leading causes of pain and disability in the community, and one of the largest global contributors to years lived with a disability.[2] Femoroacetabular impingement (FAI) syndrome is a common cause of hip-related pain in adults,[3] and evident in 49% of young and middle-aged adults with hip-related pain.[4] It is diagnosed with a triad of imaging findings, patient reported hip-related symptoms, and clinical signs that are associated with excessive bone formation at the femoral head-neck junction (Figure 1). The most commonly reported altered bony shape is cam morphology, which describes excessive bone formation at the femoral head-neck junction.[5] Cam morphology may lead to aberrant joint forces during functional movements in the position of hip impingement (primarily involving flexion, rotation, and abduction or adduction), and subsequent damage to the articular cartilage of the hip joint.[6]

Figure 1. Diagrammatic representation of cam morphology at the femoral head-neck junction.[7]

Insert figure 1 here

While most studies focus on MSK pain affecting the elderly (e.g. osteoarthritis), there is compelling and increasing evidence that FAI syndrome in younger adults (e.g. aged 18-50 years) creates a substantial burden in society,[8 9] associated with persistent hip-related pain and symptoms,[10] impaired physical function,[11] reduced sports and physical activity participation, and impaired quality of life (QOL). The burden of FAI syndrome is amplified by the high daily physical demands (e.g. occupational, familial responsibilities, and recreational activities) encountered by younger adults.

Treatment options for FAI syndrome can be surgical or non-surgical.[12] Non-surgical approaches are recommended as the first line options for other MSK pain conditions (evident from clinical guidelines for osteoarthritis,[13] low back pain,[14] and chronic whiplash associated disorders[15]), due to the far greater costs and risks associated with surgery. However, rates of hip arthroscopy surgery have risen rapidly over the last 15 years.[16-19] Recently published RCTs comparing hip arthroscopic surgery to a physiotherapist-led intervention for FAI syndrome found small[20 21] to moderate[22] between-group differences favouring hip arthroscopy, with a greater cost and risk of adverse events associated with surgery.[20-22] The physiotherapist-led interventions used for comparison to hip arthroscopy were varied in the degree of detail reported and content of the exercise interventions. The RCT by Griffin et. al. compared hip arthroscopy to personalised hip therapy, which included an exercise programme featuring individualisation, progression, and supervision.[20] Palmer et. al. described a tailored

programme to improve core stability and movement control, but little detail was provided on how this was delivered.[22] Mansell et. al. described in detail their programme of stretching and motor control exercises.[21] However it is unclear whether the exercises described in these studies were developed based on contemporary knowledge of impairments in FAI syndrome[23], or be of sufficient stimulus and dosage[12 24] to address the deficits in strength and functional performance that exist in these patients[25]. Thus, a physiotherapist-led intervention that compares exercise interventions should be developed and tested.

A recent consensus meeting recommended exercise-based intervention as the first-line treatment for young adults with hip-related pain.[12] However, absence of a full-scale RCT comparing the head-to-head effectiveness of two exercise-based, physiotherapist-led interventions for FAI syndrome[23 26 27] limited the strength of such recommendations. Therefore, the primary aim of this RCT is to compare effectiveness of a physiotherapist-led intervention with targeted strengthening to a physiotherapist-led intervention with standardised stretching in 164 participants with FAI syndrome on hip-related QOL (International Hip Outcome Tool 33 (iHOT-33)) and patient-perceived global improvement at 6-months[28]. We hypothesise that, compared to the standardised stretching physiotherapist-led intervention, the targeted strengthening physiotherapist-led intervention will result in greater improvement in: (i) hip-related QOL and/or (ii) perceived improvement. Secondary aims are to measure: (i) the cost-effectiveness of the targeted strengthening physiotherapist-led intervention compared to the standardised stretching physiotherapist-led intervention; (ii) the effects of targeted strengthening physiotherapist-led intervention on physical activity levels; (iii) the effects of targeted strengthening physiotherapist-led intervention on hip strength; and explore (iv) the effects of targeted strengthening physiotherapist-led intervention on hip biomechanics; and (v) the effects of targeted strengthening physiotherapist-led intervention on hip joint structure.

METHODS

Participants

This participant and assessor-blinded superiority RCT aligns with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.[29] We will recruit 164 participants from the general community in urban (greater Melbourne) and regional Victoria (Ballarat) (Australia) with a history of hip-related pain. The recruited cohort will be randomised into two parallel intervention groups. Block randomisation will be utilised with a 1:1 ratio, with the primary end-points of hip-related QOL and patient-perceived improvement after 6-months. This RCT study was prospectively registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12617001350314) and ethics approval obtained through the La Trobe University Human Ethics Committee (HEC 17-080).

Inclusion and Exclusion criteria

Eligibility for this RCT was based on clinical and radiographic features,[3] which were used in our previous pilot RCT for FAI syndrome.[6]

Inclusion criteria: (i) aged 18-50 years; (ii) hip-related (anterior hip or groin) pain which is aggravated by prolonged sitting or hip movements into positions of impingement;[3] (iii) hip-related pain ≥3/10 on numerical pain scale for ≥6 weeks; (iv) cam morphology (defined as radiographic alpha angle ≥60°),[30] as described below; and (v) a positive flexion–adduction–internal rotation (FADIR) test.

The alpha angle represents the sphericity of the femoral head and is used to identify and then quantify cam morphology if greater than 60° (Figure 2). To determine the presence of cam morphology, the potential participants will undergo a standing anteroposterior (AP) and Dunn 45° radiograph, following a standardised protocol.[3 30] Following previously described methods,[5] the alpha angle will be calculated by one examiner (JLK) using both the AP and the Dunn 45° radiographs, to quantify the asphericity of the femoral head.

Figure 2. Alpha angle measurement from AP radiograph.[30]

Insert figure 2 here

Exclusion criteria: (i) physiotherapy treatment for the hip in the past three months; (ii) previous hip or back surgery; (iii) planned lower limb surgery in the following year; (iv) radiographic hip osteoarthritis (Kellgren and Lawrence score ≥2,[31] representing moderate to severe hip osteoarthritis); (v) intra-articular hip-joint injection in the previous three months; (vi) neurological, other MSK, or systemic arthritis conditions including other significant musculoskeletal conditions where FAI syndrome was not considered to be the primary cause of hip pain; (vii) unable to perform testing procedures; (viii) unable to commit to a 6-month physiotherapy-led intervention or associated outcome assessments; (ix) contraindications to x-ray (including self-reported pregnancy and pregnancy during the study); or (x) inability to understand English language.

Procedures

The study procedure flow-chart is shown in Figure 3. Following clinical and radiographic screening to confirm study eligibility, participants will attend La Trobe University or Lake Health Group, Victoria, Australia to complete written and informed consent. Demographic characteristics will be recorded, and baseline patient reported outcome measures (PROMs) completed using an electronic data collection system (Promptus, Melbourne, Australia). Participants will undergo clinical and

biomechanical assessment (where appropriate) of their hip by a blinded assessor at baseline and upon study follow-up (6-months). Magnetic resonance imaging will be completed at baseline and 12 months follow-up. Participants will be blinded to the randomisation procedure.

Figure 3. Study procedure flow-chart.

Insert Figure 3 here

Randomisation

Following baseline assessment, participants will be randomised into one of two intervention groups. To ensure concealed intervention allocation, we will use the telephone-based interactive voice response randomisation services (National Health and Medical Research Council Clinical Trials Centre, University of Sydney, Sydney, Australia). The randomisation schedule (blocks of 8 to 12) will be revealed to the unblinded assessor (JK, RJ) after the baseline assessment, who will communicate intervention allocation to the participant's study physiotherapist.

Blinding

As the primary outcomes are self-reported, participants are considered assessors; therefore, participants (and thus assessors) will be blinded to previous scores during the testing time points. Participants will be blinded to the physiotherapist-led interventions and consent will involve limited disclosure. Participants will become unblinded once the data analyses are complete. We do not expect that emergency unblinding will be required due to the very low incidence of adverse events seen in our pilot study of the same trial interventions.

Physiotherapist-led interventions

Study participants will receive one of two physiotherapist-led interventions (targeted strengthening physiotherapist-led treatment or standardised stretching physiotherapist-led treatment) across four clinical sites within Victoria (Australia). Registered physiotherapists will lead the two-phase intervention that will be delivered over a 6-month period and has been described using the Template for Intervention Description and Replication (TIDieR) guidelines (Table 1).[32] Physiotherapists will be trained to deliver the intervention to both groups. Training of the physiotherapists will occur at the commencement of the study and annually thereafter. Treating physiotherapists will also be provided with written treatment manuals and training materials to refer to. In order to limit the likelihood of contamination between treatment groups, treating physiotherapists will be instructed to not have participants from different treatment groups attend the clinic at the same time. We have previously reported treating therapists' beliefs that both interventions are credible. [6] In order to maintain participant blinding, treating physiotherapists will be trained to deliver both interventions with equal enthusiasm. Each of the four clinical sites will have between three and five therapists trained, depending on clinic requirements. The treating physiotherapists were recruited from four large private physiotherapy clinics in Australia, and represent a typical therapist in an Australian private practice where people with FAI syndrome might seek care.

Targeted strengthening Physiotherapist-led Treatment

A team of expert physiotherapists with extensive clinical experience in FAI syndrome management (all with >15 years of individual experience) designed both physiotherapist intervention programs.[33-37] The targeted strengthening physiotherapist-led treatment was developed based on knowledge of physical impairments observed in FAI syndrome,[23] and a previous pilot study.[6] The targeted strengthening physiotherapist-led intervention is personalised to the individual participant's impairments and goals and has seven key elements: (i) progressive hip muscle strengthening exercises; (ii) progressive trunk muscle strengthening exercises; (iii) progressive functional exercises; (iv) progressive plyometric exercises; (v) a progressive physical activity/return to sport program; (vi) a personalised education program; and (vii) tailored manual therapy. Videos of all exercises in the targeted strengthening physiotherapist-led intervention can be found at [insert hyperlink here when accepted]. The targeted progressive hip and trunk strengthening exercises were designed using strength and conditioning guidelines outlined by the American College of Sports Medicine.[38] Adherence to these guidelines aims to facilitate hip joint loading tolerance utilising exercise dosages, volume, and progressions that will increase muscular strength-hypertrophy and strength-endurance. Full details of the targeted physiotherapist-led intervention program are contained in Supplementary File 1. An example of how a participant may be provided with progressive targeted hip adductor strengthening exercises are presented in Figure 4. The participants will use the Physitrack® application (Physitrack, Ltd, London, UK), a web-based application compatible with smartphones, tablets, and computers, which provides photos, videos, and instructions of prescribed exercises to be played in real time. Those unable to access the Physitrack® application will be provided with paper-based pictures for exercise instruction.

Standardised stretching physiotherapist-led intervention

The standardised stretching physiotherapist-led intervention consists of tailored health education, non-specific, standardised stretching, a standardised physical activity program and manual therapy individualised to participants' needs. In order to control for the psychosocial effects of therapist contact inherent with physiotherapy intervention, this program will provide a credible alternative to physiotherapy exercises to reduce the possibility of resentful demoralisation. Stretching was chosen as our pilot work showed a smaller effect than a targeted strengthening intervention on hip-related quality of life and muscle strength. [6] (Supplementary File 2).

Delivery of both physiotherapist-led interventions

Phase 1: 0-3 months (6 physiotherapist-led interventions (1 per fortnight); 12 supervised gym sessions (1 per week), with a further two unsupervised gym sessions encouraged per week).

Phase 2: 4-6 months. Both intervention groups will receive a 3-month gym membership to continue with the unsupervised exercises independently. They will receive additional physiotherapy visits at

months 4, 5, and 6 (i.e. 3 in total), with the aim of increasing adherence to the unsupervised intervention All clinical-site physiotherapists will receive treatment manuals and undergo three group training sessions (theory and practical) in the delivery of both interventions. Treating physiotherapists will then deliver either intervention. Clinics will be audited annually for treatment fidelity.

Participant adherence to intervention, adverse events and concomitant care

Participants will choose to attend one of four physiotherapy clinics to minimise transport burden within Melbourne and regional Victoria. The lead researcher (JLK) will maintain regular contact with study participants via the online PROM system (via weekly questionnaires on treatment adherence) and the Physitrack® app to monitor adverse responses to treatment.[6] Any adverse events will be reported to the Human Research Ethics Committee. Participants will be asked to refrain from concomitant physiotherapist-led treatment, other musculoskeletal therapies (chiropractic care, osteopathy, myotherapy or similar), or exercise interventions for their hip pain during the study. Participants will be allowed to continue care for other unrelated pre-existing conditions. There are minimal known risks associated with the physioFIRST study interventions, as such the physioFIRST study will not have a formal data monitoring committee or plans for post-trial care, and does not require an interim analysis.

Table 1: Intervention delivery described using the TIDieR guidelines for both groups

Phase	What	Targeted strengthening physiotherapist-led treatment	Standardised stretching physiotherapist-led treatment
Phase 1. Month 0-3	**Who**	Physiotherapists	
	How	Face-to-face individual sessions	
	Where	Physiotherapy clinics (& clinic gyms) in Melbourne/Regional Victoria	
	When & how much	Fortnightly: 30 mins physiotherapy; and weekly: 30 mins supervised gym sessions. Exercises progressed based on assessment at each session	
	Tailoring	Tailored selection and progression of hip, trunk and functional strength exercises & manual therapy techniques Progressive, tailored physical activity program	Standardised non-specific stretching exercises Tailored education and standardised information on increasing physical activity
	How well	Treatment response in files and adherence recorded in mobile phone app	
	What	**Targeted strengthening physiotherapist-led treatment**	**Standardised stretching physiotherapist-led treatment**
Phase 2. Month 4-6	**Who**	Physiotherapists and local gymnasium	
	How	Face-to-face individual sessions & Membership to gymnasium	
	Where	Physiotherapy clinics & gymnasiums Melbourne/Regional Victoria	
	When & how much	3x 30 minute "top-up" physio sessions at month 4, 5 and 6. 3-times weekly unsupervised gym attendance	
	Tailoring	Semi-standardised with selection of exercise targeted to assessment	Standardised / non-specific stretching exercises
	How well	Treatment response in files and adherence recorded in mobile phone app	

Figure 4. An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises.

Insert figure 4 here

Measures to be collected

Measures to be collected will include primary and secondary outcomes, descriptive measures of the population, treatment modifiers, and treatment mediators. These are listed with timepoints of collection in Table 2.

Descriptive measures of the population

Participant baseline demographic characteristics, such as age, sex, height, body mass leg length, and waist and hip circumference, will be recorded. In addition, response to pain provocation tests will be recorded (Supplementary File 3).

Patient reported outcome measures

Primary Outcomes

We will collect multiple (two) primary endpoints.[28]

Hip-related QOL will be measured using the iHOT-33. The iHOT-33 questionnaire consists of 33 individual questions scored on a visual analogue scale from zero (worst possible score) to 100 (best possible score). The iHOT-33 has acceptable psychometric properties and is recommended for use in active adults with hip-related pain.[39 40] It has a low standard error of measurement (6 points),[41] is responsive,[42] with reported minimal clinically important differences ranging from 6 to 10 points [42] and minimal detectable change (groups) of 2 points.[41]

Patient-perceived global improvement will be measured on a 7-point Likert scale ('much improved', 'improved', 'a little improved', 'no change', 'a little worse', 'worse', 'much worse'). This is a clinically relevant tool for evaluating an individual patient's perspective on meaningful improvement.[43]

Secondary Outcomes

The Copenhagen Hip and Groin Outcome Score (HAGOS)[44] is a self-reported questionnaire consisting of six subscales that evaluates dimensions of hip and/or groin pain including: pain, symptoms, physical function of daily living, physical function in sport and recreation, participation in physical activities, and hip-related QOL. The HAGOS subscales are each scored out of 100 points (100=best possible score) has acceptable reliability and validity in young people with hip and groin pain.[45]

Workplace Activity Limitations Scale (WALS) is a 12-item questionnaire that aims to identify arthritis related activity limitations specific to various employment related tasks. Responses are made using a 4-point Likert scale and a total score is measured out of 33 (higher scores=more impairment).[46]

EQ-5D-5L (Registration ID 34190_TOU) is a reliable and valid measure of QOL.[47] The EQ-5D-QL asks the participant to indicate their health state according to five dimensions that assess: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[47 48]

Treatment modifiers

Pain Detect Questionnaire (PD-Q) evaluates the presence and severity of seven qualitative characteristics of pain, including: burning sensation, hyperesthesia, allodynia, shock-like, thermal, numbness, and tenderness. Based on the participant's self-reported scores, the likelihood for pain to be attributable to neuropathic factors is then classified as: (a) likely; (b) unlikely (and thus the pain type is identified as nociceptive); or (c) ambiguous (indicating the pain type is unclear and identified as having a mixed pattern).[49 50] The PD-Q is a reliable screening questionnaire for pain types with ICC's for measurement of pain intensities varying between 0.81 (95% CI: 0.75-0.87) and 0.87 (955 CI: 0.82-0.91).[50]

Keele STarT MSK Tool© Clinical version, contains 10 items that ask the participant about their function and disability, pain and coping, comorbidity, and the impact of pain. Once scored, it places the patient into three categories based on their risk of a poor outcome (low, medium, high). This tool has moderate-to-good level predictive ability in the identification of patients who develop persistent disabling pain.[51]

Tampa scale for Kinesiophobia (TSK), consists of 17 statements which measure pain-related fear of movement in patients with chronic MSK pain.[52] Each statement is provided with a 4-point Likert scale, and total scores range from 17 to 51, with a higher score indicating more fear of movement. The TSK demonstrates moderate reliability and validity when tested on patients with acute and chronic MSK pain.[53 54]

Physical impairment and functional outcome measures

Hip muscle strength will be measured with previously described methods,[55 56] as a secondary outcome and as a treatment mediator. A full description of the hip muscle strength tests are contained in Supplementary File 3.

Range of motion tests and functional performance tests are secondary outcomes and will be measured using previously published standardised methods (Supplementary File 3).[37 57] These tests of physical

impairment will be measured at baseline and 6-months (Table 2). The tests have excellent reliability (ICC=0.82-0.95)[55] and were selected as they are frequently used in clinical practice and are associated with functional capacity of the hip and lower limb.[6 58]

Imaging measures

Radiographic hip alpha angle[30], as described above, will be used to describe the population and to determine its effect as a treatment modifier.

Hip joint cartilage structure at baseline will be quantified using the Scoring Hip Osteoarthritis with MRI (SHOMRI) semi-quantitative scoring system on a subset of 50 participants (25 per group).[59] The SHOMRI classification quantifies cartilage features in 10 subregions.[59] The SHOMRI scoring system has excellent previously published intra- and inter-reader reliability (ICC = 0.91-0.97; κ: 0.55-0.79).[59] This measure will be a secondary outcome and will also be used as a treatment modifier.

Hip biomechanics

Hip biomechanics will be secondary outcomes. Using three-dimensional motion analysis according to our previously described protocol,[56] participants biomechanics during walking, running, the single leg squat, and the y-balance test will be examined in a subset of 50 participants (25 per group) at baseline and at 6-months. Changes in hip biomechanics during these tasks will be measured. Details of the biomechanics testing procedures are contained in Supplementary File 4.

Physical activity

Physical activity (average daily step count over 14 days) is a secondary outcome and will be measured using the Fitbit Surge™ on a subset of 40 participants. The Fitbit Surge™ is a lightweight wrist worn device that tracks physical activity and has demonstrated reliability in people aged 18-50 years.[60]

Long term follow-up

Participants will be invited to complete the patient-reported outcome measures listed in Table 2 at annual intervals to 5-years, and then again at 10-years to enable the assessment of long-term predictors of outcome, and progression to hip surgery, including hip arthroscopy and hip arthroplasty.

Table 2. Trial measures to be collected and their purpose.

PhysioFIRST TIMELINE														
MEASURE	**PURPOSE**	**TIME POINTS (MONTHS) COLLECTED**												
		0	**1**	**2**	**3**	**4**	**5**	**6#**	**7**	**8**	**9**	**10**	**11**	**12**
DESCRIPTIVE MEASURES														
Age (years)	Describe population, treatment modifier	X												
Sex	Describe population, treatment modifier	X												
Height (m)	Describe population	X												
Body mass (kg)	Describe population	X												
Leg length (cm)	Describe population	X												
Waist and hip circumference (cm)	Describe population	X												
PAIN PROVOCATION TESTS														
Hip Internal Rotation Test	Describe population	X						X						
Flexion/Adduction/Internal Rotation Test (FADIR)	Describe population	X						X						
Bent Knee Fall Out (BKFO)	Describe population	X						X						
PATIENT REPORTED OUTCOME MEASURES (PROMS)														
International Hip Outcome Tool (IHOT-33)	Primary outcome	X			X			X			X			X
Patient-perceived global improvement	Primary outcome				X			X			X			X
The Copenhagen Hip and Groin Outcome Score (HAGOS)	Secondary outcome	X			X			X			X			X
Workplace Activity Limitations Scale (WALS)	Secondary outcome	X			X			X			X			X
EQ-5D-5L	Secondary outcome	X			X			X			X			X
Pain Detect Questionnaire	Secondary outcome, treatment modifier	X			X			X			X			X
Keele STarT MSK Tool	Secondary outcome, treatment modifier	X			X			X			X			X
Tampa Scale for Kinesophobia	Secondary outcome, treatment mediator	X			X			X			X			X
HIP STRENGTH TESTS														
Hip Abduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Adduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Extension (prone)	Secondary outcome, treatment mediator	X						X						
Hip External Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Internal Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Flexion (sitting)	Secondary outcome, treatment mediator	X						X						
FUNCTIONAL TESTS														
Trunk Muscle Endurance (side lying)	Secondary outcome, treatment mediator	X						X						

One Leg Rise	Secondary outcome, treatment mediator	X						X						
Star excursion Balance Test	Secondary outcome	X						X						
Hop for Distance	Secondary outcome	X						X						
Single leg squat (video analysis)	Secondary outcome	X						X						
RANGE OF MOTION (Degrees)														
Hip Flexion	Secondary outcome	X						X						
Hip External Rotation	Secondary outcome	X						X						
Hip Internal Rotation	Secondary outcome	X						X						
IMAGING														
Hip MRI cartilage	Secondary outcome, treatment modifier	X												X
Hip alpha angle	Describe population, treatment modifier	X												
BIOMECHANICS TESTS														
Walking	Secondary outcome	X						X						
Y-Balance	Secondary outcome	X						X						
Single Leg Squat	Secondary outcome	X						X						
Running	Secondary outcome	X						X						
ACTIVITY MONITORING														
Fitbit Activity Monitoring (2 Week Block)	Secondary outcome	X			X			X						X
COST EFFECTIVENESS														
Incremental cost per Quality Adjusted Life Year	Secondary outcome							X						

[#] = primary end-point; m=meters; kg=kilograms; MRI = magnetic resonance imaging

Data management

Data quality will be ensured via practitioner training, assessing procedural quality, and random checks of protocol adherence, data completeness, and accuracy. Intervention adherence will be defined as completing ≥80% of the physiotherapist-led treatments and supervised gym sessions and will be tracked by the clinical site booking system and weekly questionnaires or the Physitrack® app. All participants will be included in the intention to treat analyses, including participants adhering to <80% of treatment and those participants who withdraw from the study.[61]

Sample size

A power calculation was conducted for this RCT based on data from our previous pilot study that utilised and compared a similar tailored strengthening intervention to a standardised stretching intervention.[6] The power calculation was based on the observed baseline standard deviation (SD) and the between-group differences in the scores of our first primary outcome measure (hip-related QOL (iHOT-33)) (baseline SD = 25 points; mean difference 15 points out of 100).[6 57] In our pilot study, we observed a standardised mean difference (SMD) of 0.68 for the iHOT-33. However, this SMD is likely to be variable due to the small sample (n=24) in the pilot study. In addition, we need to account for the difference in the expertise of treating physiotherapists in a full-scale study. Therefore, the proposed SMD was reduced to 0.50. This is consistent with previously reported between-group SMD for the second primary outcome (patient-perceived global improvement) of 0.50.[62] Estimated sample sizes for a two-sample means test t test assuming 80% power, α=0.025 (accounting for both primary outcomes), results in a sample size estimate of 156 participants. To account for an estimated 5% drop-out due to the study duration, a recommended sample size of 164 participants (82 in each group) will be recruited in this RCT.

Statistical analyses

Data will be analysed using intention to treat (ITT), with all randomised participants included in analyses, regardless of protocol adherence. An experienced biostatistician (AJS) will perform blinded analyses of primary and secondary outcomes. The two primary endpoints chosen will be evaluated separately, such that a significant treatment effect against either of the endpoints will be taken as evidence of efficacy.[28] Linear mixed models (with baseline value as a covariate and treatment condition as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at 3 and 6 months. Models will be adjusted for age and sex. In addition to the primary ITT analysis, sensitivity

analyses for missing outcome data will be performed on multiple imputed datasets, and Complier Average Causal Effects (CACE) methods will be used to estimate the treatment effect at full and partial levels of participation in addition to the primary ITT analysis.

