

## **Supplementary Appendix**

This Supplementary Appendix has been provided to supply readers with additional information about this work.

**Education plus exercise versus corticosteroid injection use versus a wait and see approach on global outcome and pain from gluteal tendinopathy: prospective, single blinded, randomised clinical trial**

## Table of Contents

List of Investigators .....	4
Supplementary Appendices .....	5
Appendix S1. Inclusion and Exclusion Criteria .....	5
Table S2. Descriptions of LEAP study interventions .....	8
Table S3. Percentage of prescribed exercises completed by EDX participants, based on percentage of completed exercise sessions as reported in the exercise diary, on a weekly basis, as well as total program adherence. ....	17
Table S4. Summarized descriptions of secondary outcome measures.....	18
Table S5 – Secondary outcome measures. ....	21
Figure S6.....	24

## List of Investigators

Dr Rebecca Mellor, B.Phty (Hons), M.Phty (MuscSk), PhD

Prof Kim Bennell, BAppSci(Physio), PhD

Dr Alison Grimaldi, B.Phty(Hons), M.Phty(MuscSk), PhD

Philippa Nicolson, BPhy, PhD Candidate

Dr Jessica Kasza, B Sc (Hons), PhD

Prof Paul Hodges, PhD MedDr (Neuroscience), BPhy(Hons)

Dr Henry Wajswelner, ClinDocPhysio (Melbourne)

Professor Bill Vicenzino, BPhy, GradDipSportsPhty, MSc, PhD

## Supplementary Appendices

### Appendix S1. Inclusion and Exclusion Criteria

**Extract from [1] Mellor, R., et al., *Exercise and load modification versus corticosteroid injection versus 'wait and see' for persistent gluteus medius/minimus tendinopathy (the LEAP trial): a protocol for a randomised clinical trial.* BMC Musculoskelet Disord, 2016. 17(1): p. 196.**

#### *Selection Criteria:*

We will include participants between the ages of 35 and 70 years who have experienced lateral hip pain for at least three months, of an intensity of  $\geq 4/10$  on an 11-point numeric rating scale on most days of the last three months. Table 1 outlines the selection criteria for inclusion into the study. These criteria were based on a previous study [2].

As clinical tests to diagnose gluteal tendinopathy appear to have limited validity [3], we have included a small battery of clinical tests that have been considered to be most provocative in reproducing symptoms of gluteal tendinopathy [4]. To be eligible, the participant must experience pain on direct palpation of the gluteal tendons' insertion on the greater trochanter. They must also test positive (reproduction of trochanteric pain) to at least one of the following clinical tests: the Hip FADER (passive) test, static muscle test in the FADER position, the FABER (Patrick's) test, passive hip adduction in side lying (ADD), a static muscle contraction in the ADD test position, and a Single Leg Stance on the affected leg for 30 seconds.

A. *Hip FADER* – With the patient supine, the hip is passively flexed to 90°, adducted and externally rotated to end of range (FADER=Flexion/Adduction/External Rotation). The pain NRS and area of pain is recorded. This test positions the ITB over the greater trochanter and places the Gluteus Medius (GMed) and Gluteus Minimus (GMin) tendons under tension while being compressed against the greater trochanter by the overlying fascia of the ITB. The test is only recorded as positive if the pain ( $\geq 2/10$ ) is experienced over the lateral hip.

B. *Hip FADER with Static muscle test* (internal rotation) at end of range (*FADER-R*). In the FADER position, the participant actively resists an external rotation force – i.e. performs static internal rotation (IR). At 90° hip flexion all portions of GMed and GMin are internal rotators [5]. This test requires the participant to activate these muscles, and therefore place further tension across their tendons, while they are in a compressed state. Again, a positive result refers to reproduction of pain at the lateral hip. As clinical features of gluteal tendinopathy include pain reproduction with elongation and compression of the involved tendons, as well as active contraction of these tendons, these two tests together may have improved diagnostic accuracy. This test is a modification of the resisted external de-rotation test, which has been reported to have 88% sensitivity and 97.3% specificity [6].

C. *Hip FABER* – (FABER=Flexion/Abduction/External Rotation). The lateral malleolus of the test leg is placed above the patella of the opposite side, the pelvis is stabilised via the opposite anterior superior iliac spine (ASIS) and the knee is passively lowered into abduction and external rotation. This test places the anterior portions of the GMed and GMin on tensile load. A positive pain response is usually felt in the lateral hip region. Lateral hip pain with a FABER test has been shown to have a high sensitivity, specificity, positive and negative predictive value (82.9%, 90%, 94.4% and 72% respectively) for differentiating the diagnosis for greater trochanteric pain syndrome from hip osteoarthritis [7].

D. *Passive Hip Adduction in Side Lying (ADD)* – The participant is placed in side-lying, with the underneath hip and knee flexed 80-90°, and the uppermost leg supported by the examiner with the knee extended, in neutral rotation, and the femur in line with the trunk. The anterior superior iliac spines are aligned vertically in the frontal plane. The examiner passively moves the hip through a pure frontal plane motion into end range hip adduction with overpressure, while stabilising the pelvis with the other hand. This test places the lateral insertions of the gluteal tendons under compressive load, and a positive response is felt over the lateral hip. This is based on Ober's test, which has been reported as having a high specificity (95%), but a low sensitivity (41%) and low negative predictive value (45.2%) [7].

E. *ADD with resisted isometric abduction (ADD-R)* – In the ADD test end position, the participant is asked to push the thigh up, against the resistance of the examiner's hand at the lateral knee. This test places tensile load on the compressed tendons, with pain elicited over the lateral hip.

F. *Single Leg Stance for 30 seconds (SLS)* – the participant stands side-on to a wall with one finger touching the wall at shoulder height for balance, then lifts the foot closest to the wall, maintaining single leg stance for up to 30 seconds. The participant is asked to immediately report the development of pain by pointing to the area of pain. If the region of the greater trochanter is indicated, the timer is stopped, the test ceased and recorded as positive. This time is reported, as well as the intensity of the pain. The single leg stance test has been shown to have good sensitivity and specificity (100% and 97.3% respectively) [6] for the diagnosis of tendinopathy and bursitis in people with MRI-documented gluteal tendinopathy.

