Effects of education plus exercise versus corticosteroid injection versus no treatment on global outcome and pain among patients with gluteal tendinopathy: a randomized clinical trial.

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Abstract

Objectives: To compare effects of an education, load management and exercise program (EDX), corticosteroid injection (CSI), and no treatment (control) on pain and global improvement in people with gluteal tendinopathy (GT).

Design: Prospective, three-arm, single blinded randomised clinical trial.

Setting: Multicentre (Brisbane and Melbourne)

Participants: 204 participants (167 female) aged 35 to 70, with lateral hip pain for >3months, >3/10 on numeric rating scale, with clinically- and MRI-confirmed diagnosis of GT, and no CSI in previous 12 months, current physiotherapy, total hip replacement or neurological conditions.

Interventions: Participants allocated to a physiotherapy-led 14-session/8-week EDX (n=69), a single CSI (n=66), or advice only (n=69).

Main Outcomes: Primary outcomes were patient-reported Global Rating of Change (GROC) in hip condition on 11-point scale dichotomised to success and non-success, and pain intensity (0=no pain, 10=worst pain) at 8 weeks, with follow-up at 52 weeks.

Results: Of 204 randomized participants (mean age 54.8 (SD 8.8) years), 189 (92.6%) completed 12-month follow-up. At 8 weeks, success was reported by 51/66 EDX participants, 38/65 CSI and 20/68 control. EDX (Risk Difference (95%CI): 49.1% (34.6 to 63.5); NNT (95% CI): 2.0(1.6 to 2.9)) and CSI (29.2% (13.2 to 45.2); 3.4(2.2 to 7.6)) were better than control. EDX was better than CSI (19.9% (4.7 to 35.0); 5.0(2.9 to 21.1)). Pain was 1.5 (1.5) out of 10 for EDX, 2.7 (2.4) for CSI and 3.8 (2.0) for control. EDX (Mean Difference (95%CI): -2.2 (-2.89 to-1.54)) and CSI (-1.04 (-1.72 to -0.37)) were better than control. EDX was better than CSI (-1.04 (-1.72 to -0.37)). At 52 weeks, 51/65 EDX participants reported success, 36/63 CSI and 31/60 control, with EDX better than CSI (20.4% (4.9 to 35.9); 4.9(2.8 to 20.6)) and control (26.8% (11.3 to 42.3); 3.7(2.4 to 8.8)). Pain at 52 weeks was 2.1

(2.2) for EDX, 2.3 (1.9) CSI and 3.2 (2.6) control, with EDX not different from CSI (Mean Difference (95%CI): -0.26 (-1.06 to 0.55)) but both less than control (EDX (-1.13 (-1.93 to -0.33)); CSI (0.87 (-1.68 to -0.07)).

Conclusions: In GT, EDX and CSI resulted in higher rates of patient-reported global improvement and lower pain intensity at 8 weeks, than control. EDX was better than CSI. EDX exhibited better global improvement than CSI at 52 weeks, but no difference in pain intensity. These results support use of EDX for GT, whereas CSI might only have short-term utility.

Trial Registration: The trial was prospectively registered (Australian New Zealand Clinical Trials Registry ACTRN12612001126808).

Introduction

Gluteal tendinopathy, which is often referred to as greater trochanteric bursitis or greater trochanteric pain syndrome, is prevalent (10-25%), experienced by one in four women aged over 50 years (1, 2). It presents as pain and tenderness over the greater trochanter and often interferes with sleep and physical function. The level of disability and quality-of-life is commensurate with severe hip osteoarthritis (3). Effective management strategies are required.

Corticosteroid injection is commonly employed in the management of gluteal tendinopathy and although early outcomes are promising, medium-term benefit is significantly less, and long-term outcomes are no better than a wait-and-see approach (4, 5). A contemporary approach for managing other tendinopathies is to combine education to reduce load on the tendon during sustained postures and function (i.e. load management) with exercises (6) that target the underlying pathology. This approach has not been tested in randomized clinical trials for gluteal tendinopathy. One non-randomized clinical trial compared a home exercise program to corticosteroid injection and radial shock wave therapy, reporting that home exercise performed poorly by comparison at 1 and 4 months (5). No load management advice was provided and exercise selection for the gluteal tendons and muscles (7) did not specifically address adverse loading.

A randomized clinical trial was conducted to compare the effects of a program of education about tendon load management plus specific exercise (8), a single corticosteroid injection and a no treatment control on pain and global improvement in individuals with gluteal tendinopathy. The hypothesis was that both education plus exercise and corticosteroid injection would be better than control in the short-term (8 weeks), while education plus exercise would be better than injection in the longer-term (52 weeks).

Methods

This was a multicentre, parallel, 3-group pragmatic randomized clinical trial. The trial was prospectively registered (Australian New Zealand Clinical Trials Registry ACTRN12612001126808) and the protocol published (8). The trial adhered to the principles of the Declaration of Helsinki (9), with ethical approval obtained from the Human Research Ethics Committees of the Universities of Queensland (#2012000930) and Melbourne (ID 1238598). Participants provided written informed consent. There were no protocol deviations in the conduct of the trial, but there were several minor variations in planned statistical analyses in the form of the following refinements: multiple imputation was specified, the stratifying variable of study site was to be included in regression models, regression models to be fit separately at each time point, and for binary outcomes, binary regression models with a log link would be used. These were published prior to close out of the study (https://espace.library.uq.edu.au/view/UQ:409744). A post hoc analysis of the pain data was performed by dichotomising the continuous interval scale data based on a clinically important difference and was considered as a secondary outcome.