Exploratory moderation analysis will be conducted to determine the strength of evidence provided by the study that treatment effects are moderated by the factors outlined as potential moderators in Table 2, by incorporating an interaction term between the potential moderator and the treatment group indicator in the linear mixed models for the ITT sample for the primary outcomes. Investigation of the mediation of the treatment effect for the primary outcomes for the ITT sample by the potential mediator variables outlined in Table 2 will also be conducted. Standardised estimates of the mediated treatment effect with bootstrapped 95% confidence intervals will be presented.

Cost-effectiveness (Incremental cost per Quality Adjusted Life Year)

The economic evaluation will estimate the incremental cost (healthcare system perspective) per quality adjusted life year (QALY) from the EQ-5D-QL assessment. Healthcare resource utilisation, including co-interventions for hip-related pain (e.g. medicines, complementary treatments, and details of hospital presentations) will be collected from several sources to facilitate data analysis, reporting, and corroboration. Data sources will include the Medicare and Pharmaceutical Benefits Scheme (MBS and PBS) databases (includes rebated, private health insurance, and out-of-pocket costs). Resources used to deliver the trial interventions for each respective trial arm will also inform the economic evaluation.

Trial status

Recruitment commenced in February 2018 and it is anticipated that this will be completed by September 2020. In March 2020, adjustments were made to the study protocol due to COVID-19, these are described in Supplementary File 5.

Conclusion

This RCT aims to compare the effectiveness of a physiotherapist-led intervention with targeted strengthening to a physiotherapist-led intervention with standardised stretching in 164 participants with FAI syndrome on hip-related QOL and patient-perceived global improvement. It may provide an evidence-based framework for physiotherapists to implement the first line of care for the treatment of FAI syndrome.

Ethics and dissemination

This study complies with the Declaration of Helsinki and has been approved by La Trobe University human research ethics committee. All participants will provide written informed consent prior to enrolment in the study. Participant information and consent forms for the study are included as supplementary file 6 and 7. Participants will undergo a single pelvic radiograph for study inclusion, thus ensuring that the exposure to ionising radiation is no more than that in standard clinical exposure. The ethical and safety considerations associated with this trial are very low. We will disseminate study outcomes via submission to high-impact international peer-reviewed journals and presentation at international scientific conferences. By targeting a general medical journal, we will ensure study findings are disseminated to a variety of health professions.

Patient and public involvement

Patients were involved in the planning stages of this project. Patients provided input via questionnaires and interviews.

Patients' priorities gathered during the questionnaires and interviews informed the development of the research question.

Patients and clinicians provided input into the development of the interventions, the frequency of treatment, and their treatment goals.

Patients were not involved in the recruitment and conduct of the study.

Patients were asked to assess the burden of the intervention and time required to participate in the study during the planning stages of the study.

Patients and clinicians will provide input into the dissemination of study results by assisting with the decision on what information to share and in what format.

Acknowledgements

The authors acknowledge the staff of Lake Health Group, Ballarat, Australia; Lake Imaging, Ballarat, Australia; Imaging at Olympic Park, Melbourne, Australia; Clifton Hill Physiotherapy, Melbourne, Australia; Mill Park Physiotherapy, South Morang, Melbourne, Australia; and Complete Sports Care, Hawthorn, Melbourne, Australia.

Data statement

Dataset will be publicly available after publication of study findings at Figshare (add url on publication)

Author contributions

JLK and KMC conceived the study design. JLK and RTJ prepared the manuscript. SLC, DMJ, AGS, BFM, MGK, MJS, DOS, AJS, SMM, and KMC all contributed to the drafting of the manuscript and approved the final version.

Competing interests

The authors declare that they have no competing interests.

Patient consent

Obtained.

Ethics Approval

Ethical approval was obtained from the La Trobe University Human Ethics Committee registration number HEC 17-080.

Funding

Dr J L Kemp is funded by the National Health and Medical Research Council of Australia (NHMRC ECF GNT:1119971).

Provenance and peer review

Not commissioned; externally peer reviewed.

Figure Legends

Figure 1. Diagrammatic representation of cam morphology at the femoral head-neck junction.[7]

Figure 2. Alpha angle measurement from AP radiograph.[30]

Figure 3. Study procedure flow-chart.

Figure 4. An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises.

References

1. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2020:bjsports-2019-101453. doi: 10.1136/bjsports-2019-101453
2. Vos T, Lim SS, Abbafati C, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet* 2020;396(10258):1204-22. doi: 10.1016/S0140-6736(20)30925-9
3. Griffin DR, Dickenson EJ, O'Donnell J, et al. The Warwick Agreement on femoroacetabular impingement syndrome (FAI syndrome): an international consensus statement. *Br J Sports Med* 2016;50(19):1169-76. doi: 10.1136/bjsports-2016-096743 [published Online First: 2016/09/16]
4. Mascarenhas VV, Rego P, Dantas P, et al. Imaging prevalence of femoroacetabular impingement in symptomatic patients, athletes, and asymptomatic individuals: A systematic review. *European journal of radiology* 2016;85(1):73-95. doi: 10.1016/j.ejrad.2015.10.016 [published Online First: 2016/01/03]
5. Agricola R, Waarsing JH, Thomas GE, et al. Cam impingement: defining the presence of a cam deformity by the alpha angle: Data from the CHECK cohort and Chingford cohort. *Osteoarthritis and Cartilage* 2014;22(2):218-25. doi: https://doi.org/10.1016/j.joca.2013.11.007
6. Kemp JL, Coburn SL, Jones DM, et al. The Physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A Pilot Randomized Controlled Trial. *J Orthop Sports Phys Ther* 2018;48(4):307-15. doi: 10.2519/jospt.2018.7941 [published Online First: 2018/04/03]
7. Brukner P, Khan K. Brukner & Khan's Clinical Sports Medicine: Injuries, Fifth Edition: McGraw-Hill Education (Australia) 2016.
8. Byrd JWT. Femoroacetabular impingement in athletes, part 1: cause and assessment. *Sports health* 2010;2(4):321-33. doi: 10.1177/1941738110368392
9. Byrd JWT, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-46. doi: 10.1007/s11999-008-0659-8 [published Online First: 12/19]
10. Weir A, Brukner P, Delahunt E, et al. Doha agreement meeting on terminology and definitions in groin pain in athletes. *Br J Sports Med* 2015;49(12):768-74. doi: 10.1136/bjsports-2015-094869 [published Online First: 2015/06/03]
11. Kemp JL, Beasley I. 2016 international consensus on femoroacetabular impingement syndrome: the Warwick Agreement-why does it matter? *Br J Sports Med* 2016;50(19):1162-3. doi: 10.1136/bjsports-2016-096831 [published Online First: 2016/09/16]
12. Kemp JL, Risberg MA, Mosler A, et al. Physiotherapist-led treatment for young to middle-aged active adults with hip-related pain: consensus recommendations from the International Hip-related Pain Research Network, Zurich 2018. 2019:bjsports-2019-101458. doi: 10.1136/bjsports-2019-101458 %J British Journal of Sports Medicine
13. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Care Res (Hoboken)* 2020;72(2):149-62. doi: 10.1002/acr.24131 [published Online First: 2020/01/08]

14. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* 2018;27(11):2791-803. doi: 10.1007/s00586-018-5673-2 [published Online First: 2018/07/05]
15. Bussières AE, Stewart G, Al-Zoubi F, et al. The Treatment of Neck Pain–Associated Disorders and Whiplash-Associated Disorders: A Clinical Practice Guideline. *Journal of Manipulative & Physiological Therapeutics* 2016;39(8):523-64.e27. doi: 10.1016/j.jmpt.2016.08.007
16. Cvetanovich GL, Chalmers PN, Levy DM, et al. Hip Arthroscopy Surgical Volume Trends and 30-Day Postoperative Complications. *Arthroscopy* 2016;32(7):1286-92. doi: 10.1016/j.arthro.2016.01.042 [published Online First: 2016/04/14]
17. Montgomery SR, Ngo SS, Hobson T, et al. Trends and demographics in hip arthroscopy in the United States. *Arthroscopy* 2013;29(4):661-5. doi: 10.1016/j.arthro.2012.11.005 [published Online First: 2013/02/05]
18. Maradit Kremers H, Schilz SR, Van Houten HK, et al. Trends in Utilization and Outcomes of Hip Arthroscopy in the United States Between 2005 and 2013. *J Arthroplasty* 2017;32(3):750-55. doi: 10.1016/j.arth.2016.09.004 [published Online First: 2016/10/30]
19. Davies O, Grammatopoulos G, Pollard TCB, et al. Factors increasing risk of failure following hip arthroscopy: a case control study. *Journal of hip preservation surgery* 2018;5(3):240-46. doi: 10.1093/jhps/hny020 %J Journal of Hip Preservation Surgery
20. Griffin DR, Dickenson EJ, Wall PDH, et al. Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial. *The Lancet* 2018;391(10136):2225-35. doi: 10.1016/S0140-6736(18)31202-9
21. Mansell NS, Rhon DI, Meyer J, et al. Arthroscopic surgery or physical therapy for patients with femoroacetabular impingement syndrome: a randomized controlled trial with 2-year follow-up. *Am J Sports Med* 2018:363546517751912. doi: 10.1177/0363546517751912 [published Online First: 2018/02/15]
22. Palmer AJR, Ayyar Gupta V, Fernquest S, et al. Arthroscopic hip surgery compared with physiotherapy and activity modification for the treatment of symptomatic femoroacetabular impingement: multicentre randomised controlled trial. *BMJ* 2019;364:l185. doi: 10.1136/bmj.l185
23. Freke MD, Kemp J, Svege I, et al. Physical impairments in symptomatic femoroacetabular impingement: a systematic review of the evidence. *Br J Sports Med* 2016;50(19):1180. doi: 10.1136/bjsports-2016-096152 [published Online First: 2016/06/16]
24. Toigo M, Boutellier U. New fundamental resistance exercise determinants of molecular and cellular muscle adaptations. *European Journal of Applied Physiology* 2006;97(6):643-63. doi: 10.1007/s00421-006-0238-1
25. Kemp JL, King MG, Barton C, et al. Is exercise therapy for femoroacetabular impingement in or out of FASHIoN? We need to talk about current best practice for the non-surgical management of FAI syndrome. *Br J Sports Med* 2019;53(19):1204-05. doi: 10.1136/bjsports-2018-100173 [published Online First: 2019/01/11]
26. Kemp JL, Collins NJ, Makdissi M, et al. Hip arthroscopy for intra-articular pathology: a systematic review of outcomes with and without femoral osteoplasty. *Br J Sports Med*

2012;46(9):632-43. doi: 10.1136/bjsports-2011-090428 [published Online First: 2011/12/24]
27. Reiman MP, Thorborg K, Holmich P. Femoroacetabular Impingement Surgery Is on the Rise-But What Is the Next Step? *J Orthop Sports Phys Ther* 2016;46(6):406-8. doi: 10.2519/jospt.2016.0605 [published Online First: 2016/06/02]
28. McLeod C, Norman R, Litton E, et al. Choosing primary endpoints for clinical trials of health care interventions. *Contemp Clin Trials Commun* 2019;16:100486-86. doi: 10.1016/j.conctc.2019.100486
29. Chan AW, Tetzlaff JM, Gotzsche P, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346(e7586)
30. Agricola R, Heijboer MP, Bierma-Zeinstra SMA, et al. Cam impingement causes osteoarthritis of the hip: A nationwide prospective cohort study (CHECK). *Annals of the Rheumatic Diseases* 2013;72(6):918-23.
31. Kellgren JH, Lawrence JS. Radiological Assessment of Osteoarthrosis. *Ann Rheum Dis* 1957;16:494-502.
32. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical Journal* 2014;348 doi: 10.1136/bmj.g1687
33. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
34. Crossley K, Grimaldi A, Kemp J. Grieve's Modern Musculoskeletal Physiotjerapy. Hip Related Pain. 4th ed. London2015.
35. JL K, KM C, AG S, et al. Hip-related pain. In: PD B, Khan KM, KM C, et al., eds. Brukner and Khan's Clinical Sports Medicine. Sydney: McGraw Hill 2017.
36. Kemp JL, Moore K, Fransen M, et al. A phase II trial for the efficacy of physiotherapy intervention for early-onset hip osteoarthritis: study protocol for a randomised controlled trial. *Trials* 2015;16:26. doi: 10.1186/s13063-014-0543-7 [published Online First: 2015/01/28]
37. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
38. Medicine ACoS. ACSM's guidelines for exercise testing and prescription. 10th ed. Philadelphia, PA.: Wolters Kluwer/Lippincott Williams & Wilkins 2017.
39. Mohtadi NG, Griffin DR, Pedersen ME, et al. The Development and validation of a self-administered quality-of-life outcome measure for young, active patients with symptomatic hip disease: the International Hip Outcome Tool (iHOT-33). *Arthroscopy* 2012;28(5):595-605; quiz 06-10.e1. doi: 10.1016/j.arthro.2012.03.013 [published Online First: 2012/05/01]
40. Impellizzeri FM, Jones DM, Griffin D, et al. Patient-reported outcome measures for hip-related pain: a review of the available evidence and a consensus statement from the International Hip-related Pain Research Network, Zurich 2018. 2020:bjsports-2019-101456. doi: 10.1136/bjsports-2019-101456 %J British Journal of Sports Medicine
41. Kemp JL, Collins NJ, Roos EM, et al. Psychometric properties of patient-reported outcome measures for hip arthroscopy. *American Journal of Sports Medicine* 2013;41:2065-73. doi: http://dx.doi.org/10.1016/j.joca.2013.02.582
42. Mohtadi NGH, Griffin DR, Pedersen ME, et al. The Development and Validation of a Self-Administered Quality-of-Life Outcome Measure for Young, Active Patients

With Symptomatic Hip Disease: The International Hip Outcome Tool (iHOT-33). *Arthroscopy: The Journal of Arthroscopic & Related Surgery* 2012;28(5):595-610.e1. doi: http://dx.doi.org/10.1016/j.arthro.2012.03.013

43. ten Klooster PM, Drossaers–Bakker KW, Taal E, et al. Patient-perceived satisfactory improvement (PPSI): Interpreting meaningful change in pain from the patient's perspective. *Pain* 2006;121(1–2):151-57. doi: http://dx.doi.org/10.1016/j.pain.2005.12.021
44. Thorborg K, Hölmich P, Christensen R, et al. The Copenhagen Hip and Groin Outcome Score (HAGOS): development and validation according to the COSMIN checklist. *British Journal of Sports Medicine* 2011;45(6):478. doi: 10.1136/bjsm.2010.080937
45. Thorborg K, Branci S, Stensbirk F, et al. Copenhagen hip and groin outcome score (HAGOS) in male soccer: reference values for hip and groin injury-free players. *British Journal of Sports Medicine* 2014;48(7):557. doi: 10.1136/bjsports-2013-092607
46. Beaton DE, Tang K, Gignac MA, et al. Reliability, validity, and responsiveness of five at-work productivity measures in patients with rheumatoid arthritis or osteoarthritis. *Arthritis Care Res (Hoboken)* 2010;62(1):28-37. doi: 10.1002/acr.20011 [published Online First: 2010/03/02]
47. Conner-Spady BL, Marshall DA, Bohm E, et al. Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. *Quality of Life Research* 2015;24(7):1775-84. doi: 10.1007/s11136-014-0910-6
48. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
49. Nakawaki M, Fukushima K, Inoue G, et al. Use of the painDETECT questionnaire to differentiate the nature of hip pain associated with a labrum tear. *Asia-Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology* 2018;11:1-5. doi: https://doi.org/10.1016/j.asmart.2017.10.002
50. Tampin B, Bohne T, Callan M, et al. Reliability of the English version of the painDETECT questionnaire. *Current Medical Research and Opinion* 2017;33(4):741-48. doi: 10.1080/03007995.2017.1278682
51. Campbell P, Hill JC, Protheroe J, et al. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *Journal of pain research* 2016;9:807-18. doi: 10.2147/jpr.s116614 [published Online First: 2016/10/30]
52. Miller RP KS, Todd D. "The Tampa Scale: A Measure of Kinisophobia.". *The Clinical Journal of Pain* 1991;7(1):51-52.
53. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85(3):317-32. [published Online First: 2000/04/27]
54. Kvist J, Ek A, Sporrstedt K, et al. Fear of re-injury: a hindrance for returning to sports after anterior cruciate ligament reconstruction. *Knee Surgery, Sports Traumatology, Arthroscopy* 2005;13(5):393-97. doi: 10.1007/s00167-004-0591-8
55. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16:292-96.
56. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]

57. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
58. Culvenor AG, Collins NJ, Vicenzino B, et al. Predictors and effects of patellofemoral pain following hamstring-tendon ACL reconstruction. *Journal of Science and Medicine in Sport* 2016;19(7):518-23. doi: https://doi.org/10.1016/j.jsams.2015.07.008
59. Lee S, Nardo L, Kumar D, et al. Scoring Hip Osteoarthritis with MRI (SHOMRI): a Novel Whole Joint Osteoarthritis Evaluation System. *Journal of Magnetic Resonance Imaging* 2014;under review
60. Jones D, Crossley K, Dascombe B, et al. VALIDITY AND RELIABILITY OF THE FITBIT FLEX™ AND ACTIGRAPH GT3X+ AT JOGGING AND RUNNING SPEEDS. *International journal of sports physical therapy* 2018;13(5):860-70.
61. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ : British Medical Journal* 2013;346:e7586. doi: 10.1136/bmj.e7586
62. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *The Journal of manual & manipulative therapy* 2009;17(3):163-70. doi: 10.1179/jmt.2009.17.3.163

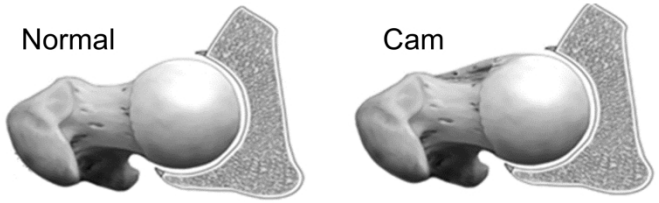


Figure 1
Diagrammatic representation of cam morphology at the femoral head-neck junction

338x190mm (400 x 400 DPI)

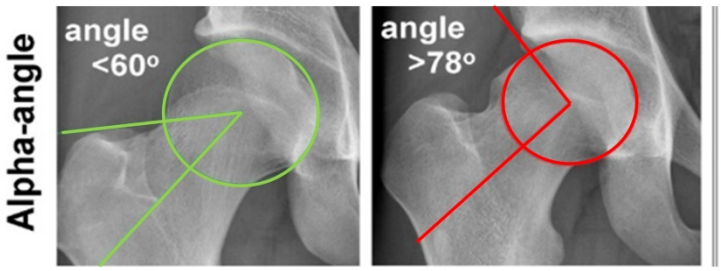


Figure 2
Alpha angle measurement from AP radiograph

338x190mm (400 x 400 DPI)

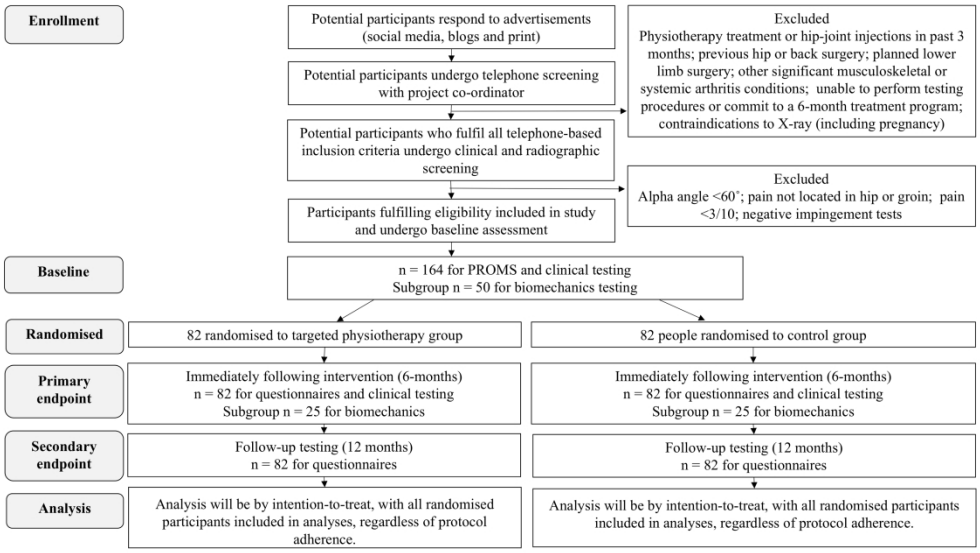


Figure 3
Study procedure flow-chart

338x190mm (400 x 400 DPI)

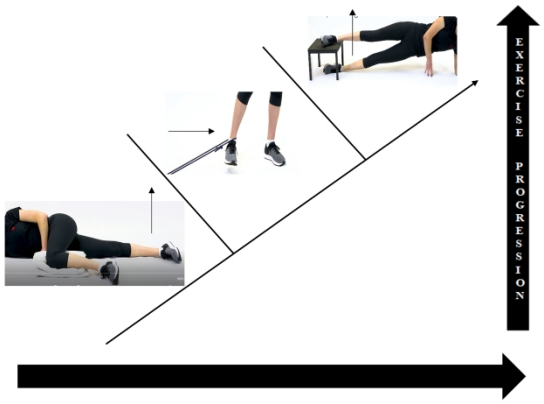


Figure 4
An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises

338x190mm (400 x 400 DPI)

Supplementary File 1: Targeted Physiotherapist-led treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Lion group refers to the progressive, semi-standardised rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The six components of the rehabilitation program were selected based on current knowledge of the highest level of evidence for physical impairments in FAI, and from the results of our recent pilot study.