In addition to these tests, the physical screening will also ensure that the participant has  $\geq 90^\circ$  hip flexion range of movement bilaterally, knee flexion range  $\geq 90^\circ$  and full knee extension bilaterally, and that the hip quadrant test [8] is clear bilaterally. If groin pain on quadrant testing is greater than 5/10 on the Pain NRS, or the difference in pain levels between sides is greater than 2/10, the participant is excluded. Additionally, the participant must be able to flex the trunk forward with hands reaching at least to the knees with  $\leq 2/10$  back pain, and have adequate hip, knee and ankle mobility to be able to perform a squat to 60° flexion at the hips.

The participant will then be referred for MRI (if no contraindications e.g. cardiac pacemaker, metal implants etc.) and X-ray investigations at a participating radiology clinic, as a confirmed diagnosis of gluteal tendinopathy on MRI, based on a classification system from a previous study [9] will also be required for eligibility. Tendinopathy will be defined as an intratendinous increase in signal intensity on T2-weighted images (Table 2). Participants must have no contraindications to MRI (e.g. cardiac pacemaker, metal implants etc). An X-ray (AP and Lateral) is required to grade osteoarthritis severity using the Kellgren-Lawrence Scale [10]. Those with a score of  $>2$  will be excluded from the study. To minimize unnecessary radiation exposure, if the patient has had previous appropriate X-rays within the last six months, they will not require a second lateral hip X-ray.

Table 1 – Inclusion and Exclusion criteria

---

<b>Inclusion Criteria</b>
Lateral hip pain, worst over the greater trochanter, present for a minimum of 3 months
Age 35 – 70 years
Pain at an average intensity of $\geq 4$ out of 10 on most days of the week.
Tenderness on palpation of the greater trochanter
Reproduction of pain on at least one of five diagnostic clinical tests (FABER test, Static muscle contraction in FABER position, FADER test, Adduction test, Static muscle contraction in Adduction position i.e. resisted abduction) or single leg stand
Demonstrated tendon pathology on MRI (see Table 2 for criteria)

---

<b>Exclusion Criteria</b>
Previous cortisone injection in the region of the lateral hip in the last 12 months
Physiotherapy intervention or regular appropriate Pilates in the last 3 months
Lumbar spine or lower limb surgery in the previous six months
Any known advanced hip joint pathology where groin pain is the primary complaint and/or where groin pain is experienced at an average intensity of $\geq 2$ on most days of the week, or Kellgren-Lawrence score of $>2$ (mild) on XRay.
Where range of pure hip joint flexion is $<90^\circ$
Significant signs of lumbar pathology
Known advanced knee pathology or restricted range of knee motion (must have minimum $90^\circ$ flexion and full extension)
Any systemic diseases affecting the muscular or nervous system, and uncontrolled diabetes
Malignant tumour
Systemic inflammatory disease
Any factors that would preclude the participant from having an MRI (e.g. pacemaker, metal implants, pregnancy, claustrophobia)
If the participant is involved in a legal/workcover/TAC or other injury claim
If the participant is unable to commit to an eight week exercise programme with twice weekly supervised sessions
Fear of needles (trypanophobia)
If the participant is unable to write, read or comprehend English

---

Table S2. Descriptions of LEAP study interventions

**1. Education, Load management and Exercise program (EDX)**





- 14 individualised Physiotherapy sessions over 8 weeks plus daily home exercise program (4-6 exercises). Physio sessions once/week for first two weeks, then twice/week for remaining six weeks. A weekly diary was completed recording exercises performed, any issues/problems
- Detailed advice and education on tendon care – handouts, verbal explanation, DVD
- Exercises included functional retraining, targeted strengthening for hip (particularly abductor) and thigh muscles, and dynamic control of adduction during function.
- Exercise difficulty gradually increased, to optimise improvements in muscle strength and function without significant aggravation of pain. Difficulty level monitored with the Borg Scale [11] where warm up is performed at a light level (Borg 11-12), functional retraining at a somewhat hard to hard level (Borg 13-15), and the slow heavy targeted strengthening moving from somewhat hard towards the hard to very hard level (14-17), depending on response to loading.
- No change in trochanteric pain was acceptable during functional retraining, as this may indicate inadequate alignment control, and excessive compressive tendon loading. A maximum of NRS 5/10 pain was tolerated as long as this eased afterwards and did not result in increased pain levels that night or the next morning.
- Responses to the exercises closely monitored, and loading levels adjusted as required to prevent any increases in pain from week to week.





Stage	Exercise	Effort	Speed	Reps	Sets	Freq
Week 1- Familiarisation	<u>Low load activations</u> <b>Static Abduction:</b> Supine lying Standing	Light	Slow onset	10	1-2	BD
		Light	Hold 5-10 sec Slow onset Hold 5-15 sec	3-5	1	BD
	<u>Pelvic Control during Functional Loading:</u> <b>Bridging</b> Double Leg Bridging <b>Functional Strengthening:</b> Double leg squats	Light	Moderate	10	1	daily
		Light-SWH	Slow	10	1	daily
	<u>Abductor Loading via Frontal Plane Movement:</u> <b>Sidestepping</b>	Light	Moderate	10 each	1	daily
Week 2 – Early Loading & Movement Optimisation	<u>Low load activations</u> <b>Static Abduction:</b>	Maintain as per week 1				
	<u>Pelvic Control during Functional Loading:</u> <b>Bridging:</b> Double leg bridging	Light	Slow	10	1	daily
		SWH	Slow	5	1	