The six key components targeted in this program include:

1. **ROM (flexion)**
2. **Hip muscle strength (Extension, Abduction, Adduction)**
3. **Trunk strength/endurance**
4. **Functional task performance (strength and plyometric)**
5. **Cardiovascular training/load management**
6. **Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Review of exercise program and progression of program as appropriate, for each of the targeted elements (hip adductor, abductor, extensor strength, trunk strength, functional strength and plyometric). ***Note: each patient should always be doing one exercise from each targeted element.*** See Tables 2-7 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
5. Review of cardiovascular fitness program as appropriate. See Table 8 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
6. Tailored education based on patient preference, three patient-focussed goals, and other topics raised by patient during treatment. Answers to common questions outlined below in Table 9.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, the 3 patient-focussed goals, and ensure patient appointments are booked into the system.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current exercises in hip strength (adduction, abduction, extension), trunk strength and functional strength exercises, including full sets and reps.
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app
3. Progression of exercises for each of the targeted elements where appropriate
4. Continuation of tailored education program

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Hip extension strength program

Extension			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging Gluteal squeeze and lift up into bridge hold and lower	3x10 reps 5 sec hold Weight = 10RM (10kg max)

2		Single leg Bridging Gluteal squeeze and lift up into bridge position, extend one leg, hold, extend other leg, hold, lower	3x10 reps 5 sec holds Weight = 10RM (10kg max)
3		Prone Hold Hip Extension - knees From knees move affected leg into hip extension, hold and lower leg, Cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
4		Prone Hold Hip Extension - toes From toes move affected leg into hip extension, hold and lower leg, cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
5		Standing single leg arabesque, weight in opposite hand	3x10 reps 5 sec ecc, 5 sec conc Weight = 10RM (10kg max)
6		Standing single leg arabesque, weight in opposite hand	3x20 reps 5 sec ecc, 5 sec conc Weight = 20RM (10kg max)

Table 3: Hip abduction strength program

Abduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging with band Bridge with band around knees, gently abduct against light band.	1x20 reps 5kg on pelvis 5 sec hold Band = 20RM
2		Bridging with band Bridge with band around knees, gently abduct against light band.	3x10 reps 5 kg on pelvis 5 sec hold Band = 10RM
3		Bridging with band Bridge with band around knees, gently abduct against heavy band.	3x10 reps 10 kg on pelvis 5 sec hold Band = 10 RM
4		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both feet on ground.	3x10 reps 5kg on pelvis 5 sec hold Band = 10RM

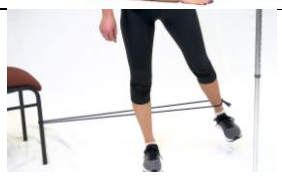
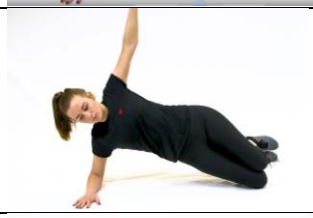
5		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both legs on ground.	3x10 reps 10kg on pelvis 5 sec hold Band = 10RM
6		Standing abduction with band or pulley, abduction to 30-45˚	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
7		Side lie abduction with band	3x10 reps 3 sec conc 3 sec ecc Band = 10RM

Table 4: Hip adduction strength program

Adduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	1x30 reps 5 sec hold 5 kg on hips
2		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	2x30 reps 5 sec hold 5 kg on hips
3		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	2x8 reps 5 sec hold
4		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x8 reps 5 sec hold
5		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold
6		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold Cuff weight = 10RM, 5kg max

7		Standing adduction with band or pulley	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
8		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower	3x10 reps 5 sec hold
9		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower. Cuff weight on ankle	3x10reps 5 sec hold Cuff weight = 10RM

Table 5: Trunk strength and endurance program

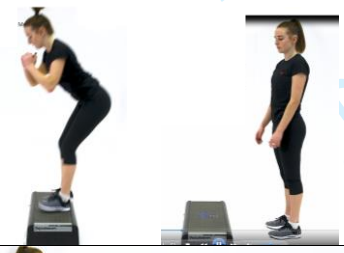
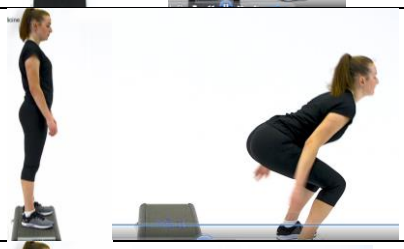
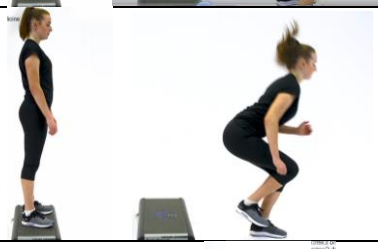
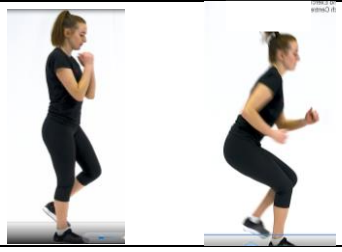
Trunk muscle strength (both sides in all patients)			
Phase	**Exercise**	**Description**	**Dosage**
1		Side bridge knees	30 secs hold 5 reps each side
2		Side bridge knees with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
3		Side bridge toes	30 secs hold 5 reps each side
4		Side bridge toes with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
5		Side bridge toes with arm rotations, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

6		Side plank with stability ball	30 secs hold 5 reps each side
7		Side plank with stability ball, with arm lifts. Can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

Table 6: Functional strengthening program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1	Box/chair squats.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing	3x10 reps 5 secs conc, 5 secs ecc
2	Box/chair squats with weight.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
3	Backwards lunges.	Step back and drop back knee towards ground, then stand up. Ensure good alignment	3x10 reps each side 5 secs conc, 5 secs ecc
4	Backwards lunges with weight.	Step back and drop back knee towards ground, then stand up. Ensure good alignment. Hold weight plate to chest	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
5	Repeater Step Ups	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor.	3x10 reps 5 secs conc, 5 secs ecc
6	Repeater Step Ups with weight	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
7	Single Leg Squats	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing	3x10 reps 5 secs conc, 5 secs ecc
8	Single Leg Squats with weight	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)

Table 7: Functional plyometric program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1		Jump forwards as far as possible – double leg take-off and landing	20 reps
2		Jump forwards as far as possible – double leg take off, single leg landing	20 reps each leg
3		Jump up onto box/step double leg take-off and landing	20 reps
4		Jump down off box/step/bosu double leg take-off and landing	20 reps
5		Jump down off box/step/bosu double leg take off, single leg landing	20 reps each side
6		Single leg hop forwards	20 reps each leg

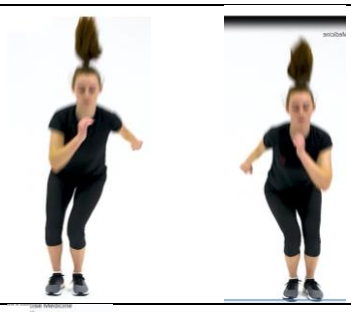
7		Multidirectional jump double leg	20 reps
8		Multidirectional hop single leg	20 reps each leg

Table 8: Cardiovascular fitness progressive program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	10 minutes every second day
2	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	20 minutes every second day
3	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes every second day
4	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes total, including 5x60 seconds high intensity every second day
5	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic	30 minutes including up to 10x60secs or 5x2 minutes

		activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	high intensity every second day
6	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	45 minutes including up to 15 minutes total high intensity every second day
7	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	15 mins every second day (can be combined with 30 mins level 1 activity)
8	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	20 mins every second day (can be combined with 25 mins level 1 activity)
9	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	30 mins every second day (can be combined with 20 mins level 1 activity)
10	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	45 mins every second day, including 10 mins higher intensity (can be combined with 15 mins level 1 activity)
11	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	50 mins every second day, including 20 minutes high intensity (can be combined with 10 mins level 1 activity).
12	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	Up to 1 hour, 3 time/week, full load

Table 9. Key education components

1. Weight maintenance with recommended weight loss if BMI ≥ 25. This may require referral to dietician or GP. Generally, evidence suggests that a 3kg weight loss can result in 25% reduction in symptoms in people with OA.
2. Patients' expectations of treatments. Hip pain due to FAI is not "curable" but can be well managed with appropriate treatment. Flares of pain are common and usually settle well with appropriate physiotherapy treatment. Small increases in pain (up to 3/10) can occur when starting or increasing exercises. This is nothing to be afraid of, and will settle as the body adapts to the new activity. It is of paramount importance to not completely rest, as this reduces this body's capacity to cope with normal day-to-day loads.
3. Patients' specific goals of treatment, based on baseline assessment. Important to discuss with patient whether these are appropriate, and then plan to most appropriately achieve these.

4. Patients' expectations of returning to sport, and whether this is possible. This may require a modification of expectations. To date there is no evidence to indicate that running sports, and kicking sports are likely to lead to short-term and long-term problems in people with FAI, and in most patients, it is possible to return to these types of activity in a sensible and gradually progressive way.

Supplementary File 2: Standardised treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Tiger group refers to the usual care, control group rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The four components of the rehabilitation program were selected to represent what could be "usual care" for hip pain, and has been tested in our pilot study

The four key components of the control program include:

1. **ROM (flexion)**
2. **Standardised stretching**
3. **Standardised cardiovascular training/load management advice**
4. **Standardised Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Provision of standardised stretching program. See Table 2 for each weekly set of exercises
5. Provision of standardised cardiovascular fitness program. This should be handed out in first treatment and patient asked to progress self through program. See Table 3 for details below.
6. Standardised education Table 4.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, and ensure patient appointments are booked into the system.

Please note, if patients complain of increasing pain during treatment that is concerning them or you, please contact Joanne Kemp to discuss. Do not allow the patient to continue to deteriorate without discussion.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current stretching exercises
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Weekly stretching program

Week 1								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip Flexor stretch off plinth.	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Thoracic rotation in supine	5 x 5sec holds to each side
	b) Short adductor stretch	30 sec hold, repeat x3,					b) Trunk rotation in Supine	5 x 5sec holds to each side.
	c) Hamstring stretch	Symptomatic leg 30 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 2								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Trunk rotation in Supine	5 x 5sec holds to each side.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in Supine	5 x 5sec holds to each side.
	b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 40 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 3								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Short adductor stretch	60 sec hold, repeat x2.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) ITB stretch	Symptomatic leg 60 sec hold, repeat x2.						

Week 4								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 40 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 60 sec hold, repeat x2.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		c) Tib Ant stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hold/relax Hamstring stretch (Therapist assisted)	At movement barrier, 20% contraction x 3.						
	d) Gluteal stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 5								
Hip			**Lower leg**			**Trunk**		
Exercise	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 60 sec hold, repeat x2.		a) Calf roller stretch	Symptomatic leg 40 sec x 2.		a) Trunk rotation in standing	5 x 5sec holds to each side
	b) Adductor stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		c) Tib Ant stretch in kneeling	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	40 sec hold x 2
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) Gluteal stretch	Symptomatic leg 40 sec hold, repeat x3.						

Week 6								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	60 sec hold x 2
	c) Hamstring foam roller in sitting	Bilateral, 40 sec x 2.					c) Elbow prop lumbar extension in prone	
	d) Gluteal stretch on wall	Symptomatic leg 30 sec hold, repeat x3.						

Week 7								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 40 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 60 sec hold, repeat x2.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) Gluteal stretch on wall	Symptomatic leg 40 sec hold, repeat x3.					c) Elbow prop lumbar extension in prone	5 x 5sec holds.
	d) Gluteal foam roller	Symptomatic leg 40 sec x 2.						

Week 8								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) LL calf stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 3 to each side.
	b) Hamstring- stretch standing	Symptomatic leg 30 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Salute to the sun	3 x 5sec holds at end of range extension and flexion
	d) ITB standing with side trunk flexion	Symptomatic leg 30 sec x 3.						

Week 9								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) calf stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Hamstring- hold/relax (therapist assisted)	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Extension in lying	5 x 5 second holds
	d) ITB standing	Symptomatic leg 30 sec x 3.						

Week 10								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 5 to each side.
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) calf stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) Gluteal foam roller	Symptomatic leg 60-120 sec.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 11								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 12								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 60 sec hold, repeat x2.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Table 3: Cardiovascular fitness standardised program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breastroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	As much as hip pain will allow. Progress to Level 2 when patient feels ready
2	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	As much as hip pain will allow

Table 4. Key education components

1.	Weight maintenance with recommended weight loss if BMI ≥ 25. Patients are encouraged to seek their own guidance for weight loss. Specific patient questions can be answered.
2.	Patients' expectations of treatment and activity. Patients are encouraged to do as much activity as their hip pain allows. No specific guidance is offered around activity modification, but patient-specific questions can be answered.

Supplementary File 3
PhysioFIRST Clinical testing procedures

Descriptive measures

Height (m)

Body mass (kg)

Leg length (cm): Distal greater trochanter to lateral knee joint line (centre) and distal greater trochanter to distal tip lateral malleolus

Waist circumference (cm): Measured at navel level

Hip circumference (cm): Measured at widest point of greater trochanter

Pain provocation tests

Hip Internal Rotation Pain[1-3]:

Participant Position: Supine

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90° (zero-degree position). Examiner internally rotates hip to point of resistance, keeping thigh in neutral position (i.e., avoiding abduction, adduction and pelvic tilt). Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Flexion 90°/Adduction/Internal Rotation (FADIR) Pain[1-3]:

Participant Position:

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90°. Examiner adducts hip to endpoint (while avoiding movement of the pelvis) and then

internally rotates hip, maintaining flexion and adduction components. Examiner asks participant if they “feel pain or discomfort in the inner thigh, upper thigh, hip or groin area”.

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Bent Knee Fall Out (BKFO)[1]*:*

Participant position:

Participant is lying supine with knee of test leg bent so that foot touches contralateral knee.

Method:

Participant externally rotates hip of test leg, so that the bent knee lowers toward exam table. Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh, hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Hip strength tests

All strength tests done with Power track II (Commander). Each strength test will be performed 3 times, 2 seconds to generate maximum force and then 3 seconds as hard as possible. Rest time will be allowed of 5 seconds between each repetition, 30 seconds minimum between each test. Therapist matches participants force (make test).

Supine

Abduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate 5 cm above lateral malleolus.

Participant instructed to *“keep trunk stable and opposite leg still, keep your heel on the bed, toes pointing to the ceiling and push leg out to side against force plate as hard as possible”.*

"go ahead: push-push-push-push-relax"

Adduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate for long lever 5 cm above medial malleolus,

Participant instructed to "*keep trunk stable and opposite leg still, keep heel on the bed, toes pointing towards ceiling and pull leg in to centre against force plate as hard as possible"*

"go ahead: push-push-push-push-relax"

Prone

Extension strength[4 5]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant prone, with test leg knee bent to 90° and positioned off the edge of the foot of the lowered exam table, chin resting on hands.

Force plate attached to Velcro of seatbelt and placed over centre of patient's heel, patient instructed to *"push foot straight up to ceiling"*.

Therapist matches force by placing foot in lower loop of seatbelt using bodyweight as counter resistance.

"Go ahead: push-push-push-push-relax"

External rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to medial malleolus of ankle, therapist on same side of bed, close to lower leg, with two hands on HHD.

Participant instructed to *"keep your trunk and opposite leg still and turn shin inwards towards the centre as hard as possible"*

"go ahead: push-push-push-push-relax"

Internal rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to lateral malleolus of ankle, therapist standing on same side of bed close to lower leg, with two hands on HHD laterally.

Participant instructed to *"keep trunk and opposite leg still and turn shin outwards as hard as possible, keeping both knees together"*

"go ahead: push-push-push-push-relax"

Sitting (on end of plinth)

Flexion strength[4]

Moment arm measured greater trochanter to lateral joint line knee

Both legs in resting position (hip 90º flexion), belt across contra-lateral thigh (placed firmly over middle of thigh)

Force plate 5 cm proximal to superior pole patella

Ensure participant is sitting in upright sitting position

Ensure that the contralateral leg is in 90° knee flexion and not being used to stabilise against the underneath of the bed.

Be aware that if you position someone in EOR hip flexion pain will potentially limit the force they can produce. Ensure that the testing leg is raised 1cm off the bed in a comfortable range

Participant instructed to *"sit with arms folded, chest up, not to lean backwards and pull knee up towards chest against force plate"*

"go ahead: push-push-push-push-relax"

Participant instructed to "*keep arms folded, chest up, thigh and knee flat on the bed and turn shin outward, as far as possible, keeping knees together*"

Functional tests

Trunk Muscle Endurance Test[6]

The patients will be positioned in side lying on a plinth/bench or a mat on the floor, with one leg resting directly on top of the other.

Participant instruction will be: "*lift your hips off the bed, supporting your weight through your feet and forearm and hold the position for as long as possible. If you get to 3 min we will stop*"

Encouragement will be given at 30 second intervals throughout the test. The time (seconds) will be recorded from the start of the test until the participant's hips touches the plinth, which represents the end of the test.

One leg rise test[6]

Subject seated on side of plinth, foot placed in position on floor measured 10cm forward from a plumb line at the edge of the plinth, other leg held straight out in front of body, arms at rest by sides

Height of plinth adjusted so knee angle is 90º

Subject instructed to "*keep back of heel on marker, stand as many times as possible on one leg keeping arms by your side, in time with my counting. If you get to 50 we will stop.*

Star Excursion Balance test[7]

We will use the procedures described by Hertel et al (2000), where three test directions are measured; anterior, posteromedial and posterolateral. In addition, we will measure balance in the anterolateral direction. From a centre point identified as a cross, 4 tape measures will be attached to the floor in the anterior, anterolateral, posteromedial and posterolateral directions (see Figure).

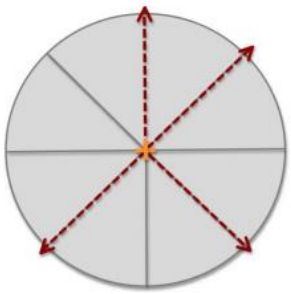


Figure. The test directions of the Star Excursion Balance Test for left leg stance

The test will be performed without shoes, starting with the uninvolved leg as the stance leg and the involved leg as the test leg. The starting position is a single-leg stance in the centre of the cross, with the most distal aspect of the great toe at the starting line and hands on hips.

While maintaining single-leg stance, the patient will be asked to reach with the free limb to touch the tip of their big toe as far as possible in all 4 directions, starting from anterior direction and moving around clockwise. The test leader will mark the reach distance in all four directions. The trial will be judged invalid if the patient i) fails to maintain unilateral stance, ii) lifts or moves the stance foot from the starting point, iii) touches down with the reach foot, or iv) fails to return the reach foot back to the starting position.

The patients will be allowed 1 practice trial in all 4 directions on both legs. Each of the four directions will be recorded on each stance leg, then the same process repeated. Two measures will be recorded for 4 directions on each stance leg, with the best reach for each direction recorded online.

Participant instruction will be: "*Keep your stance foot flat on the floor and hands on hips. Make a reach with your other leg as far as you can and lightly touch the tip of your big toe on the measuring tape, without stepping on it. Without pushing off the ground with your reaching leg, return it back to the centre of the testing grid next to stance foot. You move as much as you like to keep your balance as long as your stance foot is flat and hands are on your hips, otherwise we will repeat test, eg if you slide your foot, miss the tape, lift your heel, move hand off hips or can't return foot to start position.*"

Hop for distance test[6]

Subjects stand on starting line on one foot in bare feet hands held behind back

Instructed to "*hop as far forward as possible landing on the same foot*"

Distance recorded from the back of the landing foot with an inflexible tape measure

Subjects will be given 1 practice and then 3 trials each leg, with the greatest distance for each leg recorded.

Subjects must keep their balance on landing but can put the other foot down to record the distance of the landing foot.

Single Leg Squat[8]

The order of limb testing will be right followed by left to reduce order effects.

Single-leg squat recording:

Performance will be recorded with a digital video camera (HDR-XR150, Sony, Tokyo, Japan) fixed to a tripod. The camera will be positioned at a height of 37 cm, perpendicular to the frontal plane, 3 m in front of the participant.

The participant's unique code will be filmed prior to single-leg squat performance to allow later identification.

Single leg squat set-up:

Bilateral surface landmarks will be marked with black ink over the anterior superior iliac spine, the midpoint between the lateral and medial femoral condyles anteriorly, and the midpoint between the lateral and medial ankle malleoli anteriorly.

Participants will stand in front of standard height stool 65cm from floor to seat, with their foot position standardized on a template whereby the medial edge of the first metatarsophalangeal joint and the center of the posterior aspect of the heel were lined up on parallel lines 12 cm apart, and heel 10 cm from point where a vertical line at edge of stool touches the floor.

Single leg squat performance:

Participants will stand on their right leg with the trunk upright and contralateral leg in approximately 20° of hip flexion, with the knee extended and toes off the floor (Figure I).

Participant instruction will be “Hold this starting position for 3 seconds, then lower pelvis down until the buttocks lightly touch the stool (Figure II) and return to the starting position, taking 4 seconds in total.

Five consecutive squats will be performed, and the procedure repeated on the left leg.

Range of motion tests

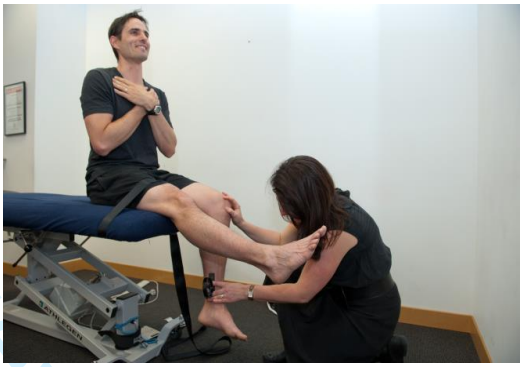
Flexion range of motion[9]

Both legs extended at rest, contra-lateral leg restrained with seat belt (placed firmly over middle of thigh), arms crossed over chest

Centre of inclinometer triangle placed on testing thigh 5cm above superior pole of patella, starting angle noted.

Participant instructed to *"keep arms folded and bend knee towards chest as far as possible"*.

Active external rotation range of motion



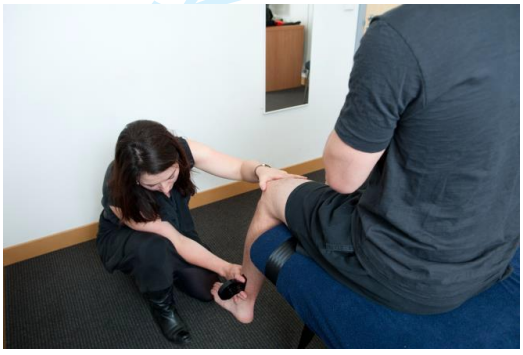
Sitting on the end of the plinth, belt over contra-lateral thigh

Centre of inclinometer triangle held to inside of shin 5 cm proximal to medial malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright position

Participant instructed "*keep arms folded, chest up and turn shin inward as far as possible, keeping thigh and knee flat and keeping other knee extended to allow clearance*"

Active internal rotation range of motion



Sitting on end of plinth, belt over contra-lateral thigh (placed firmly over middle of thigh)

Centre of Inclinometer triangle held to inside of shin 5 cm above lateral malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright sitting position

Participant instructed "*keep arms folded, chest up and turn shin outward as far as possible, keeping thigh and knee flat and buttocks flat on the bed*"

References for Supplementary File 3.

1. Reiman MP. Orthopedic Clinical Examination 1ed. USA: Human Kinetics Publishers 2016.
2. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2019;Online first doi: doi: 10.1136/bjsports-2019-101453
3. Reiman MP, Goode AP, Cook CE, et al. Diagnostic accuracy of clinical tests for the diagnosis of hip femoroacetabular impingement/labral tear: a systematic review with meta-analysis. *British Journal of Sports Medicine* 2015;49(12):811-11. doi: 10.1136/bjsports-2014-094302
4. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
5. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]
6. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
7. Risberg MA, Ageberg E, Nilstad A, et al. Arthroscopic Surgical Procedures Versus Sham Surgery for Patients With Femoroacetabular Impingement and/or Labral Tears: Study Protocol for a Randomized Controlled Trial (HIPARTI) and a Prospective Cohort Study (HARP). *J Orthop Sports Phys Ther* 2018;48(4):325-35. doi: 10.2519/jospt.2018.7931 [published Online First: 2018/04/03]
8. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
9. Hatton AL, Kemp JL, Brauer SG, et al. Dynamic single-leg balance performance is impaired in individuals with hip chondropathy. *Arthritis care & research* 2014;66(5):709-16.

Supplementary File 4: PhysioFIRST hip biomechanics assessment and calculation.

As outlined, hip biomechanics will be a secondary outcome of the study. Forty participants (20 per group) will undergo a baseline (pre-intervention) and 6-month follow-up (post-intervention) biomechanical assessment at the La Trobe University Gait Laboratory.

Experimental data collection: Participants will be required to change into a pair of running shorts, running singlet, and a pair of Teva Original-Universal sandals (Deckers Brands, Goleta, CA) to allow adequate exposure of bony landmarks for accurate marker placement. Forty-nine small (14 mm) spherical reflective markers (B & L Engineering, Albion, Australia) will be placed on the participant's body utilising a previously published protocol [1]. In summary, for the upper body and trunk, marker locations are on the C7 spinous process, acromioclavicular joints, lateral epicondyle of the humerus, and the posterior joint line of the wrists. A thermoplastic plate with four markers is affixed to the pelvis of the participant using a belt at the height of the posterior superior iliac spine, with two additional markers placed on the anterior superior iliac spines. For the lower limbs and feet, markers will be placed on the medial and lateral femoral condyles, medial and lateral malleoli, 5^{th} and 1^{st} metatarsal heads, and the great toes. Four additional segment tracking markers are placed on each thigh (two anterior, two lateral), three on the shank (two anterior, one lateral), and two on the midfoot (one superior, one lateral) [1]. Such marker locations are consistent with previously published biomechanics studies in hip pain [2-4].

Marker trajectories will be collected using a ten camera opto-reflective motion capture system (Vicon Motion Systems Ltd, Oxford, UK) sampling at 100 Hz. Ground reaction force (GRF) data will be collected using two 600mm*400mm force plates in series (Advanced Mechanical Technology, Watertown, MA) and one 1200mm*600mm force plate (for running only) (Advanced Mechanical Technology, Watertown, MA) mounted in the laboratory floor. GRF data will be sampled at 1000 Hz. Marker trajectories and GRF data will be recorded concurrently using Vicon Nexsus version 2.8 (Vicon Motion Systems Ltd, Oxford, UK).

Functional task data collection: Prior to data collection of the functional tasks, a static calibration trial will be captured, with the participant standing in an upright neutral posture, with their arms out to the side, to calculate anthropometric properties and lower limb joint centres. Following this, participants will complete four functional tasks for biomechanical data collection; walking, single-leg squats, the Y-balance test, and running.

- Walking: participants will be instructed to walk along a 10-metre walkway through the capture volume of the cameras at a comfortable self-selected speed.
- Single-leg squat: Participants will complete 10 (5 each leg) single-leg squats on the force plates in time with a metronome at 60 beats per minute. Participants will be instructed to maintain a stationary single-leg stance for two beats, descend for two beats, ascend for two beats and maintain a stationary single-leg stance for a final two beats. A maximal depth indicator will be located 10 cm behind the participant and set to a height whereby the end of the descent phase corresponds to 60 degrees knee flexion (calculated via the use of a hydraulic plinth and goniometer during participant setup).
- Y-balance test: participants will complete six y-balance tests (three each limb) within the capture volume of the cameras as per standard protocol [5].
- Running: participants will be instructed to run along a 20-metre walkway through the capture volume of the cameras (utilising the larger force plate) at speed between 3 and 3.5 m/s (calculated using timing gates placed 5 m apart inside the capture volume). Verbal

feedback will be given to the participants to speed up or slow down after each trial until the prescribed speed is obtained.

Hip joint kinematics and kinetics: A seven-segment (pelvis, left/right thigh, left/right shank, left/right foot) customised biomechanical model will be generated in Vicon BodyBuilder 3.6.4 (Vicon Motion Systems Ltd, Oxford, UK). This model will utilise previously defined anatomical co-ordinate systems by Schache and Baker [6]. The hip joint centre will be defined according to Harrington, Zavatsky, Lawson, Yuan, & Theologis [7] and a dynamic optimisation approach will be used to determine the knee flexion and extension axis [8]. Pelvis angles will be calculated in reference to the lab (global) co-ordinate system utilising the Cardan sequence recommended by Baker [9]. Hip joint angles will be calculated using a joint co-ordinate system convention [10], with a standard inverse dynamic method used to calculate external joint moments [6]. External joint moments will be reported in the same non-orthogonal joint co-ordinate system as the calculated hip, knee, and ankle angles [6]. Joint moments will be normalised to body mass and reported as Newton metres per kilogram (Nm/kg) for analysis.

References

1. Crossley, K.M., et al., *Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study.* J Physiother, 2018. **64**(1): p. 55.
2. King, M.G., et al., *Lower limb biomechanics during low- and high-impact functional tasks differ between men and women with hip-related groin pain.* Clin Biomech (Bristol, Avon), 2019. **68**: p. 96-103.
3. King, M.G., et al., *Sub-elite Football Players With Hip-Related Groin Pain and a Positive Flexion, Adduction, and Internal Rotation Test Exhibit Distinct Biomechanical Differences Compared With the Asymptomatic Side.* J Orthop Sports Phys Ther, 2018. **48**(7): p. 584-593.
4. King, M.G., et al., *Lower-Limb Biomechanics in Football Players with and without Hip-related Pain.* Med Sci Sports Exerc, 2020.
5. Shaffer, S.W., et al., *Y-balance test: a reliability study involving multiple raters.* Mil Med, 2013. **178**(11): p. 1264-70.
6. Schache, A.G. and R. Baker, *On the expression of joint moments during gait.* Gait Posture, 2007. **25**(3): p. 440-52.
7. Harrington, M.E., et al., *Prediction of the hip joint centre in adults, children, and patients with cerebral palsy based on magnetic resonance imaging.* J Biomech, 2007. **40**(3): p. 595-602.
8. Schache, A.G., R. Baker, and L.W. Lamoreux, *Defining the knee joint flexion-extension axis for purposes of quantitative gait analysis: an evaluation of methods.* Gait Posture, 2006. **24**(1): p. 100-9.
9. Baker, R., *Pelvic angles: a mathematically rigorous definition which is consistent with a conventional clinical understanding of the terms.* Gait Posture, 2001. **13**(1): p. 1-6.
10. Grood, E.S. and W.J. Suntay, *A joint coordinate system for the clinical description of three-dimensional motions: application to the knee.* J Biomech Eng, 1983. **105**(2): p. 136-44.

Supplementary file 5: COVID-19 Project changes implemented April 2020

Changes made	Reason for the changes
Suspension of Phase 1 of study (n=22 participants).	Normally, phase 1 of the study is provided through weekly face to face sessions over 12 weeks administered by study physiotherapists. Due to COVID-19 restrictions we were no longer able to undertake this phase of the study. We explored telehealth options but decided the validity of the treatment would be significantly impacted without face to face contact. Therefore, we decided to suspend this phase of the study until face to face treatment was able to be used again. Participants were offered the opportunity to withdraw or recommence treatment once it is safe. All participants chose to remain in the study until it recommenced. The chief investigator (JLK) maintained fortnightly contact with these participants over this time to check on their wellbeing and answer any questions.
Provision of telehealth treatment sessions (n=23 participants) in Phase 2 of study	Normally, phase 2 of the study is provided through once-monthly face to face sessions administered by study physiotherapists. We decided to use telehealth appointments to undertake these treatment sessions during the COVID-19 shutdown. This enabled this phase of the study to continue and also protect the health of investigators and study participants.
Postpone the time point of follow-up clinical and biomechanics (secondary outcome) assessment from 6 months post randomization to as soon as is safe following COVID-19 closure.	As it was no longer safe or legally possible for participants to attend the laboratory at La Trobe University, we postponed all face to face follow-up testing until it was safe to do so. The primary outcome of the study, collected via online questionnaires, is not impacted by this postponement.

LA TROBE UNIVERSITY Participant Code: PF ___ ___ ___ physioFIRST STUDY

La Trobe Sports and Exercise Medicine Research Centre

Consent form for persons participating in research projects

LTU ethics approval number HEC17-080

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

Investigators: Dr Joanne Kemp, Sally Coburn, Denise Jones, Dr Anthony Schache, Dr Benjamin Mentiplay
Associate Professor Dr Steven McPhail, Professor Kay Crossley

I, _____, have read and understood the **participant information statement and consent form**, and any questions I have asked have been answered to my satisfaction. I understand that even though I agree to be involved in this project, I can withdraw from the study at any time, up to four weeks following the completion of my participation in the research. Further, in withdrawing from the study, I can request that no information from my involvement be used. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

I consent to my data being included in other research projects. I acknowledge that my data will be coded, but can be potentially identified.	Yes ☐	No ☐
I consent to my single leg squat test being videoed. I acknowledge that any video data will be de-identified.	Yes ☐	No ☐
I understand my participation will not affect my current or future staff/student affiliation/physiotherapy management with: _____	Yes ☐	No ☐
I consent to be involved in the additional testing of physical activity using the Fitbit device	Yes ☐	No ☐
I consent to be involved in the additional testing of my movement patterns through biomechanical assessment	Yes ☐	No ☐
I consent to be involved in the additional testing of hip joint structure via Magnetic Resonance Imaging (MRI) scans	Yes ☐	No ☐
I wish to have a have a summary report sent to me at the conclusion of my participation in this project.	Yes ☐	No ☐

LA TROBE UNIVERSITY

Participant Code: PF ___ ___ ___

physiFIRST STUDY

Last Name:		Given Name:
DOB:	Age:	Contact Phone number:
Address:		
Signature:		Date:
Witness name:		Date:
Investigator:		Date:

Name and phone number of contact person in case of an emergency:

Name:	Phone:
Family Doctor:	Phone:

La Trobe Sports and Exercise Medicine Research Centre

LTU ethics approval number HEC17-080

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

Investigators: Dr Joanne Kemp, Sally Coburn, Denise Jones, Dr Anthony Schache, Dr Benjamin Mentiplay
Associate Professor Dr Steven McPhail, Professor Kay Crossley

Participant Information Statement

We invite you to participate in our project: "The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy to reduce pain and improve function for hip impingement."

We would like to give you some background information to explain why we think this project is important and describe what we would like you to do if you decide to join us in this research.

What is the purpose of this study?

Femoroacetabular (hip) impingement is a painful condition that commonly affects healthy active younger adults. It can limit their ability to continue playing sport and perform normal daily activities. It can be related to extra bone formation at the hip joint known as a cam deformity. Physiotherapy is one treatment people may use to reduce their symptoms and improve their function. We would like to compare the benefits of two different physiotherapy treatments to find the best way to manage this condition. Funding for this project has been provided by La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, an Arthritis Australia State/Territory Affiliate grant and a National Health and Medical Research Council Early Career Fellowship grant to Dr Kemp.

Who can participate in this study?

- People aged 18 to 50 years
- People with hip or groin pain aggravated by activity some of the time for more than 6 weeks
- People with signs of hip impingement when the hip is tested by a physiotherapist
- People with x-rays showing you have a 'cam deformity'

You are not eligible to participate in this study if:

- You cannot understand written or spoken English
- You have had physiotherapy in the past three months
- You have had hip surgery before
- You are not able to commit to a
  - **12-week physiotherapy program**
  - **a subsequent 12-week gym program, where you attend three times per week**
  - **baseline** (beginning) physical assessment
  - **follow-up** (24 weeks - after all treatments) physical assessment

- You are unable to have an x-ray of your pelvis (both hips at once) eg. You are pregnant or breastfeeding/unwilling

What does the project involve?

1. *Screening assessment (10 mins)*

You will be asked some questions about your hip over the phone to ensure you are eligible for the study. You will be asked to provide details of where any previous x-rays of your sore hip were taken for assessment of the digital copy to see if you have a 'cam deformity'. If you don't have x-rays we will organise a free hip (pelvic) x-ray for you at an x-ray clinic convenient to you (Imaging at Olympic Park, 60 Olympic Blvd, Melbourne or at Lake Imaging, Howitt St, Ballarat) if you are willing and able. The x-ray assessment will take about 30 minutes.

2. *Physical testing of your hip and questionnaires – Baseline (45 mins)*

If your movement tests and x-rays indicate you are eligible, we will ask you to attend an appointment at a mutually convenient time at La Trobe University, Melbourne, or at Lake Health Group, Ballarat, to undergo baseline measurement of your hip movements and strength. These baseline tests will take about half an hour.

Following the assessment we will ask you to complete several questionnaires online, and will be provided with instructions for access to the website. If you prefer you may complete a paper version of the questionnaires instead. The questionnaires will ask you questions about your hip/groin pain, other hip-related symptoms and your levels of physical activity and take about 15 minutes to complete.

3. *Biomechanical assessment of your movement (60 minutes)*

If you are willing to, we will undergo biomechanical assessment of your movement patterns after your physical testing described above. This testing will occur at La Trobe University, Melbourne. You will be asked to wear shorts (either you can bring some or we will provide you will shorts) and a singlet whilst you perform a series of tests including walking, running, squatting, jumping, and going up/down stairs. Reflective skin markers will be placed over your upper and lower body. Testing should take no longer than 60 minutes to complete. Participation in this section of the research is optional.

4. *Collection of activity data using Fitbit Flex 2™*

If you are willing to participate in this portion of the research, you will be given a Fitbit flex™ to wear on a daily basis for 14 consecutive days. It is important that you are able to wear the device every day on the wrist of your dominant hand. You will also need access to a computer so that you can set up and upload the information from the device. You will be given a password and email address that will be linked to the device you are given. Participation in this section of the research is optional.

Once the device is set up you will have access to your own Fitbit™ interface (called a dashboard), the same as any other user. This interface is accessible only by yourself (although you do have the option to share with your friends should you chose to do so).

Once the Fitbit™ is linked to your computer, the information from the Fitbit™ will be automatically synched to the computer via a USB dongle.

When data is uploaded from your Fitbit™, it is stored by Fitbit™ on an online server. The information collected by the research team will be gathered from that server using a program that will remotely log in and download the data. The research team will not need to log into your account through the Fitbit™ web page and will not access the personal dashboard and information that you set up.

5. *A free MRI of your hip (45 mins)*

If you are willing to participate in this portion of the research, we will investigate your hip joint structure in detail via a magnetic resonance imaging (MRI) scan at Imaging at Olympic Park, 60 Olympic Blvd, Melbourne. Parking is free and parking instructions are on the referral. The MRI will take place prior to the intervention period as well as after to examine any changes in your hip joint. You may not be able to participate in this section of the testing if you have a pacemaker, metal implants, or claustrophobia. Participation in this section of the research is optional.

6. *Physiotherapy treatment (12 weeks)*

After the first assessment and completion of the questionnaires, you will be randomly allocated to one of the physiotherapy treatment groups. Both treatments are used regularly by physiotherapists. You will then be asked to attend one of three physiotherapy clinics in Melbourne (or at Lake Health Group in Ballarat). Your treatment will comprise two phases which is provided free of charge and includes physiotherapy treatments and a 3 month gym membership.

In Phase 1, you will receive 6 free physiotherapy treatments over a period of twelve weeks. Each fortnightly treatment will last 30 minutes and will be performed by an experienced and project-trained physiotherapist. You will also be asked to perform a gym-based exercise program once per week in the gym at the same clinic. There are also exercises to complete at home twice per week. All treatments and any use of gym equipment will be provided at no cost to you.

7. *Gym membership (12 weeks)*

In Phase 2, you will receive a free 3-month gym membership and continue the exercise program you received in Phase 1 three times per week. You will receive a further three free physiotherapist reviews to continue to monitor your progress.

8. *Physical testing of your hip and questionnaires – Follow-up (45 mins)*

You will then return to La Trobe University (or Lake Health Group, Ballarat) for a final physical assessment. This will take approximately the same amount of time as the first assessment (about 45 minutes) and will also include biomechanics assessment if you participated in this before the intervention (about 60 minutes). The examiner physiotherapist will not know which treatment you have received. We ask you not to discuss your treatment with the examiner. We will also provide the same follow-up questionnaires for you to complete again (15 minutes), on paper, or online, and will ask you some questions about your experience of the project.

You will not receive any payment for your participation, however you will have free x-ray (and MRI if applicable) and assessment of your hip problem and free comprehensive physiotherapy if you are eligible and choose to participate.

We will also give you a $100 gift voucher for attending the final 6-month assessment of your hip at La Trobe University, as your assessment provides data critical to the success of our study. You may also ask for a copy of your assessment results.

We also ask that if you are considering another treatment for your hip or another musculoskeletal condition, you discuss the impact this might have on the study with the project leader, Dr Joanne Kemp.

Are there any potential side-effects?

The impingement and movement tests represent usual examination by a physiotherapist. You may experience a small amount of discomfort in the joints or tiredness in the muscles during the movement

and strength testing and interventions. Please report any undue discomfort or pain experienced during the testing. If the pain or discomfort is deemed to be excessive by yourself or the examiner, testing or treatment will cease.

If you have not already had a hip xray and require one to determine if you may participate, you will be exposed to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.32 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low. If you decide to participate in the MRI scans, there is no further exposure to radiation with MRI.

If required, emergency procedures will be used to deal with any medical event that arises during testing or physiotherapy treatments. La Trobe University and participating physiotherapy clinics and gymnasiums have documented procedures for emergencies. This includes annual first aid and CPR training and appropriate management of fire for all staff.

What if I have any concerns during the study?

This study is funded La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora, Arthritis Australia and National Health and Medical Research Council fellowship grant to Dr Kemp. This study adheres to the La Trobe University Human Ethics Guidelines and National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your initial participation in this study with the project coordinator (Sally Coburn ph: 0408 761 237), you may want to talk an officer of the University not involved with the study. If so, you may contact the Ethics Manager, Heidi Gaulke on ph: (03) 9479 1443. If you choose to participate, you are free to call the project chief investigator with any queries following the baseline assessment of your hip (Dr Joanne Kemp ph: 0484 776 536)

Can I withdraw from the study if I wish?

Your participation in the study is voluntary. If you do not wish to take part you are under no obligation to do so. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. You may also withdraw any unprocessed data previously supplied by you.

If you are a student of La Trobe University, your decision whether to take part or not to take part, or to withdraw, will not affect your affiliation with the university in any way.

If you are a patient of any of the investigators or project physiotherapists, your decision whether to take part or not to take part, or to withdraw, will not affect your relationship with the physiotherapy clinic or your future physiotherapy management in any way.

Will my details be kept confidential?

Our procedures require allocation of a code number to identify you and any data associated with your participation. This assures your anonymity as your name will not be used. You will be videoed performing a single leg squat but will be de-identified for analysis. No findings that identify you will be published and access to individual results is restricted to the investigators. Coded data will be stored for at least 5 years. All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The chief investigator is responsible for maintaining this confidentiality. This project is subject to the requirements of the La Trobe University Human Ethics Guidelines. However, you must be aware that there are legal limitations to data confidentiality.

What will happen to the results of the study?

Summaries of the study results will be sent to participants, if requested on the consent form. It is possible that results from this study will be presented at a local, national or international conference, or published in a peer reviewed journal. Results may also be used for teaching purposes and web-based translational material. All results are **de-identified**.

How do I get more information?

You should ask for any information you want. If you would like more information about the study, or if there is any matter that concerns you, either now or in the future, do not hesitate to ask one of the investigators or project coordinator. Before deciding whether or not you should take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this. A newsletter will be sent to update you during the project. A project summary will be available, on request via email/post at the conclusion of the study and will include no identifiable information.

About the investigators:

Prof Kay Crossley is a sports physiotherapist and professor at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Joanne Kemp is a sports physiotherapist and post-doctoral researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Sally Coburn is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Denise Jones is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Anthony Schache is a physiotherapist and senior research fellow at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Benjamin Mentiplay is an exercise scientist and researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

A/Prof Steven McPhail is a health economist at University of Queensland

Contacts:

Enquiries and eligibility:

Sally Coburn

Mob: 0484 761 237

Email: s.coburn@latrobe.edu.au.

If you have commenced participation:

Dr Joanne Kemp

Email: j.kemp@latrobe.edu.au

Mob: 0484 776 536

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page number in manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	20
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, Supp files 1 and 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15, Table 1, Supp 3 and 4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig 3 and 4, 9-12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18-19

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	10
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	LTU
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19-20
	31b	Authorship eligibility guidelines and any intended use of professional writers	20
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	LTU
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041742.R2
Article Type:	Protocol
Date Submitted by the Author:	11-Feb-2021
Complete List of Authors:	Kemp, Joanne; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Johnston, Richard; La Trobe University - Bundoora Campus, La Trobe Sports and Exercise Medicine Research Centre Coburn, Sally; La Trobe University, La Trobe Sports and Exercise Medicine Research Centre Jones, Denise; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Schache, Anthony; La Trobe University, La Trobe Sports and Exercise Medicine Centre Mentiplay, Benjamin ; La Trobe University, King, Matthew; La Trobe University Scholes, Mark; La Trobe University De Oliveira Silva, Danilo; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre Smith, Anne; Curtin University, School of Physiotherapy McPhail, Steven; Queensland University of Technology, Australian Centre for Health Service Innovation and School of Public Health & Social Work Crossley, Kay; La Trobe University, La Trobe Sport and Exercise Medicine Research Centre
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Rehabilitation medicine
Keywords:	Hip < ORTHOPAEDIC & TRAUMA SURGERY, SPORTS MEDICINE, REHABILITATION MEDICINE

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

Title page

Physiotherapist-led treatment for Femoroacetabular Impingement Syndrome (The PhysioFIRST study): A protocol for a participant and assessor-blinded randomised controlled trial.

Joanne L Kemp,[1] Richard TR Johnston,[1] Sally L Coburn,[1] Denise M Jones,[1] Anthony G Schache,[1] Benjamin F Mentiplay,[1] Matthew G King,[1] Mark J Scholes,[1] Danilo de Oliveira Silva,[1] Anne J Smith,[2] Steven M McPhail,[3,4] Kay M Crossley.[1]

[1] La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Human Services and Sport, La Trobe University, Bundoora, Victoria, Australia.

[2] School of Physiotherapy and Exercise Science, Curtin University, Perth, Western Australia, Australia.

[3] School of Physiotherapy & Social Work and Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Queensland, Australia.

[4] Centre for Functioning and Health Research, Metro South Health, Brisbane, Queensland, Australia.

Correspondence to:

Dr Joanne L Kemp, La Trobe Sport and Exercise Medicine Research Centre, La Trobe University, Bundoora, Victoria 3086, Australia

j.kemp@latrobe.edu.au

Word count: 3604

ABSTRACT

Introduction: This double-blind, randomised controlled trial (RCT) aims to estimate the effect of a physiotherapist-led intervention with targeted strengthening compared to a physiotherapist-led intervention with standardised stretching, on hip-related quality of life (QOL) or perceived improvement at 6-months in people with femoroacetabular impingement (FAI) syndrome. We hypothesise that at 6-months, targeted strengthening physiotherapist-led treatment will be associated with greater improvements in hip-related QOL or greater patient-perceived global improvement when compared to standardised stretching physiotherapist-led treatment.

Methods and analysis: We will recruit 164 participants with FAI syndrome who will be randomised into one of the two intervention groups, both receiving one-on-one treatment with the physiotherapist over 6-months. The targeted strengthening physiotherapist-led treatment group will receive a personalised exercise therapy and education programme. The standardised stretching physiotherapist-led treatment group will receive standardised stretching and personalised education program. Primary outcomes are change in hip-related QOL using International Hip Outcome Tool (iHOT-33)) and patient-perceived global improvement. Secondary outcomes include cost-effectiveness, muscle strength, range of motion, functional task performance, biomechanics, hip cartilage structure and physical activity levels. Statistical analyses will make comparisons between both treatment groups by intention-to-treat, with all randomised participants included in analyses, regardless of protocol adherence. Linear mixed models (with baseline value as a covariate and treatment condition as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at primary end-point (6-months).

Ethics and dissemination: The study protocol was approved (La Trobe University Human Ethics Committee (HEC17-080)) and prospectively registered with the Australian New Zealand Clinical Trials Registry. The findings of this RCT will be disseminated through peer reviewed scientific journals and conferences. Patients were involved in study development and will receive a short summary following the completion of the RCT.

Trial registration number: ACTRN12617001350314

Keywords: Hip joint, rehabilitation, exercise therapy, femoroacetabular impingement, physiotherapy

Strengths and limitations of this study

- This prospective, double-blind RCT is the first full-scale study to test a head-to-head comparison of two exercise-based physiotherapist-led interventions for FAI syndrome.
- Patient-reported outcomes will be collected at clinically relevant time points and allows analysis of outcomes that are important to patients.
- Cost effectiveness analysis will inform clinical decision making.
- This physiotherapist-led RCT has the potential to reduce the burden of FAI syndrome and, if shown to be efficacious, may become the preferred first treatment choice for FAI syndrome.
- The blinding of participants and assessors provides the highest level of rigour to test the efficacy of the physiotherapist-led intervention.

INTRODUCTION

Musculoskeletal conditions, such as hip-related pain,[1] are leading causes of pain and disability in the community, and one of the largest global contributors to years lived with a disability.[2] Femoroacetabular impingement (FAI) syndrome is a common cause of hip-related pain in adults,[3] and evident in 49% of young and middle-aged adults with hip-related pain.[4] It is diagnosed with a triad of imaging findings, patient reported hip-related symptoms, and clinical signs that are associated with excessive bone formation at the femoral head-neck junction (Figure 1). The most commonly reported altered bony shape is cam morphology, which describes excessive bone formation at the femoral head-neck junction.[5] Cam morphology may lead to aberrant joint forces during functional movements in the position of hip impingement (primarily involving flexion, rotation, and abduction or adduction), and subsequent damage to the articular cartilage of the hip joint.[6]

Figure 1. Diagrammatic representation of cam morphology at the femoral head-neck junction.[7]

Insert figure 1 here

While most studies focus on MSK pain affecting the elderly (e.g. osteoarthritis), there is compelling and increasing evidence that FAI syndrome in younger adults (e.g. aged 18-50 years) creates a substantial burden in society,[8 9] associated with persistent hip-related pain and symptoms,[10] impaired physical function,[11] reduced sports and physical activity participation, and impaired quality of life (QOL). The burden of FAI syndrome is amplified by the high daily physical demands (e.g. occupational, familial responsibilities, and recreational activities) encountered by younger adults.

Treatment options for FAI syndrome can be surgical or non-surgical. [12] Non-surgical approaches are recommended as the first line options for other musculoskeletal pain conditions (evident from clinical guidelines for osteoarthritis, [13] low back pain, [14] and chronic whiplash associated disorders[15]), due to the higher costs and risks associated with surgery. Recently published RCTs comparing hip arthroscopic surgery to physiotherapist-led interventions for FAI syndrome found small[16] [17] to moderate[18] between-group differences favouring hip arthroscopy, with a greater cost and risk of adverse events associated with surgery. [16-18] The physiotherapist-led interventions used for comparison to hip arthroscopy involved a diversity of exercise interventions including stretching, motor control, core stability and strengthening, and provided varied detail regarding the individualisation and the content of the exercise interventions. Hence, the specific components of exercise programmes that are effective are not known. A recent consensus meeting recommended individualised, exercise-based

interventions as the first-line treatment for young adults with hip-related pain, however no recommendation was made regarding one type of exercise over another. [12] Such a recommendation could not be provided because of the absence of a full-scale RCT comparing the head-to-head effectiveness of different exercise-based, physiotherapist-led interventions for FAI syndrome[19-21]. Thus, a physiotherapist-led intervention that compares exercise interventions needs to be developed and tested.

Therefore, the primary aim of this RCT is to estimate the effect of a physiotherapist-led intervention with targeted strengthening compared to a physiotherapist-led intervention with standardised stretching in 164 participants with FAI syndrome on hip-related QOL (International Hip Outcome Tool 33 (iHOT-33)) or patient-perceived global improvement at 6-months[22]. We hypothesise that, compared to the standardised stretching physiotherapist-led intervention, the targeted strengthening physiotherapist-led intervention will result in greater improvement in: (i) hip-related QOL or (ii) perceived improvement. Secondary aims are to measure: (i) the cost-effectiveness of the targeted strengthening physiotherapist-led intervention compared to the standardised stretching physiotherapist-led intervention; (ii) the effects of targeted strengthening physiotherapist-led intervention on physical activity levels; (iii) the effects of targeted strengthening physiotherapist-led intervention on hip strength; and explore (iv) the effects of targeted strengthening physiotherapist-led intervention on hip biomechanics; and (v) the effects of targeted strengthening physiotherapist-led intervention on hip joint structure.