Stage	Exercise	Effort	Speed	Reps	Sets	Freq
	Single leg biased exercise: Offset bridging <b>Functional Strengthening:</b> Double leg squats Single leg biased exercise: Offset squat	Light SWH	Slow Slow	10 5	1 1	daily
	<u>Abductor Loading via Frontal Plane Movement:</u> <b>Sidestepping</b>	Light	Moderate	15 each	1	daily
Week 3-8 – Graduated Loading	<u>Low load activations</u> <b>Static Abduction:</b>	Maintain as per week 1				
	<u>Pelvic Control during Functional Loading:</u> <b>Bridging:</b> Double leg bridging Single leg biased exercise <b>Functional Strengthening:</b> Double leg squats Single leg biased exercise	Light SWH – Hard  Light SWH - Hard	Slow  Slow	5 5 – 10  5 5 - 10	1 2  1 2	daily  daily
	<u>Abductor Loading via Frontal Plane Movement:</u> <b>Sidestepping</b> <b>Band Sideslides</b>	Light SWH- Hard	Moderate	10 each 5-10 each	1 1-2	daily
Week 3-8 – Graduated Loading; Sliding platform with spring resistance	All supervised by Physiotherapist in Clinic					
<i>Warm up</i>	<u>Abductor Loading via Frontal Plane Movement:</u> <b>Bilateral Abduction:</b> Upright Minisquat	Light Light	Moderate Moderate	5 each way 5 each way	1 1	Twice weekly
<i>Higher level loading</i>	<u>Abductor Loading via Frontal Plane Movement:</u> <b>Bilateral Abduction:</b> Upright Minisquat	SWH-VH SWH-VH	Slow Slow	5-10 each way 5-10 each way	1 1	Twice weekly
	<u>Pelvic Control during Functional Loading:</u> <b>Scooter</b>	Light - SWH	Moderate	5 - 10	1-2	Twice weekly




Reps= Repetitions; Freq=Frequency; BD=Bi-Daily; SWH= Somewhat Hard; VH=Very Hard





Exercise	Position	Exercise Description
<p><b>Static Abduction</b></p> <p>1. In Lying</p> <p>2. In Standing</p>	 	<p><b>Aim: To gently activate the deep gluteal muscles at the side of your hips</b></p> <p>1. Lying on your back, knees just slightly wider than hip width. Pillow under the knees, belt/scarf around lower thighs. Now very slowly &amp; gently start to move your knees apart, but only enough to just take up the slack in the belt. This may only be 1-2mm of movement. All the big superficial muscles you can feel around your hips and thighs should remain soft and relaxed. You should just be aware of a deep gentle tension at the side of your hips/buttocks.</p> <p>2. Standing feet slightly wider than your hips <i>Slowly and gently</i> imagine you are going to slide your legs apart – ‘Imaginary splits’. Think of a slow ‘ramp’ of activation, rather than a fast movement. You should only be aware of a deep gentle tension at the side of your hips/buttocks. All the big superficial muscles you can feel around your hips and thighs should remain soft and relaxed. If you are unable to relax your superficial muscles, you can start this exercise leaning your back against a wall.</p>
<p><b>Bridging</b></p> <p>1. Double Leg Bridge</p>		<p><b>Aim: To strengthen the gluteals</b></p> <p>1. Draw in your lower abdomen gently. Contract your lower gluteals/buttocks without tucking or tilting your pelvis. Press your heels into the bed (ankles/toes stay relaxed), and lift your pelvis/bottom from the bed. Do not fully straighten the hips – no need to lift that high. Only lift in a comfortable range – this may be only just taking the pressure off your buttocks initially. There must be no discomfort in the lower back. Use no or one flat pillow to avoid strain of the neck.</p> <p>2. Ensure you focus on your gluteals and don't let your hamstrings take over. If you are getting cramps in your hamstrings, your buttocks are not doing enough work. Try positioning your feet closer to your buttocks. Lift slowly – 3-4 seconds up &amp; 3-4 secs down, gluteals working <b><i>all</i></b> the way.</p>
<p>2. Offset Bridging</p>		<p>2. Bring one foot in closer to the buttock, and place the other foot further away. The bridge should now be performed primarily with the ‘close’ side, with the weight of the other leg just resting, supported by the ground. Pre-set your muscles as above and complete the lift slowly – 3-4 seconds up and 3-4 seconds down. Your pelvis should remain level.</p>

<p>3. Single Foot Hover</p>		<p>Start as per double leg bridge, lifting your pelvis/bottom through 2 legs. Then <u>slowly peel</u> one foot off the ground, keeping the pelvis level. <u>Do not</u> rapidly pull the foot off the ground. Keep the pelvis 'tucked under' from the weightbearing side to keep the pelvis level. Do not let the pelvis sag. Return your foot to the ground slowly, then return your bottom to the bed.</p>
<p>4. Single Leg Extension</p>		<p>Perform this exercise as per the single foot hover, except once you have lifted your foot, slowly extend the knee of the non-weightbearing leg. Keep the pelvis level and knees about the same height. Slowly bend the leg again, return the foot to the floor, then return the bottom to the bed slowly.</p>
<p>5. Single Leg Dips</p>		<p>Draw in your lower abdomen slowly, tighten your lower gluteals and push through both feet as for double leg bridging. Now slowly peel one foot from the floor and extend your knee. Keeping your pelvis level, slowly lower the pelvis to just touch the ground/bed (but do not relax), and then slowly lift back up to the start position.</p> <p>DO NOT over extend, by lifting up your pelvis too high. Initially you may need to return your foot to the ground, and even bring your pelvis back to the ground to rest in between repetitions. As your strength and endurance improves you may be able to do a number of dips in a row before returning to the ground.</p>
<p><b>Functional Retraining</b></p> <p>1. Double Leg Squats</p>		<p><b>Aim: To strengthen the gluteals and thighs &amp; practice good movement patterns</b></p> <p>1. Double leg squats Start with your weight equally on both feet, weight 2/3rds on the heels, and thighs and buttocks relaxed, as for good posture. Now bend at the hips and knees, translating the hips backwards, and the body forward, like when you sit down. Keep your knees facing straight ahead – light 'headlights'. Keep your back long and relaxed. Do not arch your back. Your physiotherapist will tell you how deep to go – usually start at 1/3 or 1/2 of the distance to a chair. Move slowly down over around 3 seconds, then return slowly to standing over 3 seconds, focusing on pushing through your heels and feeling the tension in your buttocks. As you reach the top again, grow tall into that good posture.</p>