METHODS

Participants

This participant and assessor-blinded superiority RCT aligns with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines.[23] We will recruit 164 participants from the general community in urban (greater Melbourne) and regional Victoria (Ballarat) (Australia) with a history of hip-related pain. The recruited cohort will be randomised into two parallel intervention groups. Block randomisation will be utilised with a 1:1 ratio, with the primary end-points of hip-related QOL and patient-perceived improvement after 6-months. This RCT study was prospectively registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12617001350314) and ethics approval obtained through the La Trobe University Human Ethics Committee (HEC 17-080).

Inclusion and Exclusion criteria

Eligibility for this RCT was based on clinical and radiographic features,[3] which were used in our previous pilot RCT for FAI syndrome.[6]

Inclusion criteria: (i) aged 18-50 years; (ii) hip-related (anterior hip or groin) pain which is aggravated by prolonged sitting or hip movements into positions of impingement;[3] (iii) hip-related pain ≥3/10 on numerical pain scale for ≥6 weeks; (iv) cam morphology (defined as radiographic alpha angle ≥60°),[24] as described below; and (v) a positive flexion–adduction–internal rotation (FADIR) test.

The alpha angle represents the sphericity of the femoral head and is used to identify and then quantify cam morphology if greater than 60° (Figure 2). To determine the presence of cam morphology, the potential participants will undergo a standing anteroposterior (AP) and Dunn 45° radiograph, following a standardised protocol.[3 24] Following previously described methods,[5] the alpha angle will be calculated by one examiner (JLK) using both the AP and the Dunn 45° radiographs, to quantify the asphericity of the femoral head.

Figure 2. Alpha angle measurement from AP radiograph.[24]

Insert figure 2 here

Exclusion criteria: (i) physiotherapy treatment for the hip in the past three months; (ii) previous hip or back surgery; (iii) planned lower limb surgery in the following year; (iv) radiographic hip osteoarthritis (Kellgren and Lawrence score ≥2,[25] representing moderate to severe hip osteoarthritis); (v) intra-articular hip-joint injection in the previous three months; (vi) neurological, other MSK, or systemic arthritis conditions including other significant musculoskeletal conditions where FAI syndrome was not considered to be the primary cause of hip pain; (vii) unable to perform testing procedures; (viii) unable to commit to a 6-month physiotherapy-led intervention or associated outcome assessments; (ix) contraindications to x-ray (including self-reported pregnancy and pregnancy during the study); or (x) inability to understand English language.

Procedures

The study procedure flow-chart is shown in Figure 3. Following clinical and radiographic screening to confirm study eligibility, participants will attend La Trobe University or Lake Health Group, Victoria, Australia to complete written and informed consent. Demographic characteristics will be recorded, and baseline patient reported outcome measures (PROMs) completed using an electronic data collection system (Promptus, Melbourne, Australia). Participants will undergo clinical and biomechanical assessment (where appropriate) of their hip by a blinded assessor at baseline and upon study follow-up (6-months). Magnetic resonance imaging will be completed at baseline and 12 months follow-up. Participants will be blinded to the randomisation procedure.

Figure 3. Study procedure flow-chart.

Insert Figure 3 here

Randomisation

Following baseline assessment, participants will be randomised into one of two intervention groups. To ensure concealed intervention allocation, we will use the telephone-based interactive voice response randomisation services (National Health and Medical Research Council Clinical Trials Centre, University of Sydney, Sydney, Australia). The randomisation schedule (blocks of 8 to 12) will be revealed to the unblinded assessor (JK, RJ) after the baseline assessment, who will communicate intervention allocation to the participant's study physiotherapist.

Blinding

As the primary outcomes are self-reported, participants are considered assessors; therefore, participants (and thus assessors) will be blinded to previous scores during the testing time points. Participants will be blinded to the physiotherapist-led interventions and consent will involve limited disclosure. Participants will become unblinded once the data analyses are complete. We do not expect that emergency unblinding will be required due to the very low incidence of adverse events seen in our pilot study of the same trial interventions.

Physiotherapist-led interventions

Study participants will receive one of two physiotherapist-led interventions (targeted strengthening physiotherapist-led treatment or standardised stretching physiotherapist-led treatment) across four clinical sites within Victoria (Australia). Registered physiotherapists will lead the two-phase intervention that will be delivered over a 6-month period and has been described using the Template for Intervention Description and Replication (TIDieR) guidelines (Table 1).[26] Physiotherapists will be trained to deliver the intervention to both groups. Training of the physiotherapists will occur at the commencement of the study and annually thereafter. Treating physiotherapists will also be provided with written treatment manuals and training materials to refer to. In order to limit the likelihood of contamination between treatment groups, treating physiotherapists will be instructed to not have participants from different treatment groups attend the clinic at the same time. We have previously reported treating therapists' beliefs that both interventions are credible. [6] In order to maintain participant blinding, treating physiotherapists will be trained to deliver both interventions with equal enthusiasm. Each of the four clinical sites will have between three and five therapists trained, depending on clinic requirements. The treating physiotherapists were recruited from four large private physiotherapy clinics in Australia, and represent a typical therapist in an Australian private practice where people with FAI syndrome might seek care.

Targeted strengthening Physiotherapist-led Treatment

A team of expert physiotherapists with extensive clinical experience in FAI syndrome management (all with >15 years of individual experience) designed both physiotherapist intervention programs.[27-31] The targeted strengthening physiotherapist-led treatment was developed based on knowledge of physical impairments observed in FAI syndrome,[19] and a previous pilot study.[6] The targeted strengthening physiotherapist-led intervention is personalised to the individual participant's impairments and goals and has seven key elements: (i) progressive hip muscle strengthening exercises; (ii) progressive trunk muscle strengthening exercises; (iii) progressive functional exercises; (iv) progressive plyometric exercises; (v) a progressive physical activity/return to sport program; (vi) a personalised education program; and (vii) tailored manual therapy. Videos of all exercises in the targeted strengthening physiotherapist-led intervention can be found at [insert hyperlink here when accepted]. The targeted progressive hip and trunk strengthening exercises were designed using strength and conditioning guidelines outlined by the American College of Sports Medicine.[32] Adherence to these guidelines aims to facilitate hip joint loading tolerance utilising exercise dosages, volume, and progressions that will increase muscular strength-hypertrophy and strength-endurance. Full details of the targeted physiotherapist-led intervention program are contained in Supplementary File 1. An example of how a participant may be provided with progressive targeted hip adductor strengthening exercises are presented in Figure 4. The participants will use the Physitrack® application (Physitrack, Ltd, London, UK), a web-based application compatible with smartphones, tablets, and computers, which provides photos, videos, and instructions of prescribed exercises to be played in real time. Those unable to access the Physitrack® application will be provided with paper-based pictures for exercise instruction.

Standardised stretching physiotherapist-led intervention

The standardised stretching physiotherapist-led intervention consists of tailored health education, non-specific, standardised stretching, a standardised physical activity program and manual therapy individualised to participants' needs. In order to control for the psychosocial effects of therapist contact inherent with physiotherapy intervention, this program will provide a credible alternative to physiotherapy exercises to reduce the possibility of resentful demoralisation. Stretching was chosen as our pilot work showed a smaller effect than a targeted strengthening intervention on hip-related quality of life and muscle strength. [6] (Supplementary File 2).

Delivery of both physiotherapist-led interventions

Phase 1: 0-3 months (6 physiotherapist-led interventions (1 per fortnight); 12 supervised gym sessions (1 per week), with a further two unsupervised gym sessions encouraged per week).

Phase 2: 4-6 months. Both intervention groups will receive a 3-month gym membership to continue with the unsupervised exercises independently. They will receive additional physiotherapy visits at

months 4, 5, and 6 (i.e. 3 in total), with the aim of increasing adherence to the unsupervised intervention All clinical-site physiotherapists will receive treatment manuals and undergo three group training sessions (theory and practical) in the delivery of both interventions. Treating physiotherapists will then deliver either intervention. Clinics will be audited annually for treatment fidelity.

Participant adherence to intervention, adverse events and concomitant care

Participants will choose to attend one of four physiotherapy clinics to minimise transport burden within Melbourne and regional Victoria. The lead researcher (JLK) will maintain regular contact with study participants via the online PROM system (via weekly questionnaires on treatment adherence) and the Physitrack® app to monitor adverse responses to treatment.[6] Any adverse events will be reported to the Human Research Ethics Committee. Participants will be asked to refrain from concomitant physiotherapist-led treatment, other musculoskeletal therapies (chiropractic care, osteopathy, myotherapy or similar), or exercise interventions for their hip pain during the study. Participants will be allowed to continue care for other unrelated pre-existing conditions. There are minimal known risks associated with the physioFIRST study interventions, as such the physioFIRST study will not have a formal data monitoring committee or plans for post-trial care, and does not require an interim analysis.

Table 1: Intervention delivery described using the TIDieR guidelines for both groups

Phase	What	Targeted strengthening physiotherapist-led treatment	Standardised stretching physiotherapist-led treatment
Phase 1. Month 0-3	**Who**	Physiotherapists	
	How	Face-to-face individual sessions	
	Where	Physiotherapy clinics (& clinic gyms) in Melbourne/Regional Victoria	
	When & how much	Fortnightly: 30 mins physiotherapy; and weekly: 30 mins supervised gym sessions. Exercises progressed based on assessment at each session	
	Tailoring	Tailored selection and progression of hip, trunk and functional strength exercises & manual therapy techniques Progressive, tailored physical activity program	Standardised non-specific stretching exercises Tailored education and standardised information on increasing physical activity
	How well	Treatment response in files and adherence recorded in mobile phone app	
	What	**Targeted strengthening physiotherapist-led treatment**	**Standardised stretching physiotherapist-led treatment**
Phase 2. Month 4-6	**Who**	Physiotherapists and local gymnasium	
	How	Face-to-face individual sessions & Membership to gymnasium	
	Where	Physiotherapy clinics & gymnasiums Melbourne/Regional Victoria	
	When & how much	3x 30 minute "top-up" physio sessions at month 4, 5 and 6. 3-times weekly unsupervised gym attendance	
	Tailoring	Semi-standardised with selection of exercise targeted to assessment	Standardised / non-specific stretching exercises
	How well	Treatment response in files and adherence recorded in mobile phone app	

Figure 4. An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises.

Insert figure 4 here

Measures to be collected

Measures to be collected will include primary and secondary outcomes, descriptive measures of the population, treatment modifiers, and treatment mediators. These are listed with timepoints of collection in Table 2.

Descriptive measures of the population

Participant baseline demographic characteristics, such as age, sex, height, body mass leg length, and waist and hip circumference, will be recorded. In addition, response to pain provocation tests will be recorded (Supplementary File 3).

Patient reported outcome measures

Primary Outcomes

We will collect multiple (two) primary endpoints.[22]

Hip-related QOL will be measured using the iHOT-33. The iHOT-33 questionnaire consists of 33 individual questions scored on a visual analogue scale from zero (worst possible score) to 100 (best possible score). The iHOT-33 has acceptable psychometric properties and is recommended for use in active adults with hip-related pain.[33 34] It has a low standard error of measurement (6 points),[35] is responsive,[36] with reported minimal clinically important differences ranging from 6 to 10 points [36] and minimal detectable change (groups) of 2 points.[35]

Patient-perceived global improvement will be measured on a 7-point Likert scale ('much improved', 'improved', 'a little improved', 'no change', 'a little worse', 'worse', 'much worse'). This is a clinically relevant tool for evaluating an individual patient's perspective on meaningful improvement.[37] For the analysis, patient-perceived global improvement will be used as a continuous scale.

Secondary Outcomes

The Copenhagen Hip and Groin Outcome Score (HAGOS)[38] is a self-reported questionnaire consisting of six subscales that evaluates dimensions of hip and/or groin pain including: pain, symptoms, physical function of daily living, physical function in sport and recreation, participation in physical activities, and hip-related QOL. The HAGOS subscales are each scored out of 100 points (100=best possible score) has acceptable reliability and validity in young people with hip and groin pain.[39]

Workplace Activity Limitations Scale (WALS) is a 12-item questionnaire that aims to identify arthritis related activity limitations specific to various employment related tasks. Responses are made using a 4-point Likert scale and a total score is measured out of 33 (higher scores=more impairment).[40]

EQ-5D-5L (Registration ID 34190_TOU) is a reliable and valid measure of QOL.[41] The EQ-5D-QL asks the participant to indicate their health state according to five dimensions that assess: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[41 42]

Treatment modifiers

Pain Detect Questionnaire (PD-Q) evaluates the presence and severity of seven qualitative characteristics of pain, including: burning sensation, hyperesthesia, allodynia, shock-like, thermal, numbness, and tenderness. Based on the participant's self-reported scores, the likelihood for pain to be attributable to neuropathic factors is then classified as: (a) likely; (b) unlikely (and thus the pain type is identified as nociceptive); or (c) ambiguous (indicating the pain type is unclear and identified as having a mixed pattern).[43 44] The PD-Q is a reliable screening questionnaire for pain types with ICC's for measurement of pain intensities varying between 0.81 (95% CI: 0.75-0.87) and 0.87 (955 CI: 0.82-0.91).[44]

Keele STarT MSK Tool© Clinical version, contains 10 items that ask the participant about their function and disability, pain and coping, comorbidity, and the impact of pain. Once scored, it places the patient into three categories based on their risk of a poor outcome (low, medium, high). This tool has moderate-to-good level predictive ability in the identification of patients who develop persistent disabling pain.[45]

Tampa scale for Kinesiophobia (TSK), consists of 17 statements which measure pain-related fear of movement in patients with chronic MSK pain.[46] Each statement is provided with a 4-point Likert scale, and total scores range from 17 to 51, with a higher score indicating more fear of movement. The TSK demonstrates moderate reliability and validity when tested on patients with acute and chronic MSK pain.[47 48]

Physical impairment and functional outcome measures

Hip muscle strength will be measured with previously described methods,[49 50] as a secondary outcome and as a treatment mediator. A full description of the hip muscle strength tests are contained in Supplementary File 3.

Range of motion tests and functional performance tests are secondary outcomes and will be measured using previously published standardised methods (Supplementary File 3).[31 51] These tests of physical

impairment will be measured at baseline and 6-months (Table 2). The tests have excellent reliability (ICC=0.82-0.95)[49] and were selected as they are frequently used in clinical practice and are associated with functional capacity of the hip and lower limb.[6 52]

Imaging measures

Radiographic hip alpha angle[24], as described above, will be used to describe the population and to determine its effect as a treatment modifier.

Hip joint cartilage structure at baseline will be quantified using the Scoring Hip Osteoarthritis with MRI (SHOMRI) semi-quantitative scoring system on a subset of 50 participants (25 per group).[53] The SHOMRI classification quantifies cartilage features in 10 subregions.[53] The SHOMRI scoring system has excellent previously published intra- and inter-reader reliability (ICC = 0.91-0.97; κ: 0.55-0.79).[53] This measure will be a secondary outcome and will also be used as a treatment modifier.

Hip biomechanics

Hip biomechanics will be secondary outcomes. Using three-dimensional motion analysis according to our previously described protocol,[50] participants biomechanics during walking, running, the single leg squat, and the y-balance test will be examined in a subset of 50 participants (25 per group) at baseline and at 6-months. Changes in hip biomechanics during these tasks will be measured. Details of the biomechanics testing procedures are contained in Supplementary File 4.

Physical activity

Physical activity (average daily step count over 14 days) is a secondary outcome and will be measured using the Fitbit Surge™ on a subset of 40 participants. The Fitbit Surge™ is a lightweight wrist worn device that tracks physical activity and has demonstrated reliability in people aged 18-50 years.[54]

Long term follow-up

Participants will be invited to complete the patient-reported outcome measures listed in Table 2 at annual intervals to 5-years, and then again at 10-years to enable the assessment of long-term predictors of outcome, and progression to hip surgery, including hip arthroscopy and hip arthroplasty.

Table 2. Trial measures to be collected and their purpose.

PhysioFIRST TIMELINE														
MEASURE	**PURPOSE**	**TIME POINTS (MONTHS) COLLECTED**												
		0	**1**	**2**	**3**	**4**	**5**	**6#**	**7**	**8**	**9**	**10**	**11**	**12**
DESCRIPTIVE MEASURES														
Age (years)	Describe population, treatment modifier	X												
Sex	Describe population, treatment modifier	X												
Height (m)	Describe population	X												
Body mass (kg)	Describe population	X												
Leg length (cm)	Describe population	X												
Waist and hip circumference (cm)	Describe population	X												
PAIN PROVOCATION TESTS														
Hip Internal Rotation Test	Describe population	X						X						
Flexion/Adduction/Internal Rotation Test (FADIR)	Describe population	X						X						
Bent Knee Fall Out (BKFO)	Describe population	X						X						
PATIENT REPORTED OUTCOME MEASURES (PROMS)														
International Hip Outcome Tool (IHOT-33)	Primary outcome	X			X			X			X			X
Patient-perceived global improvement	Primary outcome				X			X			X			X
The Copenhagen Hip and Groin Outcome Score (HAGOS)	Secondary outcome	X			X			X			X			X
Workplace Activity Limitations Scale (WALS)	Secondary outcome	X			X			X			X			X
EQ-5D-5L	Secondary outcome	X			X			X			X			X
Pain Detect Questionnaire	Secondary outcome, treatment modifier	X			X			X			X			X
Keele STarT MSK Tool	Secondary outcome, treatment modifier	X			X			X			X			X
Tampa Scale for Kinesophobia	Secondary outcome, treatment mediator	X			X			X			X			X
HIP STRENGTH TESTS														
Hip Abduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Adduction (supine)	Secondary outcome, treatment mediator	X						X						
Hip Extension (prone)	Secondary outcome, treatment mediator	X						X						
Hip External Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Internal Rotation (prone)	Secondary outcome, treatment mediator	X						X						
Hip Flexion (sitting)	Secondary outcome, treatment mediator	X						X						
FUNCTIONAL TESTS														
Trunk Muscle Endurance (side lying)	Secondary outcome, treatment mediator	X						X						

One Leg Rise	Secondary outcome, treatment mediator	X						X						
Star excursion Balance Test	Secondary outcome	X						X						
Hop for Distance	Secondary outcome	X						X						
Single leg squat (video analysis)	Secondary outcome	X						X						
RANGE OF MOTION (Degrees)														
Hip Flexion	Secondary outcome	X						X						
Hip External Rotation	Secondary outcome	X						X						
Hip Internal Rotation	Secondary outcome	X						X						
IMAGING														
Hip MRI cartilage	Secondary outcome, treatment modifier	X												X
Hip alpha angle	Describe population, treatment modifier	X												
BIOMECHANICS TESTS														
Walking	Secondary outcome	X						X						
Y-Balance	Secondary outcome	X						X						
Single Leg Squat	Secondary outcome	X						X						
Running	Secondary outcome	X						X						
ACTIVITY MONITORING														
Fitbit Activity Monitoring (2 Week Block)	Secondary outcome	X			X			X						X
COST EFFECTIVENESS														
Incremental cost per Quality Adjusted Life Year	Secondary outcome							X						

[#] = primary end-point; m=meters; kg=kilograms; MRI = magnetic resonance imaging

Data management

Data quality will be ensured via practitioner training, assessing procedural quality, and random checks of protocol adherence, data completeness, and accuracy. Intervention adherence will be defined as completing ≥80% of the physiotherapist-led treatments and supervised gym sessions and will be tracked by the clinical site booking system and weekly questionnaires or the Physitrack® app. All participants will be included in the intention to treat analyses, including participants adhering to <80% of treatment and those participants who withdraw from the study.[55]

Sample size

A power calculation was conducted for this RCT, informed by data from our previous pilot study that utilised and compared a similar tailored strengthening intervention to a standardised stretching intervention. [6] The MCID of the iHOT-33 is still uncertain in non-surgical patients with FAI syndrome and has only been estimated in hip arthroscopy cohorts. [35 36] Therefore, the power calculation was based on the observed baseline standard deviation (SD) and the between-group differences in the scores of our first primary outcome measure (hip-related QOL (iHOT-33)) from our pilot study (baseline SD = 25 points; mean difference 15 points out of 100)[6], which exceeded the previously reported MCID of 6-10 points[36]. Our pilot trial[6] observed a standardised mean difference (SMD) of 0.68 for the iHOT-33. We reduced the proposed SMD to 0.50 for this study to account for the small sample (n=24) in the pilot study, the similarities between the interventions and the difference in the expertise of treating physiotherapists in a full-scale study. This is consistent with previously reported between-group SMD for the second primary outcome (patient-perceived global improvement) of 0.50.[56] Estimated sample sizes for a two-sample means test t test assuming 80% power, α=0.025 (accounting for both primary outcomes), results in a sample size estimate of 156 participants. To account for an estimated 5% drop-out due to the study duration, a recommended sample size of 164 participants (82 in each group) will be recruited in this RCT

Statistical analyses

Data will be analysed using intention to treat (ITT), with all randomised participants included in analyses, regardless of protocol adherence. An experienced biostatistician (AJS) will perform blinded analyses of primary and secondary outcomes. The two primary endpoints chosen will be evaluated separately, such that a significant treatment effect against either of the endpoints will be taken as evidence of efficacy.[22] Linear mixed models (with baseline value as a covariate and treatment condition

as a fixed factor) will be used to evaluate the treatment effect and 95% confidence interval at 3 and 6 months. Models will be adjusted for age and sex. In addition to the primary ITT analysis, sensitivity analyses for missing outcome data will be performed on multiple imputed datasets, and Complier Average Causal Effects (CACE) methods will be used to estimate the treatment effect at full and partial levels of participation in addition to the primary ITT analysis.

For the primary analysis, patient-perceived global improvement will be assessed as a 7-point scale, with bootstrapped standard errors to account for non-normality of residuals. A secondary analysis will assess the between-group difference in the proportion of participants reporting being 'much improved' or 'improved', as an indicator of successful treatment outcome.

Exploratory moderation analysis will be conducted to determine the strength of evidence provided by the study that treatment effects are moderated by the factors outlined as potential moderators in Table 2, by incorporating an interaction term between the potential moderator and the treatment group indicator in the linear mixed models for the ITT sample for the primary outcomes. Investigation of the mediation of the treatment effect for the primary outcomes for the ITT sample by the potential mediator variables outlined in Table 2 will also be conducted. Standardised estimates of the mediated treatment effect with bootstrapped 95% confidence intervals will be presented.

Cost-effectiveness (Incremental cost per Quality Adjusted Life Year)

The economic evaluation will estimate the incremental cost (healthcare system perspective) per quality adjusted life year (QALY) from the EQ-5D-QL assessment. Healthcare resource utilisation, including co-interventions for hip-related pain (e.g. medicines, complementary treatments, and details of hospital presentations) will be collected from several sources to facilitate data analysis, reporting, and corroboration. Data sources will include the Medicare and Pharmaceutical Benefits Scheme (MBS and PBS) databases (includes rebated, private health insurance, and out-of-pocket costs). Resources used to deliver the trial interventions for each respective trial arm will also inform the economic evaluation.

Limitations

We acknowledge that our target effect size (SMD=0.5) might represent a larger between group difference than the lower bound of the previously reported between group difference (for example the lower end of the previously reported MCID for iHOT-33 of 6 points)[36]. Therefore, we powered the study for an effect size of SMD=0.50, because a moderate effect would be considered clinically meaningful. While our two interventions do contain some similar elements, our pilot trial indicated we could potentially expect larger differences than 6 points between treatment groups[6].

When we developed the two intervention groups, we deliberately sought to compare what we considered "best practice" based on our understanding of impairments (reduced strength) against a standardised comparator that would seem credible to participants, to allow for participant blinding and same level of patient-clinician contact between groups. However, this does not allow us to test whether any between group differences are due to the different exercise components of the programme (strength v stretch), or to the nature of the interventions (individualised v standard), and this would need to be explored in future studies.

Trial status

Recruitment commenced in February 2018 and it is anticipated that this will be completed by September 2020. In March 2020, adjustments were made to the study protocol due to COVID-19, these are described in Supplementary File 5.

Conclusion

This RCT aims to compare the effectiveness of a physiotherapist-led intervention with targeted strengthening to a physiotherapist-led intervention with standardised stretching in 164 participants with FAI syndrome on hip-related QOL or patient-perceived global improvement. It may provide an evidence-based framework for physiotherapists to implement the first line of care for the treatment of FAI syndrome.