<p>2. Offset Squats</p>		<p>2. Place the ball of one foot directly under that hip – in line with the other ankle. The squat should now be performed primarily with the side with the full foot on the ground, with the other leg assisting as required to achieve good alignment, and balance. Keep your knees facing straight ahead and your pelvis level. Do not let your pelvis sway or sag out to the side. Think of keeping a straight line down the side of your body. You may hold on at first with the hand opposite the main weightbearing side. Move slowly – 3-4 seconds down and 3-4 seconds up.</p>
<p>3. Single Leg Standing</p>		<p>Wake up the deep gluteal muscles at the side of your hips by doing a couple of static abductions in standing ('imaginary splits') 2 x 15 seconds. Now, hold on to a bench or a chair back on the side you will be lifting. Then, 'think tall' and transfer your weight onto one leg side, while keeping pelvis level and trunk upright. Lift the foot off the ground. Hold for as many seconds as your physiotherapist has directed – usually starting at 5 seconds and building to 15. You must only hold as long as you can keep your pelvis level and a straight line down the side of your body. Keep tall &amp; your weight 2/3rds on your heel. There should be NO pain over the bone at the side of your hip. Some fatigue ache in the buttock is normal.</p>
<p>4. Single Leg Squats</p>		<p>Wake up the deep gluteal muscles at the side of your hips by doing a couple of static abductions in standing ('imaginary splits') as above - 2 x 15 seconds. Then, holding onto a chairback initially, transfer your weight onto one leg as above. Keeping your pelvis level, perform a slow, small range squat as you did on 2 legs. Bend at the hips and knees, moving your pelvis backwards, and bringing your body a little forward. Keep your back long and relaxed Your pelvis must stay level and your knee facing straight ahead. Keep that straight line down the side of your body too – no sagging! To come back up, think of using your buttock muscle, and push through your heel bringing yourself back to your 'tall' starting position. There must be no pain over the bone at the side of the hip. The speed of the squat should be performed as per the double leg squat – 3-4 seconds down and 3-4 seconds up.</p>



<p>5. Step ups</p>		<p>Wake up the deep gluteal muscles at the side of your hips by doing a couple of static abductions in standing ('imaginary splits') as above - 2 x 15 seconds.</p> <p>Think 'tall' then place one foot up on a step directly in front of the hip, <u>not in the midline</u>. Start with hand support opposite the foot on the step. Slowly lunge forward over the foot, keeping the kneecap straight ahead, directed over 2<sup>nd</sup>-3<sup>rd</sup> toe. Push up onto the step by squeezing the buttock. Don't let the hips sway out to the side.</p> <p>Ensure the hips are level and you think about keeping a straight line down the side of your body. Keep the knee facing straight ahead. You can initially use as much hand pressure as required to keep the correct alignment. As you get stronger you will be able to reduce hand support.</p> <p>Step back down again with the trail leg first – ie last foot up, first foot down, so the leg placed on the step first is doing all the work.</p> <p>There must be <u>NO</u> pain over the bone at the side of the hip, but some fatigue ache in the buttock muscles is normal.</p> <p>The movement should be slow, like the squats – 3-4 seconds up and 3-4 seconds down.</p>
<p><b>Weightbearing abductor loading</b></p> <p>1. Sidestepping</p>		<p><b>Aim: To activate &amp; strengthen the gluteal muscles and tendons at the side of your hip</b></p> <p>Start with good posture.</p> <p>Now practice some controlled sidestepping side to side.</p> <p>The focus should be on a controlled push from one side and landing softly and with control on the other. The trunk should remain upright, and the kneecaps facing straight ahead.</p> <p>When stepping together, only step back to hip width apart. Do <b>NOT</b> bring ankles together.</p> <p>Start with 5 repetitions side to side, then gradually increase as instructed by your physiotherapist.</p>
<p>2. Doorway side slides</p>		<p>Place an elastic band around your ankles.</p> <p>Stand in a doorway with one foot on a non-slip surface, &amp; the other foot, with a sock on, on a slippery surface. Sometimes a folded handtowel can also help the sliding.</p> <p>Bend your hips and knees about 45° so you are in a shallow squat.</p> <p>Now slide the 'slip side' foot out to the side, pushing against the resistance of the band to take the knees apart, and take your knee almost to a straight position, or as far as is comfortable for your hip.</p> <p>Keep your body and non-slip side completely still.</p> <p>The movement should be slow and controlled – 2-3 seconds out and 2-3 seconds back in.</p>

<p><b>Abductor Loading via Frontal Plane Movement</b></p> <p>1. Bilateral Abduction Upright</p>		<p>Stand with one foot in the centre of each plate, knees straight but not locked backwards and 2/3rds of your bodyweight resting through the heels. With the ankles, hips and shoulders aligned on top of each other and equal weight through both feet, press through both feet to separate the legs and slide the plates slowly out to the side against the spring resistance. Keep the knees soft and the body central. Weight should remain even on both feet and the trunk upright. Control the plate slowly back to the start position.</p>
<p>2. Bilateral Abduction Mini Squat</p>		<p>Stand with one foot in the centre of each plate and equal weight through both feet. Bend the hips and knees, leaning forward from the hips, ensuring that the spine and the pelvis remain in a neutral position. From this semi-squat position, press out equally with both feet, pushing against the spring resistance. Your knees face towards your middle toes and should remain bent throughout the movement. Keep your body leaning forward, maintaining a gentle inward curve of your lower back. The movement is a separation of the thighs, not a straightening of the knees. Control the plate slowly back to the start position.</p>
<p><b><u>Pelvic Control during Functional Loading:</u></b></p> <p>Scooter</p>	 	<p>Stand to the side of the base plate with one foot on the ground and the ball of the other foot against the lip of the slide plate. Initially you may require a stick, bench or back of a chair on the side of the back leg, for balance. Lean forward and bend at the hips and knees, keeping a gentle inward curve in the lower back and ensuring that your body weight is falling through your front heel. Keep the front knee directed over the middle toes. Press back against the spring resistance with the foot on the slide plate by extending the leg. Keep a level pelvis and the knee facing forward, minimising movement of the back, pelvis and front leg. Avoid shifting the hip/pelvis out to the side of the front leg. Control the plate back to the start position.</p>