Ethics and dissemination

This study complies with the Declaration of Helsinki and has been approved by La Trobe University human research ethics committee. All participants will provide written informed consent prior to enrolment in the study. Participant information and consent forms for the study are included as supplementary file 6 and 7. Participants will undergo a single pelvic radiograph for study inclusion, thus ensuring that the exposure to ionising radiation is no more than that in standard clinical exposure. The ethical and safety considerations associated with this trial are very low. We will disseminate study outcomes via submission to high-impact international peer-reviewed journals and presentation at international scientific conferences. By targeting a general medical journal, we will ensure study findings are disseminated to a variety of health professions.

Patient and public involvement

Patients were involved in the planning stages of this project. Patients provided input via questionnaires and interviews.

Patients' priorities gathered during the questionnaires and interviews informed the development of the research question.

Patients and clinicians provided input into the development of the interventions, the frequency of treatment, and their treatment goals.

Patients were not involved in the recruitment and conduct of the study.

Patients were asked to assess the burden of the intervention and time required to participate in the study during the planning stages of the study.

Patients and clinicians will provide input into the dissemination of study results by assisting with the decision on what information to share and in what format.

Acknowledgements

The authors acknowledge the staff of Lake Health Group, Ballarat, Australia; Lake Imaging, Ballarat, Australia; Imaging at Olympic Park, Melbourne, Australia; Clifton Hill Physiotherapy, Melbourne, Australia; Mill Park Physiotherapy, South Morang, Melbourne, Australia; and Complete Sports Care, Hawthorn, Melbourne, Australia.

Data statement

Dataset will be publicly available after publication of study findings at Figshare (add url on publication)

Author contributions

JLK and KMC conceived the study design. JLK and RTJ prepared the manuscript. SLC, DMJ, AGS, BFM, MGK, MJS, DOS, AJS, SMM, and KMC all contributed to the drafting of the manuscript and approved the final version.

Competing interests

The authors declare that they have no competing interests.

Patient consent

Obtained.

Ethics Approval

Ethical approval was obtained from the La Trobe University Human Ethics Committee registration number HEC 17-080.

Funding

Dr J L Kemp is funded by the National Health and Medical Research Council of Australia (NHMRC ECF GNT:1119971).

Provenance and peer review

Not commissioned; externally peer reviewed.

Figure Legends

Figure 1. Diagrammatic representation of cam morphology at the femoral head-neck junction.[7]

Figure 2. Alpha angle measurement from AP radiograph.[30]

Figure 3. Study procedure flow-chart.

Figure 4. An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises.

References

1. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2020:bjsports-2019-101453. doi: 10.1136/bjsports-2019-101453
2. Vos T, Lim SS, Abbafati C, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet* 2020;396(10258):1204-22. doi: 10.1016/S0140-6736(20)30925-9

3. Griffin DR, Dickenson EJ, O'Donnell J, et al. The Warwick Agreement on femoroacetabular impingement syndrome (FAI syndrome): an international consensus statement. *Br J Sports Med* 2016;50(19):1169-76. doi: 10.1136/bjsports-2016-096743 [published Online First: 2016/09/16]
4. Mascarenhas VV, Rego P, Dantas P, et al. Imaging prevalence of femoroacetabular impingement in symptomatic patients, athletes, and asymptomatic individuals: A systematic review. *European journal of radiology* 2016;85(1):73-95. doi: 10.1016/j.ejrad.2015.10.016 [published Online First: 2016/01/03]
5. Agricola R, Waarsing JH, Thomas GE, et al. Cam impingement: defining the presence of a cam deformity by the alpha angle: Data from the CHECK cohort and Chingford cohort. *Osteoarthritis and Cartilage* 2014;22(2):218-25. doi: https://doi.org/10.1016/j.joca.2013.11.007
6. Kemp JL, Coburn SL, Jones DM, et al. The Physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A Pilot Randomized Controlled Trial. *J Orthop Sports Phys Ther* 2018;48(4):307-15. doi: 10.2519/jospt.2018.7941 [published Online First: 2018/04/03]
7. Brukner P, Khan K. Brukner & Khan's Clinical Sports Medicine: Injuries, Fifth Edition: McGraw-Hill Education (Australia) 2016.
8. Byrd JWT. Femoroacetabular impingement in athletes, part 1: cause and assessment. *Sports health* 2010;2(4):321-33. doi: 10.1177/1941738110368392
9. Byrd JWT, Jones KS. Arthroscopic femoroplasty in the management of cam-type femoroacetabular impingement. *Clin Orthop Relat Res* 2009;467(3):739-46. doi: 10.1007/s11999-008-0659-8 [published Online First: 12/19]
10. Weir A, Brukner P, Delahunt E, et al. Doha agreement meeting on terminology and definitions in groin pain in athletes. *Br J Sports Med* 2015;49(12):768-74. doi: 10.1136/bjsports-2015-094869 [published Online First: 2015/06/03]
11. Kemp JL, Beasley I. 2016 international consensus on femoroacetabular impingement syndrome: the Warwick Agreement-why does it matter? *Br J Sports Med* 2016;50(19):1162-3. doi: 10.1136/bjsports-2016-096831 [published Online First: 2016/09/16]
12. Kemp JL, Risberg MA, Mosler A, et al. Physiotherapist-led treatment for young to middle-aged active adults with hip-related pain: consensus recommendations from the International Hip-related Pain Research Network, Zurich 2018. 2019:bjsports-2019-101458. doi: 10.1136/bjsports-2019-101458 %J British Journal of Sports Medicine
13. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Care Res (Hoboken)* 2020;72(2):149-62. doi: 10.1002/acr.24131 [published Online First: 2020/01/08]
14. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society* 2018;27(11):2791-803. doi: 10.1007/s00586-018-5673-2 [published Online First: 2018/07/05]
15. Bussières AE, Stewart G, Al-Zoubi F, et al. The Treatment of Neck Pain–Associated Disorders and Whiplash-Associated Disorders: A Clinical Practice Guideline. *Journal of Manipulative & Physiological Therapeutics* 2016;39(8):523-64.e27. doi: 10.1016/j.jmpt.2016.08.007

16. Griffin DR, Dickenson EJ, Wall PDH, et al. Hip arthroscopy versus best conservative care for the treatment of femoroacetabular impingement syndrome (UK FASHIoN): a multicentre randomised controlled trial. *The Lancet* 2018;391(10136):2225-35. doi: 10.1016/S0140-6736(18)31202-9
17. Mansell NS, Rhon DI, Meyer J, et al. Arthroscopic surgery or physical therapy for patients with femoroacetabular impingement syndrome: a randomized controlled trial with 2-year follow-up. *Am J Sports Med* 2018:363546517751912. doi: 10.1177/0363546517751912 [published Online First: 2018/02/15]
18. Palmer AJR, Ayyar Gupta V, Fernquest S, et al. Arthroscopic hip surgery compared with physiotherapy and activity modification for the treatment of symptomatic femoroacetabular impingement: multicentre randomised controlled trial. *BMJ* 2019;364:l185. doi: 10.1136/bmj.l185
19. Freke MD, Kemp J, Svege I, et al. Physical impairments in symptomatic femoroacetabular impingement: a systematic review of the evidence. *Br J Sports Med* 2016;50(19):1180. doi: 10.1136/bjsports-2016-096152 [published Online First: 2016/06/16]
20. Kemp JL, Collins NJ, Makdissi M, et al. Hip arthroscopy for intra-articular pathology: a systematic review of outcomes with and without femoral osteoplasty. *Br J Sports Med* 2012;46(9):632-43. doi: 10.1136/bjsports-2011-090428 [published Online First: 2011/12/24]
21. Reiman MP, Thorborg K, Holmich P. Femoroacetabular Impingement Surgery Is on the Rise-But What Is the Next Step? *J Orthop Sports Phys Ther* 2016;46(6):406-8. doi: 10.2519/jospt.2016.0605 [published Online First: 2016/06/02]
22. McLeod C, Norman R, Litton E, et al. Choosing primary endpoints for clinical trials of health care interventions. *Contemp Clin Trials Commun* 2019;16:100486-86. doi: 10.1016/j.conctc.2019.100486
23. Chan AW, Tetzlaff JM, Gotzsche P, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346(e7586)
24. Agricola R, Heijboer MP, Bierma-Zeinstra SMA, et al. Cam impingement causes osteoarthritis of the hip: A nationwide prospective cohort study (CHECK). *Annals of the Rheumatic Diseases* 2013;72(6):918-23.
25. Kellgren JH, Lawrence JS. Radiological Assessment of Osteoarthrosis. *Ann Rheum Dis* 1957;16:494-502.
26. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical Journal* 2014;348 doi: 10.1136/bmj.g1687
27. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
28. Crossley K, Grimaldi A, Kemp J. Grieve's Modern Musculoskeletal Physiotjerapy. Hip Related Pain. 4th ed. London2015.
29. JL K, KM C, AG S, et al. Hip-related pain. In: PD B, Khan KM, KM C, et al., eds. Brukner and Khan's Clinical Sports Medicine. Sydney: McGraw Hill 2017.
30. Kemp JL, Moore K, Fransen M, et al. A phase II trial for the efficacy of physiotherapy intervention for early-onset hip osteoarthritis: study protocol for a randomised controlled trial. *Trials* 2015;16:26. doi: 10.1186/s13063-014-0543-7 [published Online First: 2015/01/28]
31. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes.

Journal of science and medicine in sport / Sports Medicine Australia 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
32. Medicine ACoS. ACSM's guidelines for exercise testing and prescription. 10th ed. Philadelphia, PA.: Wolters Kluwer/Lippincott Williams & Wilkins 2017.
33. Mohtadi NG, Griffin DR, Pedersen ME, et al. The Development and validation of a self-administered quality-of-life outcome measure for young, active patients with symptomatic hip disease: the International Hip Outcome Tool (iHOT-33). *Arthroscopy* 2012;28(5):595-605; quiz 06-10.e1. doi: 10.1016/j.arthro.2012.03.013 [published Online First: 2012/05/01]
34. Impellizzeri FM, Jones DM, Griffin D, et al. Patient-reported outcome measures for hip-related pain: a review of the available evidence and a consensus statement from the International Hip-related Pain Research Network, Zurich 2018. 2020:bjsports-2019-101456. doi: 10.1136/bjsports-2019-101456 %J British Journal of Sports Medicine
35. Kemp JL, Collins NJ, Roos EM, et al. Psychometric properties of patient-reported outcome measures for hip arthroscopy. *American Journal of Sports Medicine* 2013;41:2065-73. doi: http://dx.doi.org/10.1016/j.joca.2013.02.582
36. Mohtadi NGH, Griffin DR, Pedersen ME, et al. The Development and Validation of a Self-Administered Quality-of-Life Outcome Measure for Young, Active Patients With Symptomatic Hip Disease: The International Hip Outcome Tool (iHOT-33). *Arthroscopy: The Journal of Arthroscopic & Related Surgery* 2012;28(5):595-610.e1. doi: http://dx.doi.org/10.1016/j.arthro.2012.03.013
37. ten Klooster PM, Drossaers–Bakker KW, Taal E, et al. Patient-perceived satisfactory improvement (PPSI): Interpreting meaningful change in pain from the patient's perspective. *Pain* 2006;121(1–2):151-57. doi: http://dx.doi.org/10.1016/j.pain.2005.12.021
38. Thorborg K, Hölmich P, Christensen R, et al. The Copenhagen Hip and Groin Outcome Score (HAGOS): development and validation according to the COSMIN checklist. *British Journal of Sports Medicine* 2011;45(6):478. doi: 10.1136/bjsm.2010.080937
39. Thorborg K, Branci S, Stensbirk F, et al. Copenhagen hip and groin outcome score (HAGOS) in male soccer: reference values for hip and groin injury-free players. *British Journal of Sports Medicine* 2014;48(7):557. doi: 10.1136/bjsports-2013-092607
40. Beaton DE, Tang K, Gignac MA, et al. Reliability, validity, and responsiveness of five at-work productivity measures in patients with rheumatoid arthritis or osteoarthritis. *Arthritis Care Res (Hoboken)* 2010;62(1):28-37. doi: 10.1002/acr.20011 [published Online First: 2010/03/02]
41. Conner-Spady BL, Marshall DA, Bohm E, et al. Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. *Quality of Life Research* 2015;24(7):1775-84. doi: 10.1007/s11136-014-0910-6
42. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research* 2011;20(10):1727-36. doi: 10.1007/s11136-011-9903-x
43. Nakawaki M, Fukushima K, Inoue G, et al. Use of the painDETECT questionnaire to differentiate the nature of hip pain associated with a labrum tear. *Asia-Pacific Journal of Sports Medicine, Arthroscopy, Rehabilitation and Technology* 2018;11:1-5. doi: https://doi.org/10.1016/j.asmart.2017.10.002

44. Tampin B, Bohne T, Callan M, et al. Reliability of the English version of the painDETECT questionnaire. *Current Medical Research and Opinion* 2017;33(4):741-48. doi: 10.1080/03007995.2017.1278682
45. Campbell P, Hill JC, Protheroe J, et al. Keele Aches and Pains Study protocol: validity, acceptability, and feasibility of the Keele STarT MSK tool for subgrouping musculoskeletal patients in primary care. *Journal of pain research* 2016;9:807-18. doi: 10.2147/jpr.s116614 [published Online First: 2016/10/30]
46. Miller RP KS, Todd D. "The Tampa Scale: A Measure of Kinisophobia.". *The Clinical Journal of Pain* 1991;7(1):51-52.
47. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000;85(3):317-32. [published Online First: 2000/04/27]
48. Kvist J, Ek A, Sporrstedt K, et al. Fear of re-injury: a hindrance for returning to sports after anterior cruciate ligament reconstruction. *Knee Surgery, Sports Traumatology, Arthroscopy* 2005;13(5):393-97. doi: 10.1007/s00167-004-0591-8
49. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16:292-96.
50. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]
51. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
52. Culvenor AG, Collins NJ, Vicenzino B, et al. Predictors and effects of patellofemoral pain following hamstring-tendon ACL reconstruction. *Journal of Science and Medicine in Sport* 2016;19(7):518-23. doi: https://doi.org/10.1016/j.jsams.2015.07.008
53. Lee S, Nardo L, Kumar D, et al. Scoring Hip Osteoarthritis with MRI (SHOMRI): a Novel Whole Joint Osteoarthritis Evaluation System. *Journal of Magnetic Resonance Imaging* 2015;41(6):1549-57.
54. Jones D, Crossley K, Dascombe B, et al. VALIDITY AND RELIABILITY OF THE FITBIT FLEX™ AND ACTIGRAPH GT3X+ AT JOGGING AND RUNNING SPEEDS. *International journal of sports physical therapy* 2018;13(5):860-70.
55. Chan A-W, Tetzlaff JM, Gøtzsche PC, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ : British Medical Journal* 2013;346:e7586. doi: 10.1136/bmj.e7586
56. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. *The Journal of manual & manipulative therapy* 2009;17(3):163-70. doi: 10.1179/jmt.2009.17.3.163

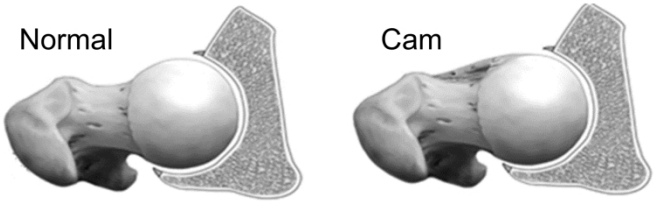


Figure 1
Diagrammatic representation of cam morphology at the femoral head-neck junction

338x190mm (400 x 400 DPI)

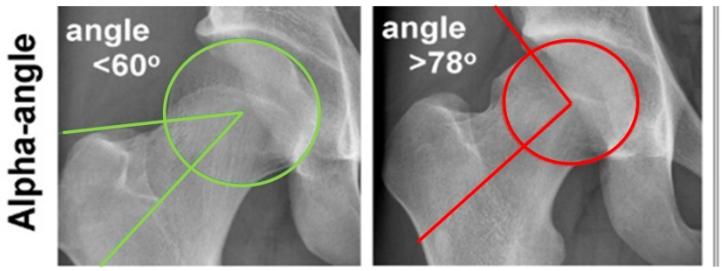


Figure 2
Alpha angle measurement from AP radiograph

338x190mm (400 x 400 DPI)

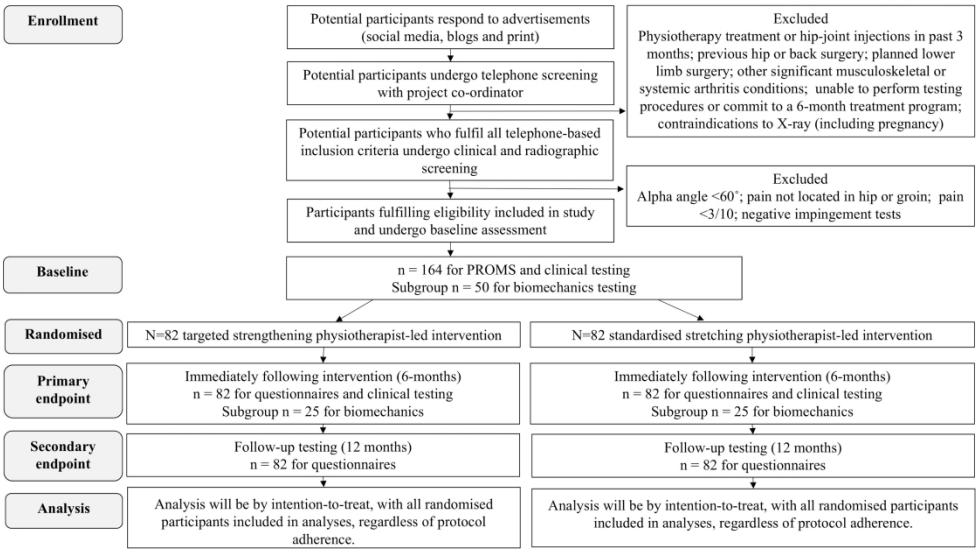


Figure 3. Study procedure flow-chart.

338x190mm (300 x 300 DPI)

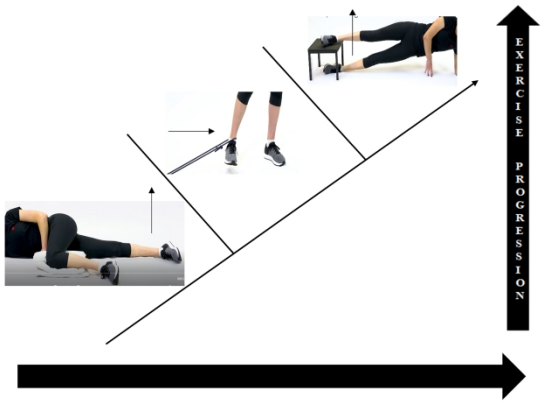


Figure 4
An example of how an individual participant is given progressive, targeted hip adductor strengthening exercises

338x190mm (400 x 400 DPI)

Supplementary File 1: Targeted Physiotherapist-led treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Lion group refers to the progressive, semi-standardised rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The six components of the rehabilitation program were selected based on current knowledge of the highest level of evidence for physical impairments in FAI, and from the results of our recent pilot study.

The six key components targeted in this program include:

1. **ROM (flexion)**
2. **Hip muscle strength (Extension, Abduction, Adduction)**
3. **Trunk strength/endurance**
4. **Functional task performance (strength and plyometric)**
5. **Cardiovascular training/load management**
6. **Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Review of exercise program and progression of program as appropriate, for each of the targeted elements (hip adductor, abductor, extensor strength, trunk strength, functional strength and plyometric). ***Note: each patient should always be doing one exercise from each targeted element.*** See Tables 2-7 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
5. Review of cardiovascular fitness program as appropriate. See Table 8 for details below. Progression to the next level will be determined by successful completion of the previous level, while maintaining VAS <20mm and Borg perceived exertion ≤5 (moderate).
6. Tailored education based on patient preference, three patient-focussed goals, and other topics raised by patient during treatment. Answers to common questions outlined below in Table 9.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, the 3 patient-focussed goals, and ensure patient appointments are booked into the system.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current exercises in hip strength (adduction, abduction, extension), trunk strength and functional strength exercises, including full sets and reps.
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app
3. Progression of exercises for each of the targeted elements where appropriate
4. Continuation of tailored education program

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Hip extension strength program

Extension			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging Gluteal squeeze and lift up into bridge hold and lower	3x10 reps 5 sec hold Weight = 10RM (10kg max)

2		Single leg Bridging Gluteal squeeze and lift up into bridge position, extend one leg, hold, extend other leg, hold, lower	3x10 reps 5 sec holds Weight = 10RM (10kg max)
3		Prone Hold Hip Extension - knees From knees move affected leg into hip extension, hold and lower leg, Cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
4		Prone Hold Hip Extension - toes From toes move affected leg into hip extension, hold and lower leg, cuff weight on ankle	3x10 reps 5 sec hold Weight = 10RM (5kg max)
5		Standing single leg arabesque, weight in opposite hand	3x10 reps 5 sec ecc, 5 sec conc Weight = 10RM (10kg max)
6		Standing single leg arabesque, weight in opposite hand	3x20 reps 5 sec ecc, 5 sec conc Weight = 20RM (10kg max)

Table 3: Hip abduction strength program

Abduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridging with band Bridge with band around knees, gently abduct against light band.	1x20 reps 5kg on pelvis 5 sec hold Band = 20RM
2		Bridging with band Bridge with band around knees, gently abduct against light band.	3x10 reps 5 kg on pelvis 5 sec hold Band = 10RM
3		Bridging with band Bridge with band around knees, gently abduct against heavy band.	3x10 reps 10 kg on pelvis 5 sec hold Band = 10 RM
4		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both feet on ground.	3x10 reps 5kg on pelvis 5 sec hold Band = 10RM

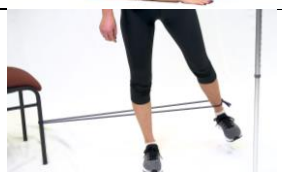
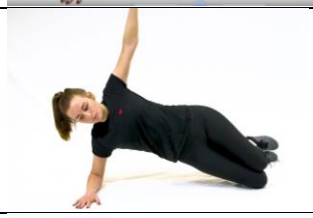
5		Bridge with band, leg extension Start: lift up with two feet on ground, extend one leg then the other then lower with both legs on ground.	3x10 reps 10kg on pelvis 5 sec hold Band = 10RM
6		Standing abduction with band or pulley, abduction to 30-45˚	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
7		Side lie abduction with band	3x10 reps 3 sec conc 3 sec ecc Band = 10RM

Table 4: Hip adduction strength program

Adduction			
Phase	**Exercise**	**Description**	**Dosage**
1		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	1x30 reps 5 sec hold 5 kg on hips
2		Bridge position, heavy band around thigh turning knee out. Pull knee to midline against band and maintain position throughout. Lift bottom, hold 3 secs and lower	2x30 reps 5 sec hold 5 kg on hips
3		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	2x8 reps 5 sec hold
4		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x8 reps 5 sec hold
5		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold
6		Side lie, affected leg down. Keep leg in neutral alignment, small lift, hold 3 secs and lower	3x10 reps 5 sec hold Cuff weight = 10RM, 5kg max

7		Standing adduction with band or pulley	3x10 reps 3 sec conc 3 sec ecc Band/pulley = 10RM
8		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower	3x10 reps 5 sec hold
9		Copenhagen adduction: unaffected leg on step, affected leg down, small lift hold 3 secs and lower. Cuff weight on ankle	3x10reps 5 sec hold Cuff weight = 10RM

Table 5: Trunk strength and endurance program

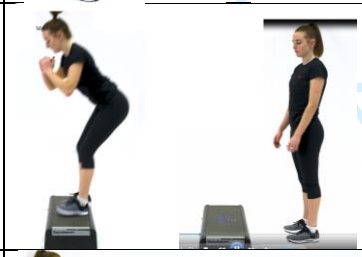
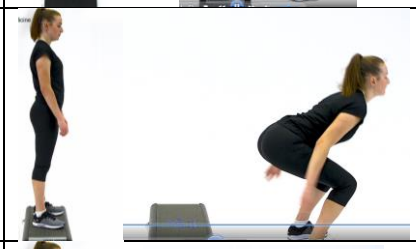
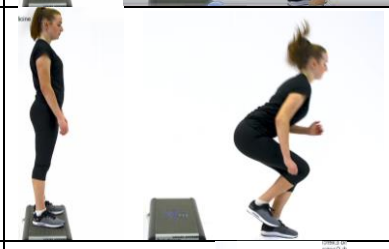
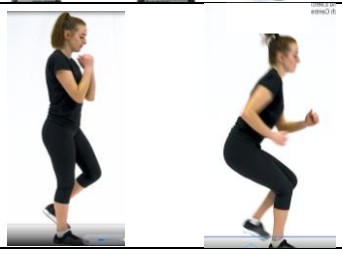
Trunk muscle strength (both sides in all patients)			
Phase	**Exercise**	**Description**	**Dosage**
1		Side bridge knees	30 secs hold 5 reps each side
2		Side bridge knees with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
3		Side bridge toes	30 secs hold 5 reps each side
4		Side bridge toes with arm lifts, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM
5		Side bridge toes with arm rotations, can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