## **2. Corticosteroid Injection (CSI)**

- One visit to Radiologist
- Informed consent obtained for following procedure. Information sought regarding allergic history and previous reactions to medications
- Patient placed in decubitus position with affected (study) side raised
- Preliminary imaging performed to identify greater trochanter, gluteus minimus and gluteus medius insertions, and the trochanteric bursa. The preferred needle path was ascertained and the approach was marked on the patient's skin
- Skin was cleaned with a solution of chlorohexidine gluconate and alcohol. Ultrasound transducer was covered and swabbed with the same solution.
- Using aseptic technique under ultrasound guidance, an appropriate 22 or 25 gauge needle was used to inject a mixture of 1 ml Celestone Chronodose (Betamethasone 5.7mg/ml) or 1ml Kenacort (triamcinolone acetonide 40mg/ml) (doses prescribed to ensure comparable anti-inflammatory potency) and 3ml Bupivacaine 0.5%
- Any procedural complications were noted, and an initial assessment of therapeutic benefit of local anaesthetic was made.
- Further explanation of what to expect was provided and advice re immediate management.
- Participants complete a weekly diary, outlining any problems that may have been encountered related to the study

## **3. Wait and See group**

- One session with a physiotherapist
- Participants receive reassurance that the condition is likely to resolve over time, and advice regarding general tendon care and self-management
- Participants also receive a standard information pamphlet about the condition and basic self-management.
- Therapists answer any questions about adopting a wait and see approach, to ensure participant is confident that this is an appropriate and sensible approach to adopt
- Participants complete a weekly diary, outlining any problems that may have been encountered related to the study

#### WHAT CAN I DO?

Rest does not cure tendinopathy, but exercising to the point of feeling pain in the tendon is also not helpful, so keeping up a walking programme that does not aggravate your pain will be worthwhile.

Walk on the flat, avoid hills and keep stairs to a minimum until your pain settles. Start with 10 minutes of walking and as your pain improves gradually increase your activity levels.

Applying heat to the hip and buttock can also provide relief.



#### LEAP PROJECT

The University of Queensland is conducting research to answer important questions about lateral hip pain.

The clinical trial that you are enrolled in will determine which of the most commonly used treatments works best.

For the findings of the study to be worthwhile, you must keep to the treatment which you have been allocated.

If you have any concerns or questions about the trial, please contact the chief investigator, Professor Bill Vicenzino at The University of Queensland on:

(07) 3365 2781 or

[b.vicenzino@uq.edu.au](mailto:b.vicenzino@uq.edu.au)



**SIRPH Research Unit  
Physio Department  
UQ**

## Lateral Hip Pain



CLINICAL TRIAL

LEAP PROJECT

## LATERAL HIP PAIN

#### WHAT IS IT?

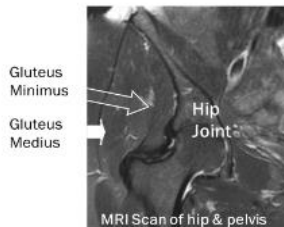
Lateral hip pain is pain that originates at the side of the hip, over the bony prominence called the greater trochanter. The main area of pain will occur around this bone, but commonly extends down the side of the thigh, and even into the top of the lower leg, below the knee. Pain may also extend a way forward into the groin, or back into the buttock.



It is often worse at night lying on either side, and may be aggravated by walking, particularly uphill and stairs, standing on one leg to dress, prolonged sitting, and there is often some pain and stiffness for the first few steps after rising to stand.



The condition has historically been diagnosed as 'trochanteric bursitis', however recently researchers have shown there to be problems of cells, collagen tissue and small blood vessels in the tendons of the buttock muscles - gluteus medius and minimus.



#### WHY DO I HAVE IT?

Tendon health depends on the loads they bear on a regular basis, and either too much or too little loading can be problematic. For example, an athlete may overload the tendon and end up with tendon problems, whereas those who are not physically active may well suffer gradual tendon deterioration.

Either way the tendon health suffers and eventually pain is experienced when the weakened tendon is exposed to a range of possible factors, such as a rapid increase in loading that might occur with suddenly increasing training loads, or even taking up walking, particularly up hills and stairs, or with a slip or fall directly landing on the side of the hip.

Sometimes you may not be able to put your finger on a single factor as it might have occurred as a result of an accumulation of a number of small things, for example a gradual increase in weight over time and a reduction in general fitness.

## References

1. Borg GA. Psychophysical bases of perceived exertion. *Medicine and science in sports and exercise.* 1982;14(5):377-81.



Table S3. Percentage of prescribed exercises completed by EDX participants, based on percentage of completed exercise sessions as reported in the exercise diary, on a weekly basis, as well as total program adherence.

<b>Percentage Adherence to EDX prescribed exercises</b>									
	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Total Program</b>
Mean $\pm$ SD (%)	85.2 (25.7)	89.3 (21.8)	89.7 (23.8)	89.8 (22.0)	92.8 (18.0)	88.5 (22.4)	93.9 (13.0)	82.5 (30.0)	88.8 (13.7)
Median	100	100	100	100	100	100	100	100	93.8
25 <sup>th</sup> percentile	71	86	100	100	100	83	100	83	83.8
50 <sup>th</sup> percentile	100	100	100	100	100	100	100	100	93.8
75 <sup>th</sup> percentile	100	100	100	100	100	100	100	100	100

Table S4. Summarized descriptions of secondary outcome measures.

Measurement Tool	Description
VISA-G	The VISA-G evaluates changes in severity of disability in people with GT. It addresses levels of pain and function and scores range from 0 to 100, with higher scores indicating less pain and better function [12].
Patient Specific Functional Scale	The Patient Specific Functional Scale (PSFS) assesses functional change. Patients identify three activities they have difficulty performing because of their problem and rate the current level of difficulty (lower scores indicate greater functional difficulty) before and after intervention [13].
EuroQoL	EuroQOL (EQ-5D™) is used as a measure of health-related quality of life. It provides a descriptive profile of health status in terms of mobility, personal care, usual activities, pain and anxiety/depression. A single utility score is generated, as an expression of the Quality Adjusted Life Years (QALY), and is commonly used in analyses of cost-effectiveness [14].
Pain Catastrophising Scale	The Pain Catastrophising Scale (PCS) measures pain catastrophizing [15]. Participants reflect on past painful experiences and indicate on a 5-point scale the degree to which they experienced certain thoughts or feelings. The total score ranges from 0-52, with higher scores indicating higher levels of pain catastrophisation and includes subscales assessing rumination, magnification and helplessness.
Pain Self-Efficacy Questionnaire	The Pain Self-Efficacy Questionnaire (PSEQ) assesses the confidence that people with chronic pain have in performing a range of everyday functional activities. Participants rate how confidently they can perform each activity on a 7-point Likert scale. The total score ranges from 0 to 60, where higher scores reflect stronger self-efficacy beliefs [16].
PHQ-9	The Patient Health Questionnaire 9 (PHQ9) is a tool for screening, diagnosing, monitoring and measuring the severity of depression and is commonly used as a clinical and research tool [17].
Active Australia Survey	The Active Australia survey measures participation in leisure-time physical activity [18]. A number of different measures of participation in physical activity can be obtained, including the proportion of people doing sufficient activity to gain health benefits.
Lateral Hip Pain Questionnaire	The Lateral Hip Pain Questionnaire (LHPQ) is a measure of pain and function specific to lateral hip pain, with two subscales. The Activities of Daily Living (ADL) subscale relates to pain aspects, impact on function, and pain beliefs. The total score ranges from 0 to 100, with higher scores indicating less pain and better function. The Sports subscale (optional if not relevant) relates to pain and impact on sporting participation [1].
Static painfree abductor muscle strength	Hip abductor muscle strength is measured in supine, with a dynamometer strapped above the lateral fibular malleolus [19]. The strongest of three 5-second maximal hip abduction contractions is recorded (Newtons, N) and the distance between the greater trochanter and the dynamometer is measured (m). Torque (Nm) is calculated by the equation $T = F (N) \times D (m)$ , and standardized to body weight (Nm/kg).

Measurement Tool	Description
Active Lag (Abductor Muscles)	Active Lag is measured in side-lying, with a plurimeter placed on the distal femur. The participant actively abducts the hip to the maximal position they are capable of, then the assessor passively abducts the hip to end of range. The difference between passive and active range is recorded as the Active Lag, and the average of three repetitions is recorded for analysis [1].

## References

- Mellor, R., et al., *Exercise and load modification versus corticosteroid injection versus 'wait and see' for persistent gluteus medius/minimus tendinopathy (the LEAP trial): a protocol for a randomised clinical trial*. BMC Musculoskelet Disord, 2016. **17**(1): p. 196.
- Rompe, J.D., et al., *Home training, local corticosteroid injection, or radial shock wave therapy for greater trochanter pain syndrome*. Am J Sports Med, 2009. **37**(10): p. 1981-90.
- Reiman, M.P., J.K. Loudon, and A.P. Goode, *Diagnostic accuracy of clinical tests for assessment of hamstring injury: a systematic review*. The Journal of orthopaedic and sports physical therapy, 2013. **43**(4): p. 223-31.
- Woodley, S.J., et al., *Lateral hip pain: findings from magnetic resonance imaging and clinical examination*. The Journal of orthopaedic and sports physical therapy, 2008. **38**(6): p. 313-28.
- Delp, S.L., et al., *Variation of rotation moment arms with hip flexion*. Journal of biomechanics, 1999. **32**(5): p. 493-501.
- Lequesne, M., et al., *Gluteal tendinopathy in refractory greater trochanter pain syndrome: diagnostic value of two clinical tests*. Arthritis and rheumatism, 2008. **59**(2): p. 241-6.
- Fearon, A.M., et al., *Greater trochanteric pain syndrome: defining the clinical syndrome*. British journal of sports medicine, 2012.
- Maitland, G.D., *Peripheral manipulation*. 3rd ed ed. 1991, London, Boston, Sydney: Butterworth-Heinemann.
- Blankenbaker, D.G., et al., *Correlation of MRI findings with clinical findings of trochanteric pain syndrome*. Skeletal Radiol, 2008. **37**(10): p. 903-9.
- Kellgren, J.H. and J.S. Lawrence, *Radiological assessment of osteo-arthritis*. Annals of the rheumatic diseases, 1957. **16**(4): p. 494-502.
- Borg, G.A., *Psychophysical bases of perceived exertion*. Medicine and science in sports and exercise, 1982. **14**(5): p. 377-81.
- Fearon, A.M., et al., *Development and validation of a VISA tendinopathy questionnaire for greater trochanteric pain syndrome, the VISA-G*. Man Ther, 2015.
- Horn, K.K., et al., *The patient-specific functional scale: psychometrics, clinimetrics, and application as a clinical outcome measure*. The Journal of orthopaedic and sports physical therapy, 2012. **42**(1): p. 30-42.
- Gusi, N., P.R. Olivares, and R. Rajendram, *The EQ-5D Health-Related Quality of Life Questionnaire*, in *Handbook of disease burdens and quality of life measures*, V.R. Preedy and R.R. Watson, Editors. 2010, Springer New York. p. 87-99.
- Sullivan, M.J., S.R. Bishop, and J. Pivik, *The Pain Catastrophizing Scale: Development and Validation*. Psychological Assessment, 1995. **7**(4): p. 524-532.
- Nicholas, M.K., *The pain self-efficacy questionnaire: Taking pain into account*. Eur J Pain, 2007. **11**(2): p. 153-63.

17. Kroenke, K., R.L. Spitzer, and J.B. Williams, *The PHQ-9: validity of a brief depression severity measure*. Journal of general internal medicine, 2001. **16**(9): p. 606-13.
18. Timperio, A., J. Salmon, and F. Bull, *Validation of adult physical activity questions for use in Australian population surveys.*, A.I.o.H.a. Aging, Editor. 2002: Canberra.
19. Ireland, M.L., et al., *Hip strength in females with and without patellofemoral pain*. The Journal of orthopaedic and sports physical therapy, 2003. **33**(11): p. 671-6.