6		Side plank with stability ball	30 secs hold 5 reps each side
7		Side plank with stability ball, with arm lifts. Can add dumbbell in top hand	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM

Table 6: Functional strengthening program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1	Box/chair squats.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing	3x10 reps 5 secs conc, 5 secs ecc
2	Box/chair squats with weight.	Flex at hips and squat to comfortable depth, tighten gluteal muscles to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
3	Backwards lunges.	Step back and drop back knee towards ground, then stand up. Ensure good alignment	3x10 reps each side 5 secs conc, 5 secs ecc
4	Backwards lunges with weight.	Step back and drop back knee towards ground, then stand up. Ensure good alignment. Hold weight plate to chest	3x10 reps each side 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
5	Repeater Step Ups	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor.	3x10 reps 5 secs conc, 5 secs ecc
6	Repeater Step Ups with weight	Stand on step on one foot, good alignment. Bring other knee up to hip level in front, then back down to touch floor. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)
7	Single Leg Squats	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing	3x10 reps 5 secs conc, 5 secs ecc
8	Single Leg Squats with weight	Stand on affected side, squat down to touch box/chair ensuring good alignment. Tighten gluteals to return to standing. Hold weight plate to chest	3x10 reps 5 secs conc, 5 secs ecc Weight = 10RM (10kg max)

Table 7: Functional plyometric program

Functional task			
Phase	**Exercise**	**Description**	**Dosage**
1		Jump forwards as far as possible – double leg take-off and landing	20 reps
2		Jump forwards as far as possible – double leg take off, single leg landing	20 reps each leg
3		Jump up onto box/step double leg take-off and landing	20 reps
4		Jump down off box/step/bosu double leg take-off and landing	20 reps
5		Jump down off box/step/bosu double leg take off, single leg landing	20 reps each side
6		Single leg hop forwards	20 reps each leg

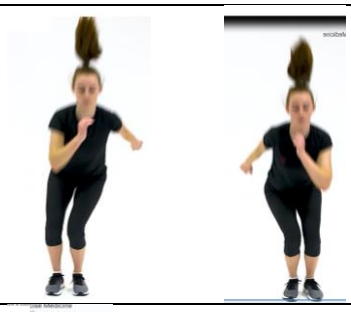
7		Multidirectional jump double leg	20 reps
8		Multidirectional hop single leg	20 reps each leg

Table 8: Cardiovascular fitness progressive program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	10 minutes every second day
2	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	20 minutes every second day
3	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes every second day
4	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	30 minutes total, including 5x60 seconds high intensity every second day
5	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic	30 minutes including up to 10x60secs or 5x2 minutes

		activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	high intensity every second day
6	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breaststroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	45 minutes including up to 15 minutes total high intensity every second day
7	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	15 mins every second day (can be combined with 30 mins level 1 activity)
8	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	20 mins every second day (can be combined with 25 mins level 1 activity)
9	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	30 mins every second day (can be combined with 20 mins level 1 activity)
10	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	45 mins every second day, including 10 mins higher intensity (can be combined with 15 mins level 1 activity)
11	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	50 mins every second day, including 20 minutes high intensity (can be combined with 10 mins level 1 activity).
12	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	Up to 1 hour, 3 time/week, full load

Table 9. Key education components

1.	Weight maintenance with recommended weight loss if BMI ≥ 25. This may require referral to dietician or GP. Generally, evidence suggests that a 3kg weight loss can result in 25% reduction in symptoms in people with OA.
2.	Patients' expectations of treatments. Hip pain due to FAI is not "curable" but can be well managed with appropriate treatment. Flares of pain are common and usually settle well with appropriate physiotherapy treatment. Small increases in pain (up to 3/10) can occur when starting or increasing exercises. This is nothing to be afraid of, and will settle as the body adapts to the new activity. It is of paramount importance to not completely rest, as this reduces this body's capacity to cope with normal day-to-day loads.
3.	Patients' specific goals of treatment, based on baseline assessment. Important to discuss with patient whether these are appropriate, and then plan to most appropriately achieve these.

4.	Patients' expectations of returning to sport, and whether this is possible. This may require a modification of expectations. To date there is no evidence to indicate that running sports, and kicking sports are likely to lead to short-term and long-term problems in people with FAI, and in most patients, it is possible to return to these types of activity in a sensible and gradually progressive way.

Supplementary File 2: Standardised treatment therapist handbook

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (physioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

The Tiger group refers to the usual care, control group rehabilitation program for patients with femoroacetabular impingement (FAI).

The treatment program lasts for 6 months and has two phases. Phase 1 refers to months 0-3; Phase 2 refers to month 4-6 of treatment. Both phases target six key components of treatment. The four components of the rehabilitation program were selected to represent what could be "usual care" for hip pain, and has been tested in our pilot study

The four key components of the control program include:

1. **ROM (flexion)**
2. **Standardised stretching**
3. **Standardised cardiovascular training/load management advice**
4. **Standardised Education**

The two phases of treatment are outlines below.

Phase 1 month 0-3

This phase consists of

i. Fortnightly one-on-one consultations with the treating physiotherapist;
ii. Weekly physiotherapist-supervised gym sessions (these can be one-on-one or small groups, as long as there is no cross-contamination between the lion and tiger groups, where patients from each group attend the gym at the same time. This is critical for patient-blinding and the integrity of the study design).
iii. Twice-weekly unsupervised exercise at home or in gym, patients' preference.

Phase 2 month 4-6

This phase consists of

i. Monthly one-on-one consultations with the treating physiotherapist
ii. Three times weekly unsupervised gym visits.

Details of one-on-one physiotherapy consultations (6 in phase 1, 3 in phase 2), physiotherapy supervised gym visits (12 in phase 1) and unsupervised gym visits (3 times week in phase 2) are detailed below.

One-on-one physiotherapy visits

These visits should last 30 minutes each. During these visits, the following should be completed

1. Flexion range of motion measured and recorded using inclinometer
2. Abduction and Adduction strength measured and recorded using hand-held dynamometer
3. Manual therapy as appropriate targeted to impairments in range of motion, and pain management. Details of therapy selection and progression outlined in Table 1 below.
4. Provision of standardised stretching program. See Table 2 for each weekly set of exercises
5. Provision of standardised cardiovascular fitness program. This should be handed out in first treatment and patient asked to progress self through program. See Table 3 for details below.
6. Standardised education Table 4.

Note: prior to the initial physiotherapy visit, the project investigator (Joanne Kemp) will contact the treating physiotherapist and provide them with details to access the exercise app, and ensure patient appointments are booked into the system.

Please note, if patients complain of increasing pain during treatment that is concerning them or you, please contact Joanne Kemp to discuss. Do not allow the patient to continue to deteriorate without discussion.

Physiotherapy-supervised gym visits

These visits should last 30-60 minutes, depending on clinic and patient preference. These can be one-on-one or small group, as long as no cross-contamination occurs where patients from each of the two treatment groups attend at the same time. During these visits, the following should be completed

1. Completion of all current stretching exercises
2. Checking patient recording of exercises from that session (and unsupervised sessions) in exercise diary or exercise app

Unsupervised gym program

Each patient will be given a gym membership for phase 2 of the program, and will be asked to

1. Attend the gym 3 times per week
2. Record each session in exercise diary or exercise app
3. Report any issues with program to the treating physiotherapist during one of the monthly one-on-one visits. Patients will also be able to contact the project investigator (Joanne Kemp) during this time with any questions about the program.

Table 1: Manual therapy overview

Target for treatment	Assessment method	Technique	Aim	Description	Dosage
Overactive secondary stabilisers	Palpation, pain, reduced ROM	Soft tissue massage and trigger point release of iliopsoas, adductor group, gluteus minimus, gluteus medius, piriformis, tensor fascia latae, erector spinae	Address soft tissue restrictions with the aim of reducing pain and increasing hip joint range of movement	Sustained digital pressure to each trigger point with the muscle positioned on stretch Massage longitudinally along the muscle belly	30-60 seconds digital pressure per trigger point 2-5 minutes of massage per muscle
Lumbar dysfunction	Pain, palpation, ROM	Mobilisation of lumbar spine	To improve lumbar spine mobility and restore normal lumbo-pelvic movement	Unilateral postero-anterior accessory glides, Grade III or IV	3-5 sets of 30-60 seconds
Capsular tightness	Palpation of femoral head glide in squat	Manual traction if ligamentum teres is intact or ligated and patient is >3 months post labral repair	Increase hip flexion and/or IR/ER range of motion	Seatbelt around patient's proximal femur and therapist's hips. Gentle inferior and/or lateral traction force applied. May include patient actively moving hip into flexion as traction is applied	3 sets of 10 seconds. If tolerated increase by 1 set per treatment session to a maximum of 6 sets in total
Bony limitations	Hard end feel in ROM tests	None	Treat with respect	None	N/A
Hip muscle weakness	Hand held dynamometry	See section 2	See section 2	See section 2	See section 2

Table 2: Weekly stretching program

Week 1								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip Flexor stretch off plinth.	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Thoracic rotation in supine	5 x 5sec holds to each side
	b) Short adductor stretch	30 sec hold, repeat x3,					b) Trunk rotation in Supine	5 x 5sec holds to each side.
	c) Hamstring stretch	Symptomatic leg 30 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 2								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Trunk rotation in Supine	5 x 5sec holds to each side.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in Supine	5 x 5sec holds to each side.
	b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 30 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 40 sec hold, repeat x3.						
	d) ITB stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 3								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 30 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Short adductor stretch	60 sec hold, repeat x2.		b) Soleus stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) ITB stretch	Symptomatic leg 60 sec hold, repeat x2.						

Week 4								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 40 sec hold, repeat x3.		a) Gastroc wall stretch	Symptomatic leg 60 sec hold, repeat x2.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		c) Tib Ant stretch	Symptomatic leg 30 sec hold, repeat x3.		b) Single leg trunk rotation in supine	Alternate sides 40 sec hold, repeat x3 to each side.
	c) Hold/relax Hamstring stretch (Therapist assisted)	At movement barrier, 20% contraction x 3.						
	d) Gluteal stretch	Symptomatic leg 30 sec hold, repeat x3.						

Week 5								
Hip			**Lower leg**			**Trunk**		
Exercise	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**	**Exercise**	**Description**	**Dosage**
	a) Hip flexor stretch in kneel	Symptomatic leg 60 sec hold, repeat x2.		a) Calf roller stretch	Symptomatic leg 40 sec x 2.		a) Trunk rotation in standing	5 x 5sec holds to each side
	b) Adductor stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		c) Tib Ant stretch in kneeling	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	40 sec hold x 2
	c) Hamstring stretch	Symptomatic leg 60 sec hold, repeat x2.						
	d) Gluteal stretch	Symptomatic leg 40 sec hold, repeat x3.						

Week 6								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in standing	5 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Lat dorsi and trunk stretch in prone kneel	60 sec hold x 2
	c) Hamstring foam roller in sitting	Bilateral, 40 sec x 2.					c) Elbow prop lumbar extension in prone	
	d) Gluteal stretch on wall	Symptomatic leg 30 sec hold, repeat x3.						

Week 7								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in side lying	Symptomatic leg 40 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Adductor stretch in standing	Symptomatic leg 60 sec hold, repeat x2.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) Gluteal stretch on wall	Symptomatic leg 40 sec hold, repeat x3.					c) Elbow prop lumbar extension in prone	5 x 5sec holds.
	d) Gluteal foam roller	Symptomatic leg 40 sec x 2.						

Week 8								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) LL calf stretch	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 3 to each side.
	b) Hamstring- stretch standing	Symptomatic leg 30 sec hold, repeat x3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Salute to the sun	3 x 5sec holds at end of range extension and flexion
	d) ITB standing with side trunk flexion	Symptomatic leg 30 sec x 3.						

Week 9								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in prone	Symptomatic leg 60 sec hold, repeat x2.		a) calf stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Trunk rotation in 4 point kneel	3 x 5sec holds to each side.
	b) Hamstring- hold/relax (therapist assisted)	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 30 sec hold, repeat x3.		b) General trunk stretch in standing	3 x 5sec holds.
	c) ITB stretch with roller	Symptomatic leg 60-240 sec ,					c) Extension in lying	5 x 5 second holds
	d) ITB standing	Symptomatic leg 30 sec x 3.						

Week 10								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Trunk rotation + hip flexion in standing	5 second holds, repeat x 5 to each side.
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) calf stretch in standing	Symptomatic leg 40 sec hold, repeat x3.		b) Thoracic extension and pec stretch with towel	3 x 30 sec holds
	c) Gluteal foam roller	Symptomatic leg 60-120 sec.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 11								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) Calf roller stretch	Symptomatic leg 60-120 sec.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) ITB standing	Symptomatic leg 40 sec hold, repeat x3.		b) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Week 12								
Hip			**Lower leg**			**Trunk**		
	Description	**Dosage**		**Description**	**Dosage**		**Description**	**Dosage**
	a) Quad stretch in standing	Symptomatic leg 30 sec hold, repeat x3.		a) LL calf stretch	Symptomatic leg 40 sec hold, repeat x3.		a) Thoracic extension and pec stretch with towel	3 x 40 sec holds
	b) Hold/relax short adductor stretch	At movement barrier, 20% contraction x 3.		b) Gastroc stretch 4 pt kneel	Symptomatic leg 60 sec hold, repeat x2.		b) ITB + trunk lateral flexion	Symptomatic leg 40 sec hold, repeat x3,
	c) Piriformis stretch in prone	Symptomatic leg 40 sec hold, repeat x3.					c) Salute to the sun	5 x 5sec holds at end ext and flexion
	d) Hamstring stretch standing	Symptomatic leg 40 sec hold, repeat x3.						

Table 3: Cardiovascular fitness standardised program

Cardiovascular training			
Phase	**Exercise**	**Description**	**Dosage**
1	Level 1 patient choice	Cycling (stationary or road bike, no MTB); swimming (no breastroke); other aquatic activity (water aerobics, water jogging no egg beater kick); walking (on flat terrain, no beach or bush walking); kayaking; rowing (if flexion ROM >100); elliptical cross trainer.	As much as hip pain will allow. Progress to Level 2 when patient feels ready
2	Level 2 patient choice	Dance, running, MTB, athletics, bush walking, netball, football (all codes), hockey, racquet sports	As much as hip pain will allow

Table 4. Key education components

1.	Weight maintenance with recommended weight loss if BMI ≥ 25. Patients are encouraged to seek their own guidance for weight loss. Specific patient questions can be answered.
2.	Patients' expectations of treatment and activity. Patients are encouraged to do as much activity as their hip pain allows. No specific guidance is offered around activity modification, but patient-specific questions can be answered.

Supplementary File 3
PhysioFIRST Clinical testing procedures

Descriptive measures

Height (m)

Body mass (kg)

Leg length (cm): Distal greater trochanter to lateral knee joint line (centre) and distal greater trochanter to distal tip lateral malleolus

Waist circumference (cm): Measured at navel level

Hip circumference (cm): Measured at widest point of greater trochanter

Pain provocation tests

Hip Internal Rotation Pain[1-3]:

Participant Position: Supine

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90° (zero-degree position). Examiner internally rotates hip to point of resistance, keeping thigh in neutral position (i.e., avoiding abduction, adduction and pelvic tilt). Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Flexion 90°/Adduction/Internal Rotation (FADIR) Pain[1-3]:

Participant Position:

Participant is aligned to right lateral edge of exam table if examining the right hip, aligned to the left lateral edge if examining the left hip.

Method:

Examiner stands on the ipsilateral side of the hip to be examined and passively flexes hip and knee to 90°. Examiner adducts hip to endpoint (while avoiding movement of the pelvis) and then

internally rotates hip, maintaining flexion and adduction components. Examiner asks participant if they “feel pain or discomfort in the inner thigh, upper thigh, hip or groin area”.

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Bent Knee Fall Out (BKFO)[1]*:*

Participant position:

Participant is lying supine with knee of test leg bent so that foot touches contralateral knee.

Method:

Participant externally rotates hip of test leg, so that the bent knee lowers toward exam table. Examiner asks participant if they "feel pain or discomfort in the inner thigh, upper thigh, hip or groin area".

Scoring:

Upper/inner thigh, hip or groin pain **present**-rate pain from **1 to 10;** pain **absent** rate **0 out of 10**

Hip strength tests

All strength tests done with Power track II (Commander). Each strength test will be performed 3 times, 2 seconds to generate maximum force and then 3 seconds as hard as possible. Rest time will be allowed of 5 seconds between each repetition, 30 seconds minimum between each test. Therapist matches participants force (make test).

Supine

Abduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate 5 cm above lateral malleolus.

Participant instructed to *“keep trunk stable and opposite leg still, keep your heel on the bed, toes pointing to the ceiling and push leg out to side against force plate as hard as possible”.*

"go ahead: push-push-push-push-relax"

Adduction strength[4]

Moment arm measured greater trochanter to lateral malleolus ankle.

Participant stabilises trunk by holding exam table.

Test leg resting in hip neutral

Force plate for long lever 5 cm above medial malleolus,

Participant instructed to "*keep trunk stable and opposite leg still, keep heel on the bed, toes pointing towards ceiling and pull leg in to centre against force plate as hard as possible"*

"go ahead: push-push-push-push-relax"

Prone

Extension strength[4 5]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant prone, with test leg knee bent to 90° and positioned off the edge of the foot of the lowered exam table, chin resting on hands.

Force plate attached to Velcro of seatbelt and placed over centre of patient's heel, patient instructed to *"push foot straight up to ceiling"*.

Therapist matches force by placing foot in lower loop of seatbelt using bodyweight as counter resistance.

"Go ahead: push-push-push-push-relax"

External rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to medial malleolus of ankle, therapist on same side of bed, close to lower leg, with two hands on HHD.

Participant instructed to *"keep your trunk and opposite leg still and turn shin inwards towards the centre as hard as possible"*

"go ahead: push-push-push-push-relax"

Internal rotation strength[4]

Moment arm measured from greater trochanter to lateral joint line of knee.

Participant stabilises trunk by holding exam table.

Force plate 5cm proximal to lateral malleolus of ankle, therapist standing on same side of bed close to lower leg, with two hands on HHD laterally.

Participant instructed to *"keep trunk and opposite leg still and turn shin outwards as hard as possible, keeping both knees together"*

"go ahead: push-push-push-push-relax"

Sitting (on end of plinth)

Flexion strength[4]

Moment arm measured greater trochanter to lateral joint line knee

Both legs in resting position (hip 90º flexion), belt across contra-lateral thigh (placed firmly over middle of thigh)

Force plate 5 cm proximal to superior pole patella

Ensure participant is sitting in upright sitting position

Ensure that the contralateral leg is in 90° knee flexion and not being used to stabilise against the underneath of the bed.

Be aware that if you position someone in EOR hip flexion pain will potentially limit the force they can produce. Ensure that the testing leg is raised 1cm off the bed in a comfortable range

Participant instructed to *"sit with arms folded, chest up, not to lean backwards and pull knee up towards chest against force plate"*

"go ahead: push-push-push-push-relax"

Participant instructed to "*keep arms folded, chest up, thigh and knee flat on the bed and turn shin outward, as far as possible, keeping knees together*"

Functional tests

Trunk Muscle Endurance Test[6]

The patients will be positioned in side lying on a plinth/bench or a mat on the floor, with one leg resting directly on top of the other.

Participant instruction will be: "*lift your hips off the bed, supporting your weight through your feet and forearm and hold the position for as long as possible. If you get to 3 min we will stop*"

Encouragement will be given at 30 second intervals throughout the test. The time (seconds) will be recorded from the start of the test until the participant's hips touches the plinth, which represents the end of the test.

One leg rise test[6]

Subject seated on side of plinth, foot placed in position on floor measured 10cm forward from a plumb line at the edge of the plinth, other leg held straight out in front of body, arms at rest by sides

Height of plinth adjusted so knee angle is 90º

Subject instructed to "*keep back of heel on marker, stand as many times as possible on one leg keeping arms by your side, in time with my counting. If you get to 50 we will stop.*

Star Excursion Balance test[7]

We will use the procedures described by Hertel et al (2000), where three test directions are measured; anterior, posteromedial and posterolateral. In addition, we will measure balance in the anterolateral direction. From a centre point identified as a cross, 4 tape measures will be attached to the floor in the anterior, anterolateral, posteromedial and posterolateral directions (see Figure).

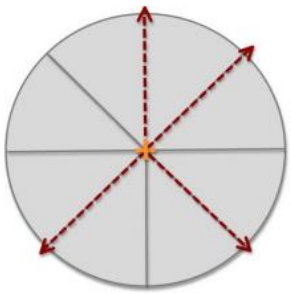


Figure. The test directions of the Star Excursion Balance Test for left leg stance

The test will be performed without shoes, starting with the uninvolved leg as the stance leg and the involved leg as the test leg. The starting position is a single-leg stance in the centre of the cross, with the most distal aspect of the great toe at the starting line and hands on hips.

While maintaining single-leg stance, the patient will be asked to reach with the free limb to touch the tip of their big toe as far as possible in all 4 directions, starting from anterior direction and moving around clockwise. The test leader will mark the reach distance in all four directions. The trial will be judged invalid if the patient i) fails to maintain unilateral stance, ii) lifts or moves the stance foot from the starting point, iii) touches down with the reach foot, or iv) fails to return the reach foot back to the starting position.

The patients will be allowed 1 practice trial in all 4 directions on both legs. Each of the four directions will be recorded on each stance leg, then the same process repeated. Two measures will be recorded for 4 directions on each stance leg, with the best reach for each direction recorded online.

Participant instruction will be: "*Keep your stance foot flat on the floor and hands on hips. Make a reach with your other leg as far as you can and lightly touch the tip of your big toe on the measuring tape, without stepping on it. Without pushing off the ground with your reaching leg, return it back to the centre of the testing grid next to stance foot. You move as much as you like to keep your balance as long as your stance foot is flat and hands are on your hips, otherwise we will repeat test, eg if you slide your foot, miss the tape, lift your heel, move hand off hips or can't return foot to start position.*"

Hop for distance test[6]

Subjects stand on starting line on one foot in bare feet hands held behind back

Instructed to "*hop as far forward as possible landing on the same foot*"

Distance recorded from the back of the landing foot with an inflexible tape measure

Subjects will be given 1 practice and then 3 trials each leg, with the greatest distance for each leg recorded.

Subjects must keep their balance on landing but can put the other foot down to record the distance of the landing foot.

Single Leg Squat[8]

The order of limb testing will be right followed by left to reduce order effects.

Single-leg squat recording:

Performance will be recorded with a digital video camera (HDR-XR150, Sony, Tokyo, Japan) fixed to a tripod. The camera will be positioned at a height of 37 cm, perpendicular to the frontal plane, 3 m in front of the participant.

The participant's unique code will be filmed prior to single-leg squat performance to allow later identification.

Single leg squat set-up:

Bilateral surface landmarks will be marked with black ink over the anterior superior iliac spine, the midpoint between the lateral and medial femoral condyles anteriorly, and the midpoint between the lateral and medial ankle malleoli anteriorly.

Participants will stand in front of standard height stool 65cm from floor to seat, with their foot position standardized on a template whereby the medial edge of the first metatarsophalangeal joint and the center of the posterior aspect of the heel were lined up on parallel lines 12 cm apart, and heel 10 cm from point where a vertical line at edge of stool touches the floor.

Single leg squat performance:

Participants will stand on their right leg with the trunk upright and contralateral leg in approximately 20° of hip flexion, with the knee extended and toes off the floor (Figure I).

Participant instruction will be “Hold this starting position for 3 seconds, then lower pelvis down until the buttocks lightly touch the stool (Figure II) and return to the starting position, taking 4 seconds in total.

Five consecutive squats will be performed, and the procedure repeated on the left leg.

Range of motion tests

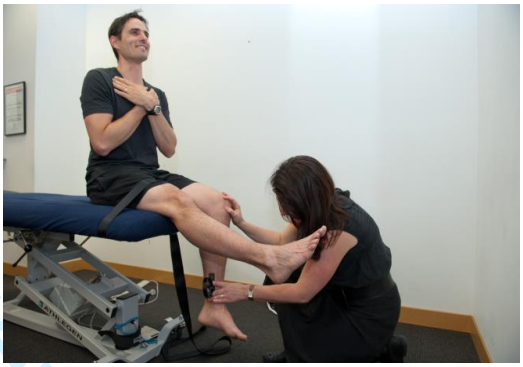
Flexion range of motion[9]

Both legs extended at rest, contra-lateral leg restrained with seat belt (placed firmly over middle of thigh), arms crossed over chest

Centre of inclinometer triangle placed on testing thigh 5cm above superior pole of patella, starting angle noted.

Participant instructed to *"keep arms folded and bend knee towards chest as far as possible"*.