**Table S5 – Secondary outcome measures.** Group descriptives (Frequency for Clinically Important Pain Reduction, Mean (SD) for all others) and between-group comparisons (Risk Difference (95%CI) for Clinically Important Pain Reduction, Mean Difference (95%CI) for all others) at each time point. EDX – Education and Exercise group; CSI- Corticosteroid Injection group; W&S- Wait and See control group; SD- Standard Deviation; CI- Confidence Interval

Week	EDX	CSI	W&S	EDX vs W&S		CSI vs W&S		EDX vs CSI	
<b>Clinically Important Pain Reduction (pain reduction &gt;2/10 on numeric pain rating scale)</b>									
		Count/Total		RD (95% CI)	NNT (95% CI)	RD (95% CI)	NNT (95% CI)	RD (95% CI)	NNT (95% CI)
4	44/66	47/65	20/66	36.6 (20.8,52.4)	2.7 (1.9,4.8)	42.7 (27.3,58.1)	2.3 (3.7,1.7)	-6.1(-21.5,9.3)	-16.4 (10.8,-4.7)
8	56/66	44/66	31/68	38.4 (20.8,52.4)	2.6 (1.9,4.2)	21.4 (5.1,37.7)	4.7 (19.8,2.7)	17.0 (2.6,31.4)	5.9 (3.2,39.2)
12	45/58	43/65	36/64	19.7 (3.3,36.1)	5.1 (2.8,30.0)	10.7 (-5.7,27.1)	9.4 (-17.4,3.7)	9.0 (-7.2,25.3)	11.1 (4.0,-13.8)
26	48/61	40/64	39/61	14.6 (-1.5,30.7)	6.8 (3.3,-68.4)	0.0 (-16.9,16.8)	-2161.2(-5.9,6.0)	14.7(-1.2,30.6)	6.8 (3.3,-82.2)
52	48/65	47/63	34/61	20.5 (4.5,36.5)	4.9 (2.7,22.1)	19.0 (2.8,35.2)	5.3 (35.5,2.8)	1.5(-13.7,16.7)	66.8 (6.0,-7.3)
<b>Patient Specific Functional Scale (0-10, lower scores indicating greater functional difficulty)</b>									
		Mean (SD)		Mean Difference (95% CI)					
4	5.7 (2.7)	6.3 (2.4)	4.8 (2.2)	1.1 (0.3, 1.9)		1.7 (0.9, 2.4)		-0.6 (-1.4, 0.2)	
8	7.3 (2.2)	6.2 (2.4)	5.2 (2.4)	2.3 (1.5, 3.1)		1.3 (0.5, 2.1)		1.0 (0.3, 1.8)	
12	7.6 (1.9)	6.3 (2.4)	5.4 (2.2)	2.2 (1.3, 3.1)		1.0 (0.2, 1.8)		1.1 (0.3, 2.0)	
26	7.4 (2.3)	6.3 (2.4)	6.0 (2.7)	1.4 (0.5, 2.34)		0.5 (-0.4, 1.4)		1.0 (0.04, 1.9)	
52	7.4 (1.9)	6.6 (2.5)	6.5 (2.6)	1.1 (0.2, 1.9)		0.2 (-0.7, 1.1)		0.9 (-0.03, 1.8)	
<b>VISA-G (0-100, with higher scores indicating less pain and better function)</b>									
4	67.7 (14.8)	69.3 (16.5)	61.0 (13.4)	6.6 (1.6, 11.6)		9.2 (4.4, 14.1)		-2.6 (-7.6, 2.3)	
8	77.0 (14.3)	71.7 (14.9)	65.0 (15.5)	12.3 (7.2, 17.4)		7.4 (2.2, 12.6)		4.9 (-0.08, 9.9)	
12	79.3 (14.3)	70.7 (15.4)	64.8 (17.2)	13.1 (7.4, 18.8)		6.6 (1.4, 11.7)		6.6 (1.2, 11.9)	
26	79.2 (15.2)	70.7 (16.0)	65.8 (18.5)	15.1 (9.3, 20.9)		7.9 (2.3, 13.6)		7.2 (1.2, 13.1)	
52	77.9 (16.6)	72.8 (15.6)	70.8 (18.0)	6.2 (-0.1, 12.5)		2.2 (-3.8, 8.3)		3.9 (-2.1, 10.0)	
<b>Lateral Hip Pain Questionnaire (0-100, lower scores indicating less pain and better function)</b>									
4	27.6 (16.3)	27.5 (18.5)	41.7 (18.2)	-14.7 (-19.9, -9.5)		-14.7 (-19.9, -9.5)		0.1 (-5.3, 5.5)	
8	17.5 (14.0)	25.8 (18.3)	36.8 (20.0)	-19.3 (-24.8, -13.9)		-11.4 (-16.8, -5.9)		-7.9 (-13.4, -2.5)	
12	17.7 (16.3)	25.8 (17.7)	34.3 (21.3)	-15.3 (-21.4, -9.3)		-8.4 (-14.3, -2.4)		-6.9 (-13.0, -0.9)	
26	18.0 (17.6)	26.2 (18.8)	30.3 (24.0)	-11.7 (-18.6, -4.7)		-4.7 (-11.5, 2.2)		-7.0 (-13.8, -0.2)	
52	17.6 (18.4)	24.4 (18.3)	31.1 (23.1)	-13.3 (-20.4, -6.1)		-8.0 (-14.9, -1.1)		-5.2 (-12.3, 1.8)	

Week	EDX	CSI	W&S	EDX vs W&S	CSI vs W&S	EDX vs CSI
<b>Pain Frequency (an item in LHPQ, 0-10, 0=No pain at all, 10=Constant pain)</b>						
4	3.3(2.3)	3.2(2.7)	5.0(2.7)	-1.5 (-2.4, -0.6)	-1.4 (-2.3, -0.6)	-0.03 (-0.9, 0.9)
8	2.1(2.2)	3.3(2.9)	4.3(2.8)	-1.9 (-2.8, -1.1)	-0.8 (-1.7, 0.1)	-1.1 (-2.0, -0.3)
12	1.9(2.1)	3.2(2.8)	4.4(2.9)	-2.3 (-3.2, -1.5)	-1.1 (-2.0, -0.23)	-1.2 (-2.0, -0.3)
26	1.9(2.3)	3.0(2.7)	3.5(3.1)	-1.3 (-2.3, -0.4)	-0.4 (-1.4, 0.6)	-0.9 (-1.9, 0.04)
52	2.0(2.3)	3.1(2.9)	3.6(2.9)	-1.3 (-2.3, -0.4)	-0.2 (-1.2, 0.8)	-1.1 (-2.1, -0.2)
<b>Torque (Nm/kg)</b>						
8	0.9 (0.3)	0.9 (0.3)	0.9 (0.4)	0.1 (0.01, 0.2)	0.1 (-0.02, 0.2)	0.02 (-0.1, 0.1)
<b>Active Lag (Degrees)</b>						
8	7.1 (4.6)	8.8 (5.7)	8.7 (6.5)	-1.6 (-3.2, 0.1)	-0.02 (-1.8, 1.7)	-1.6 (-3.4, 0.3)
<b>Active Australia Questionnaire (Minutes spent in all activity types/week)</b>						
4	374 (371)	438 (450)	427 (393)	21.2 (-110.1, 152.5)	114.8(-9.9, 239.5)	-93.6 (-232.1, 44.9)
8	447 (375)	392 (386)	507 (501)	35.5 (-82.6, 153.7)	13.2 (-107.8, 134.2)	22.3 (-95.5, 140.1)
12	490 (460)	409 (421)	516 (481)	54.6 (-91.7, 200.8)	13.9 (-129.2, 157.1)	40.6 (-98.5, 179.7)
26	494 (479)	375 (348)	493 (426)	76.9 (-71.6, 225.4)	-34.1 (-187.7, 119.4)	111.0 (-31.3, 253.3)
52	483 (486)	375 (294)	542 (465)	22.4 (-138.5, 183.2)	-81.3 (-233.5, 70.9)	103.7 (-47.9, 255.3)
<b>EuroQoL (EQ-5D)</b>						
4	0.8 (0.1)	0.8 (0.1)	0.7 (0.2)	0.1 (0.01, 0.1)	0.1 (0.01, 0.1)	0.0 (-0.04, 0.05)
8	0.9 (0.1)	0.8 (0.2)	0.8 (0.2)	0.1 (0.03, 0.1)	0.03 (-0.02, 0.1)	0.1 (0.01, 0.1)
12	0.9 (0.1)	0.8 (0.1)	0.8 (0.2)	0.1 (0.1, 0.1)	0.1 (0.01, 0.1)	0.04 (0.0, 0.09)
26	0.9 (0.1)	0.8 (0.1)	0.8 (0.2)	0.1 (0.04, 0.1)	0.03 (-0.02, 0.1)	0.1 (0.01, 0.1)
52	0.9 (0.1)	0.8 (0.2)	0.8 (0.2)	0.1 (0.03, 0.2)	0.03 (-0.04, 0.1)	0.1 (0.0, 0.1)
<b>Patient Self Efficacy Questionnaire (0-60, higher scores reflect stronger self-efficacy beliefs)</b>						
4	52.5 (7.3)	50.3 (9.5)	46.6 (11.6)	6.3 (3.4, 9.1)	3.6 (0.7, 6.5)	2.7 (-0.3, 5.6)
8	55.3 (6.2)	51.7 (9.0)	49.3 (10.0)	5.9 (3.2, 8.6)	2.5 (-0.2, 5.2)	3.4 (0.7, 6.1)
12	54.8 (8.5)	51.7 (8.7)	48.2 (11.7)	6.8(3.3, 10.3)	3.9 (0.8, 7.1)	2.8 (-0.6, 6.2)
26	56.1 (6.3)	51.9 (9.3)	51.5 (11.4)	5.4 (1.8, 8.9)	1.9 (-1.4, 5.3)	3.5 (0.2, 6.7)
52	55.5 (6.9)	53.6 (8.3)	50.2 (11.9)	4.8 (-0.4, 9.9)	3.3 (-1.9, 8.5)	1.5 (-2.2, 5.1)
<b>Patient Health Questionnaire9 (Levels of depression; 5=mild, 10=moderate, 15=moderately severe, 20= severe)</b>						
4	3.0 (3.3)	3.0 (3.9)	4.7 (4.6)	-1.3 (-2.4, -0.3)	-1.7 (-2.7, -0.7)	0.4 (-0.6, 1.4)
8	2.0 (2.9)	2.8 (3.6)	3.8 (4.3)	-1.7 (-2.7, -0.7)	-1.0 (-1.9, -0.02)	-0.7 (-1.7, 0.3)
12	2.2 (2.4)	2.7 (3.8)	4.4 (5.5)	-2.5 (-4.1, -0.8)	-2.2 (-3.8, -0.6)	-0.2 (-1.6, 1.1)
26	2.2 (2.7)	3.1 (3.8)	3.5 (4.8)	-1.2 (-2.3, -0.01)	-0.3 (-1.4, 0.8)	-0.8 (-1.9, 0.3)

Week	EDX	CSI	W&S	EDX vs W&S	CSI vs W&S	EDX vs CSI
52	2.6 (3.7)	2.7 (3.6)	3.9 (5.6)	-1.2 (-3.1, 0.6)	-1.6 (-3.2, -0.01)	0.4 (-1.3, 1.9)
<b><i>Pain Catastrophizing Scale (0-52, higher scores indicating higher levels of pain catastrophization)</i></b>						
4	7.2 (8.1)	9.9 (7.4)	12.0 (9.1)	-4.3 (-6.9, -1.7)	-2.3 (-4.6, 0.1)	-2.1 (-4.7, 0.5)
8	6.2 (8.6)	8.3 (7.1)	9.0 (7.8)	-2.6 (-5.0, -0.1)	-0.8 (-3.0, 1.3)	-1.7 (-4.1, 0.7)
12	5.5 (8.8)	7.0 (5.9)	9.0 (8.1)	-2.9 (-5.6, -0.3)	-2.6 (-5.2, 0.1)	-0.4 (-3.3, 2.5)
26	5.2 (8.4)	6.7 (6.0)	8.1 (9.2)	-2.4 (-5.5, 0.7)	-2.3 (-5.1, 0.6)	-0.2 (-2.9, 2.6)
52	5.6 (8.0)	6.0 (6.5)	8.9 (10.2)	-3.1 (-7.3, 1.1)	-4.4 (-7.8, -1.0)	1.3 (-1.9, 4.5)

Figure S6. Primary outcome measure—global rating of change in hip condition (GROC). Frequency count (%) for GROC categories at each follow-up. Trial groups were education plus exercise (EDX), corticosteroid injection use (CSI), or wait and see approach (WS)