Active external rotation range of motion



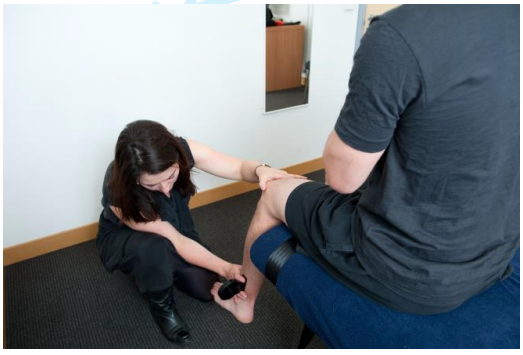
Sitting on the end of the plinth, belt over contra-lateral thigh

Centre of inclinometer triangle held to inside of shin 5 cm proximal to medial malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright position

Participant instructed "*keep arms folded, chest up and turn shin inward as far as possible, keeping thigh and knee flat and keeping other knee extended to allow clearance*"

Active internal rotation range of motion



Sitting on end of plinth, belt over contra-lateral thigh (placed firmly over middle of thigh)

Centre of Inclinometer triangle held to inside of shin 5 cm above lateral malleolus of ankle, starting angle at zero.

Ensure participant is sitting in upright sitting position

Participant instructed "*keep arms folded, chest up and turn shin outward as far as possible, keeping thigh and knee flat and buttocks flat on the bed*"

References for Supplementary File 3.

1. Reiman MP. Orthopedic Clinical Examination 1ed. USA: Human Kinetics Publishers 2016.
2. Reiman MP, Agricola R, Kemp JL, et al. Consensus recommendations on the classification, definition and diagnostic criteria of hip-related pain in young and middle-aged active adults from the International Hip-related Pain Research Network, Zurich 2018. *British Journal of Sports Medicine* 2019;Online first doi: doi: 10.1136/bjsports-2019-101453
3. Reiman MP, Goode AP, Cook CE, et al. Diagnostic accuracy of clinical tests for the diagnosis of hip femoroacetabular impingement/labral tear: a systematic review with meta-analysis. *British Journal of Sports Medicine* 2015;49(12):811-11. doi: 10.1136/bjsports-2014-094302
4. Kemp JL, Schache AG, Makdissi M, et al. Greater understanding of normal hip physical function may guide clinicians in providing targeted rehabilitation programmes. *Journal of science and medicine in sport / Sports Medicine Australia* 2013;16(4):292-6. doi: 10.1016/j.jsams.2012.11.887 [published Online First: 2012/12/26]
5. Crossley KM, Pandy MG, Majumdar S, et al. Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study. *J Physiother* 2018;64(1):55. doi: 10.1016/j.jphys.2017.10.004 [published Online First: 2018/01/01]
6. Kemp JL, Risberg MA, Schache AG, et al. Patients With Chondrolabral Pathology Have Bilateral Functional Impairments 12 to 24 Months After Unilateral Hip Arthroscopy: A Cross-sectional Study. *J Orthop Sports Phys Ther* 2016;46(11):947-56. doi: 10.2519/jospt.2016.6577 [published Online First: 2016/11/03]
7. Risberg MA, Ageberg E, Nilstad A, et al. Arthroscopic Surgical Procedures Versus Sham Surgery for Patients With Femoroacetabular Impingement and/or Labral Tears: Study Protocol for a Randomized Controlled Trial (HIPARTI) and a Prospective Cohort Study (HARP). *J Orthop Sports Phys Ther* 2018;48(4):325-35. doi: 10.2519/jospt.2018.7931 [published Online First: 2018/04/03]
8. Charlton PC, Bryant AL, Kemp JL, et al. Single-Leg Squat Performance is Impaired 1 to 2 Years After Hip Arthroscopy. *PM&R* 2016;8(4):321-30. doi: 10.1016/j.pmrj.2015.07.004
9. Hatton AL, Kemp JL, Brauer SG, et al. Dynamic single-leg balance performance is impaired in individuals with hip chondropathy. *Arthritis care & research* 2014;66(5):709-16.

Supplementary File 4: PhysioFIRST hip biomechanics assessment and calculation.

As outlined, hip biomechanics will be a secondary outcome of the study. Forty participants (20 per group) will undergo a baseline (pre-intervention) and 6-month follow-up (post-intervention) biomechanical assessment at the La Trobe University Gait Laboratory.

Experimental data collection: Participants will be required to change into a pair of running shorts, running singlet, and a pair of Teva Original-Universal sandals (Deckers Brands, Goleta, CA) to allow adequate exposure of bony landmarks for accurate marker placement. Forty-nine small (14 mm) spherical reflective markers (B & L Engineering, Albion, Australia) will be placed on the participant's body utilising a previously published protocol [1]. In summary, for the upper body and trunk, marker locations are on the C7 spinous process, acromioclavicular joints, lateral epicondyle of the humerus, and the posterior joint line of the wrists. A thermoplastic plate with four markers is affixed to the pelvis of the participant using a belt at the height of the posterior superior iliac spine, with two additional markers placed on the anterior superior iliac spines. For the lower limbs and feet, markers will be placed on the medial and lateral femoral condyles, medial and lateral malleoli, 5th and 1st metatarsal heads, and the great toes. Four additional segment tracking markers are placed on each thigh (two anterior, two lateral), three on the shank (two anterior, one lateral), and two on the midfoot (one superior, one lateral) [1]. Such marker locations are consistent with previously published biomechanics studies in hip pain [2-4].

Marker trajectories will be collected using a ten camera opto-reflective motion capture system (Vicon Motion Systems Ltd, Oxford, UK) sampling at 100 Hz. Ground reaction force (GRF) data will be collected using two 600mm*400mm force plates in series (Advanced Mechanical Technology, Watertown, MA) and one 1200mm*600mm force plate (for running only) (Advanced Mechanical Technology, Watertown, MA) mounted in the laboratory floor. GRF data will be sampled at 1000 Hz. Marker trajectories and GRF data will be recorded concurrently using Vicon Nexsus version 2.8 (Vicon Motion Systems Ltd, Oxford, UK).

Functional task data collection: Prior to data collection of the functional tasks, a static calibration trial will be captured, with the participant standing in an upright neutral posture, with their arms out to the side, to calculate anthropometric properties and lower limb joint centres. Following this, participants will complete four functional tasks for biomechanical data collection; walking, single-leg squats, the Y-balance test, and running.

- Walking: participants will be instructed to walk along a 10-metre walkway through the capture volume of the cameras at a comfortable self-selected speed.
- Single-leg squat: Participants will complete 10 (5 each leg) single-leg squats on the force plates in time with a metronome at 60 beats per minute. Participants will be instructed to maintain a stationary single-leg stance for two beats, descend for two beats, ascend for two beats and maintain a stationary single-leg stance for a final two beats. A maximal depth indicator will be located 10 cm behind the participant and set to a height whereby the end of the descent phase corresponds to 60 degrees knee flexion (calculated via the use of a hydraulic plinth and goniometer during participant setup).
- Y-balance test: participants will complete six y-balance tests (three each limb) within the capture volume of the cameras as per standard protocol [5].
- Running: participants will be instructed to run along a 20-metre walkway through the capture volume of the cameras (utilising the larger force plate) at speed between 3 and 3.5 m/s (calculated using timing gates placed 5 m apart inside the capture volume). Verbal

feedback will be given to the participants to speed up or slow down after each trial until the prescribed speed is obtained.

Hip joint kinematics and kinetics: A seven-segment (pelvis, left/right thigh, left/right shank, left/right foot) customised biomechanical model will be generated in Vicon BodyBuilder 3.6.4 (Vicon Motion Systems Ltd, Oxford, UK). This model will utilise previously defined anatomical co-ordinate systems by Schache and Baker [6]. The hip joint centre will be defined according to Harrington, Zavatsky, Lawson, Yuan, & Theologis [7] and a dynamic optimisation approach will be used to determine the knee flexion and extension axis [8]. Pelvis angles will be calculated in reference to the lab (global) co-ordinate system utilising the Cardan sequence recommended by Baker [9]. Hip joint angles will be calculated using a joint co-ordinate system convention [10], with a standard inverse dynamic method used to calculate external joint moments [6]. External joint moments will be reported in the same non-orthogonal joint co-ordinate system as the calculated hip, knee, and ankle angles [6]. Joint moments will be normalised to body mass and reported as Newton metres per kilogram (Nm/kg) for analysis.

References

1. Crossley, K.M., et al., *Femoroacetabular impingement and hip OsteoaRthritis Cohort (FORCe): protocol for a prospective study.* J Physiother, 2018. **64**(1): p. 55.
2. King, M.G., et al., *Lower limb biomechanics during low- and high-impact functional tasks differ between men and women with hip-related groin pain.* Clin Biomech (Bristol, Avon), 2019. **68**: p. 96-103.
3. King, M.G., et al., *Sub-elite Football Players With Hip-Related Groin Pain and a Positive Flexion, Adduction, and Internal Rotation Test Exhibit Distinct Biomechanical Differences Compared With the Asymptomatic Side.* J Orthop Sports Phys Ther, 2018. **48**(7): p. 584-593.
4. King, M.G., et al., *Lower-Limb Biomechanics in Football Players with and without Hip-related Pain.* Med Sci Sports Exerc, 2020.
5. Shaffer, S.W., et al., *Y-balance test: a reliability study involving multiple raters.* Mil Med, 2013. **178**(11): p. 1264-70.
6. Schache, A.G. and R. Baker, *On the expression of joint moments during gait.* Gait Posture, 2007. **25**(3): p. 440-52.
7. Harrington, M.E., et al., *Prediction of the hip joint centre in adults, children, and patients with cerebral palsy based on magnetic resonance imaging.* J Biomech, 2007. **40**(3): p. 595-602.
8. Schache, A.G., R. Baker, and L.W. Lamoreux, *Defining the knee joint flexion-extension axis for purposes of quantitative gait analysis: an evaluation of methods.* Gait Posture, 2006. **24**(1): p. 100-9.
9. Baker, R., *Pelvic angles: a mathematically rigorous definition which is consistent with a conventional clinical understanding of the terms.* Gait Posture, 2001. **13**(1): p. 1-6.
10. Grood, E.S. and W.J. Suntay, *A joint coordinate system for the clinical description of three-dimensional motions: application to the knee.* J Biomech Eng, 1983. **105**(2): p. 136-44.

Supplementary file 5: COVID-19 Project changes implemented April 2020

Changes made	Reason for the changes
Suspension of Phase 1 of study (n=22 participants).	Normally, phase 1 of the study is provided through weekly face to face sessions over 12 weeks administered by study physiotherapists. Due to COVID-19 restrictions we were no longer able to undertake this phase of the study. We explored telehealth options but decided the validity of the treatment would be significantly impacted without face to face contact. Therefore, we decided to suspend this phase of the study until face to face treatment was able to be used again. Participants were offered the opportunity to withdraw or recommence treatment once it is safe. All participants chose to remain in the study until it recommenced. The chief investigator (JLK) maintained fortnightly contact with these participants over this time to check on their wellbeing and answer any questions.
Provision of telehealth treatment sessions (n=23 participants) in Phase 2 of study	Normally, phase 2 of the study is provided through once-monthly face to face sessions administered by study physiotherapists. We decided to use telehealth appointments to undertake these treatment sessions during the COVID-19 shutdown. This enabled this phase of the study to continue and also protect the health of investigators and study participants.
Postpone the time point of follow-up clinical and biomechanics (secondary outcome) assessment from 6 months post randomization to as soon as is safe following COVID-19 closure.	As it was no longer safe or legally possible for participants to attend the laboratory at La Trobe University, we postponed all face to face follow-up testing until it was safe to do so. The primary outcome of the study, collected via online questionnaires, is not impacted by this postponement.

LA TROBE UNIVERSITY

Participant Code: PF ___ ___ ___

physioFIRST STUDY

La Trobe Sports and Exercise Medicine Research Centre

Consent form for persons participating in research projects

LTU ethics approval number HEC17-080

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

Investigators: Dr Joanne Kemp, Sally Coburn, Denise Jones, Dr Anthony Schache, Dr Benjamin Mentiplay
Associate Professor Dr Steven McPhail, Professor Kay Crossley

I, _____, have read and understood the **participant information statement and consent form**, and any questions I have asked have been answered to my satisfaction. I understand that even though I agree to be involved in this project, I can withdraw from the study at any time, up to four weeks following the completion of my participation in the research. Further, in withdrawing from the study, I can request that no information from my involvement be used. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used.

I consent to my data being included in other research projects. I acknowledge that my data will be coded, but can be potentially identified.	Yes ☐	No ☐
I consent to my single leg squat test being videoed. I acknowledge that any video data will be de-identified.	Yes ☐	No ☐
I understand my participation will not affect my current or future staff/student affiliation/physiotherapy management with: _____	Yes ☐	No ☐
I consent to be involved in the additional testing of physical activity using the Fitbit device	Yes ☐	No ☐
I consent to be involved in the additional testing of my movement patterns through biomechanical assessment	Yes ☐	No ☐
I consent to be involved in the additional testing of hip joint structure via Magnetic Resonance Imaging (MRI) scans	Yes ☐	No ☐
I wish to have a have a summary report sent to me at the conclusion of my participation in this project.	Yes ☐	No ☐

LA TROBE UNIVERSITY

Participant Code: PF ___ ___ ___

physioFIRST STUDY

Last Name:		Given Name:
DOB:	Age:	Contact Phone number:
Address:		
Signature:		Date:
Witness name:		Date:
Investigator:		Date:

Name and phone number of contact person in case of an emergency:

Name:	Phone:
Family Doctor:	Phone:

La Trobe Sports and Exercise Medicine Research Centre

LTU ethics approval number HEC17-080

The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy for hip impingement.

Investigators: Dr Joanne Kemp, Sally Coburn, Denise Jones, Dr Anthony Schache, Dr Benjamin Mentiplay
Associate Professor Dr Steven McPhail, Professor Kay Crossley

Participant Information Statement

We invite you to participate in our project: "The physiotherapy for Femoroacetabular Impingement Rehabilitation STudy (PhysioFIRST): A participant and assessor-blinded randomised controlled trial of physiotherapy to reduce pain and improve function for hip impingement."

We would like to give you some background information to explain why we think this project is important and describe what we would like you to do if you decide to join us in this research.

What is the purpose of this study?

Femoroacetabular (hip) impingement is a painful condition that commonly affects healthy active younger adults. It can limit their ability to continue playing sport and perform normal daily activities. It can be related to extra bone formation at the hip joint known as a cam deformity. Physiotherapy is one treatment people may use to reduce their symptoms and improve their function. We would like to compare the benefits of two different physiotherapy treatments to find the best way to manage this condition. Funding for this project has been provided by La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, an Arthritis Australia State/Territory Affiliate grant and a National Health and Medical Research Council Early Career Fellowship grant to Dr Kemp.

Who can participate in this study?

- People aged 18 to 50 years
- People with hip or groin pain aggravated by activity some of the time for more than 6 weeks
- People with signs of hip impingement when the hip is tested by a physiotherapist
- People with x-rays showing you have a 'cam deformity'

You are not eligible to participate in this study if:

- You cannot understand written or spoken English
- You have had physiotherapy in the past three months
- You have had hip surgery before
- You are not able to commit to a
  - **12-week physiotherapy program**
  - **a subsequent 12-week gym program, where you attend three times per week**
  - **baseline** (beginning) physical assessment
  - **follow-up** (24 weeks - after all treatments) physical assessment

- You are unable to have an x-ray of your pelvis (both hips at once) eg. You are pregnant or breastfeeding/unwilling

What does the project involve?

1. *Screening assessment (10 mins)*

You will be asked some questions about your hip over the phone to ensure you are eligible for the study. You will be asked to provide details of where any previous x-rays of your sore hip were taken for assessment of the digital copy to see if you have a 'cam deformity'. If you don't have x-rays we will organise a free hip (pelvic) x-ray for you at an x-ray clinic convenient to you (Imaging at Olympic Park, 60 Olympic Blvd, Melbourne or at Lake Imaging, Howitt St, Ballarat) if you are willing and able. The x-ray assessment will take about 30 minutes.

2. *Physical testing of your hip and questionnaires – Baseline (45 mins)*

If your movement tests and x-rays indicate you are eligible, we will ask you to attend an appointment at a mutually convenient time at La Trobe University, Melbourne, or at Lake Health Group, Ballarat, to undergo baseline measurement of your hip movements and strength. These baseline tests will take about half an hour.

Following the assessment we will ask you to complete several questionnaires online, and will be provided with instructions for access to the website. If you prefer you may complete a paper version of the questionnaires instead. The questionnaires will ask you questions about your hip/groin pain, other hip-related symptoms and your levels of physical activity and take about 15 minutes to complete.

3. *Biomechanical assessment of your movement (60 minutes)*

If you are willing to, we will undergo biomechanical assessment of your movement patterns after your physical testing described above. This testing will occur at La Trobe University, Melbourne. You will be asked to wear shorts (either you can bring some or we will provide you will shorts) and a singlet whilst you perform a series of tests including walking, running, squatting, jumping, and going up/down stairs. Reflective skin markers will be placed over your upper and lower body. Testing should take no longer than 60 minutes to complete. Participation in this section of the research is optional.

4. *Collection of activity data using Fitbit Flex 2™*

If you are willing to participate in this portion of the research, you will be given a Fitbit flex™ to wear on a daily basis for 14 consecutive days. It is important that you are able to wear the device every day on the wrist of your dominant hand. You will also need access to a computer so that you can set up and upload the information from the device. You will be given a password and email address that will be linked to the device you are given. Participation in this section of the research is optional.

Once the device is set up you will have access to your own Fitbit™ interface (called a dashboard), the same as any other user. This interface is accessible only by yourself (although you do have the option to share with your friends should you chose to do so).

Once the Fitbit™ is linked to your computer, the information from the Fitbit™ will be automatically synched to the computer via a USB dongle.

When data is uploaded from your Fitbit™, it is stored by Fitbit™ on an online server. The information collected by the research team will be gathered from that server using a program that will remotely log in and download the data. The research team will not need to log into your account through the Fitbit™ web page and will not access the personal dashboard and information that you set up.

5. *A free MRI of your hip (45 mins)*

If you are willing to participate in this portion of the research, we will investigate your hip joint structure in detail via a magnetic resonance imaging (MRI) scan at Imaging at Olympic Park, 60 Olympic Blvd, Melbourne. Parking is free and parking instructions are on the referral. The MRI will take place prior to the intervention period as well as after to examine any changes in your hip joint. You may not be able to participate in this section of the testing if you have a pacemaker, metal implants, or claustrophobia. Participation in this section of the research is optional.

6. *Physiotherapy treatment (12 weeks)*

After the first assessment and completion of the questionnaires, you will be randomly allocated to one of the physiotherapy treatment groups. Both treatments are used regularly by physiotherapists. You will then be asked to attend one of three physiotherapy clinics in Melbourne (or at Lake Health Group in Ballarat). Your treatment will comprise two phases which is provided free of charge and includes physiotherapy treatments and a 3 month gym membership.

In Phase 1, you will receive 6 free physiotherapy treatments over a period of twelve weeks. Each fortnightly treatment will last 30 minutes and will be performed by an experienced and project-trained physiotherapist. You will also be asked to perform a gym-based exercise program once per week in the gym at the same clinic. There are also exercises to complete at home twice per week. All treatments and any use of gym equipment will be provided at no cost to you.

7. *Gym membership (12 weeks)*

In Phase 2, you will receive a free 3-month gym membership and continue the exercise program you received in Phase 1 three times per week. You will receive a further three free physiotherapist reviews to continue to monitor your progress.

8. *Physical testing of your hip and questionnaires – Follow-up (45 mins)*

You will then return to La Trobe University (or Lake Health Group, Ballarat) for a final physical assessment. This will take approximately the same amount of time as the first assessment (about 45 minutes) and will also include biomechanics assessment if you participated in this before the intervention (about 60 minutes). The examiner physiotherapist will not know which treatment you have received. We ask you not to discuss your treatment with the examiner. We will also provide the same follow-up questionnaires for you to complete again (15 minutes), on paper, or online, and will ask you some questions about your experience of the project.

You will not receive any payment for your participation, however you will have free x-ray (and MRI if applicable) and assessment of your hip problem and free comprehensive physiotherapy if you are eligible and choose to participate.

We will also give you a $100 gift voucher for attending the final 6-month assessment of your hip at La Trobe University, as your assessment provides data critical to the success of our study. You may also ask for a copy of your assessment results.

We also ask that if you are considering another treatment for your hip or another musculoskeletal condition, you discuss the impact this might have on the study with the project leader, Dr Joanne Kemp.

Are there any potential side-effects?

The impingement and movement tests represent usual examination by a physiotherapist. You may experience a small amount of discomfort in the joints or tiredness in the muscles during the movement

and strength testing and interventions. Please report any undue discomfort or pain experienced during the testing. If the pain or discomfort is deemed to be excessive by yourself or the examiner, testing or treatment will cease.

If you have not already had a hip xray and require one to determine if you may participate, you will be exposed to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.32 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low. If you decide to participate in the MRI scans, there is no further exposure to radiation with MRI.

If required, emergency procedures will be used to deal with any medical event that arises during testing or physiotherapy treatments. La Trobe University and participating physiotherapy clinics and gymnasiums have documented procedures for emergencies. This includes annual first aid and CPR training and appropriate management of fire for all staff.

What if I have any concerns during the study?

This study is funded La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora, Arthritis Australia and National Health and Medical Research Council fellowship grant to Dr Kemp. This study adheres to the La Trobe University Human Ethics Guidelines and National Statement on Ethical Conduct in Human Research. Whilst you are free to discuss your initial participation in this study with the project coordinator (Sally Coburn ph: 0408 761 237), you may want to talk an officer of the University not involved with the study. If so, you may contact the Ethics Manager, Heidi Gaulke on ph: (03) 9479 1443. If you choose to participate, you are free to call the project chief investigator with any queries following the baseline assessment of your hip (Dr Joanne Kemp ph: 0484 776 536)

Can I withdraw from the study if I wish?

Your participation in the study is voluntary. If you do not wish to take part you are under no obligation to do so. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. You may also withdraw any unprocessed data previously supplied by you.

If you are a student of La Trobe University, your decision whether to take part or not to take part, or to withdraw, will not affect your affiliation with the university in any way.

If you are a patient of any of the investigators or project physiotherapists, your decision whether to take part or not to take part, or to withdraw, will not affect your relationship with the physiotherapy clinic or your future physiotherapy management in any way.

Will my details be kept confidential?

Our procedures require allocation of a code number to identify you and any data associated with your participation. This assures your anonymity as your name will not be used. You will be videoed performing a single leg squat but will be de-identified for analysis. No findings that identify you will be published and access to individual results is restricted to the investigators. Coded data will be stored for at least 5 years. All data and results will be handled in a strictly confidential manner, under guidelines set out by the National Health and Medical Research Council. The chief investigator is responsible for maintaining this confidentiality. This project is subject to the requirements of the La Trobe University Human Ethics Guidelines. However, you must be aware that there are legal limitations to data confidentiality.

What will happen to the results of the study?

Summaries of the study results will be sent to participants, if requested on the consent form. It is possible that results from this study will be presented at a local, national or international conference, or published in a peer reviewed journal. Results may also be used for teaching purposes and web-based translational material. All results are **de-identified**.

How do I get more information?

You should ask for any information you want. If you would like more information about the study, or if there is any matter that concerns you, either now or in the future, do not hesitate to ask one of the investigators or project coordinator. Before deciding whether or not you should take part you may wish to discuss the matter with a relative or friend or with your local doctor. You should feel free to do this. A newsletter will be sent to update you during the project. A project summary will be available, on request via email/post at the conclusion of the study and will include no identifiable information.

About the investigators:

Prof Kay Crossley is a sports physiotherapist and professor at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Joanne Kemp is a sports physiotherapist and post-doctoral researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Sally Coburn is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Denise Jones is a physiotherapist and research assistant at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Anthony Schache is a physiotherapist and senior research fellow at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

Dr Benjamin Mentiplay is an exercise scientist and researcher at La Trobe Sports and Exercise Medicine Research Centre at La Trobe University, Bundoora.

A/Prof Steven McPhail is a health economist at University of Queensland

Contacts:

Enquiries and eligibility:

Sally Coburn

Mob: 0484 761 237

Email: s.coburn@latrobe.edu.au.

If you have commenced participation:

Dr Joanne Kemp

Email: j.kemp@latrobe.edu.au

Mob: 0484 776 536

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	Page number in manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	NA
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	20
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	20
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8, Supp files 1 and 2
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	13-15, Table 1, Supp 3 and 4
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Fig 3 and 4, 9-12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	18
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	5
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	18
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	18
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	18
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	18-19

	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	18
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	10
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	10
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	10
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	6

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	LTU
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	10
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19-20
	31b	Authorship eligibility guidelines and any intended use of professional writers	20
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	20
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	LTU
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the

protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.