Participants

Community-dwelling participants were recruited from Brisbane and Melbourne, Australia via advertisements in print, radio, and social media. Participants were not informed of the study hypotheses. Inclusion criteria included: aged between 35 and 70 years, lateral hip pain for >3 months, pain intensity >3 on a numerical rating scale (0 = no pain, 10 = worst pain), clinical diagnosis of gluteal tendinopathy by a physiotherapist and confirmed by MRI evidence of an intra tendinous increase in signal intensity in the gluteus minimus and medius tendons on T2-weighted images of the hip (10). Major exclusion criteria were: low back pain, sciatic or groin pain >2/10 on a numerical rating scale; corticosteroid injection within the previous 12 months; current physiotherapy; total hip replacement, and other neurological conditions.

Randomization

Volunteers underwent telephone screening followed by physical examination and diagnostic imaging. After baseline assessment, those eligible were randomized (using a computer-generated schedule by an independent off-site organisation), stratified by site (Brisbane, Melbourne) to receive: 1) education on load management plus exercise, 2) corticosteroid injection, or 3) no treatment control. Allocations were sealed in opaque consecutively numbered envelopes by an independent person not involved in recruitment and kept in a central locked location. Envelopes were opened at each site sequentially.

Study Treatments

Celestone 1ml or Kenacort A40 1ml and local anaesthetic (Bupivacaine 2ml or Marcaine 1ml) was administered by injection under ultrasound guidance by an experienced radiologist. Education plus exercise involved 14 individual sessions over eight weeks (60 mins initial session, 30 mins thereafter) with a registered physiotherapist, during which participants received education on tendon care, particularly on appropriate amounts and gradual progression of tendon loading (including handouts, DVD) and a home exercise program of targeted strengthening of the hip abductor muscles and dynamic control of adduction during function (4-6 exercises to be performed daily). The no treatment control involved attendance at one session with a physiotherapist who provided general information about the condition, possible risk factors and advice regarding continuation of activity, as well as reassurance that the condition resolves over time. The treatments are described in detail in the protocol paper (8) and summarized in Supplementary Table S1.

Outcome Measures

Primary Outcome Measures

Primary outcomes were two valid and reliable self-report measures (8). The Global Rating of Change Score (GROC) is an 11-point numerical rating scale anchored with “Very Much Better” or “Very Much

Worse", on which the participant rates their perceived overall change in their hip condition (11). Responses to the GROC were dichotomised with success defined as criterion from "Moderately Better" to "Very Much Better", consistent with other studies of this condition (4, 5). Hip pain intensity was self-rated as the average amount of hip pain experienced over the previous week as measured on an 11-point numerical rating scale, with anchors of no pain = 0 and worst pain = 10.

Secondary Outcome Measures

Secondary measures (8) included: gluteal tendinopathy related pain and disability (i.e., VISA-G (12) , Lateral Hip Pain Questionnaire (8), and Patient Specific Functional Scale (PSFS) (13); physical tests of hip abductor muscle strength (torque and active abduction lag); pain measures (Pain Self-Efficacy Questionnaire (PSEQ) (14), Pain Catastrophizing Scale (PCS)(15); as well as Patient Health Questionnaire 9 (PHQ9) (16), the Active Australia survey (17) , and EuroQOL (EQ-5D^{TM}) (18). A post hoc dichotomization of the primary continuous pain outcome with respect to a minimal clinically important difference of 2/10 points (19), referred to as a clinically important pain reduction, was also undertaken. We also collected information on adherence to treatments (Supplementary Table S2), not per protocol treatments and adverse events through participant diaries and physiotherapists records. All secondary measures are described in Supplementary Table S3.

Follow-up Assessments

Follow-up via postal questionnaires was performed at 4, 8, 12, 26 and 52 weeks. Assessment of physical outcome measures was performed at eight weeks by a physiotherapist blinded to group allocation. The primary time points of interest were 8 and 52 weeks.

Statistical Analysis

An independent statistician who was blind to group allocation performed analyses. The a-priori determined statistical analysis plan and data are published and available on request. (https://espace.library.uq.edu.au/view/UQ:409744).

Sample size was based on the ability to detect a clinically relevant difference of 30% in success rate on GROC between the two treatment groups and the control group at 8 weeks from baseline using the Dunnett's test procedure, accounting for a 15% loss to follow-up, a type 1 error rate of 0.05, any-pair power of 0.95 and all-pair power of 0.80. Assuming a success rate of 40% for the control group, and 70% each for the education plus exercise and corticosteroid injection groups, the sample size was calculated at 67 participants per group for a total sample size of 201. Using the Dunnett's test procedure adjusts the required sample size to allow for the two comparisons to the control group at the 8 week time point.

Statistical analysis was conducted on an intention-to-treat basis using Stata v14.1 (StataCorp). Multiple imputation was used to account for missing outcome data. Logistic regression imputation models for were used for categorical data (GROC, clinically important pain reduction) and chained equations with predictive mean matching drawing from three nearest neighbours for continuous outcomes, imputing data for each treatment group separately. Missing baseline variables were imputed using single mean imputation (20). Estimates from 10 imputed datasets were combined using Rubin's rules (21).

For continuous outcomes, the mean difference (95% confidence interval (CI)) between groups was estimated using linear regression models adjusting for group, baseline levels of the outcome, and site (Brisbane or Melbourne) for each time point. Binary outcomes were compared between groups using risk differences (RD, 95% CI) calculated from binomial regression models with a log link, including terms for group and site at each time point. Numbers Needed to Treat was calculated for binary

outcomes from regression models for the risk difference, adjusted for the stratifying variable of site. P-values were two-sided with significance set at 0.05.

Patient Involvement

A patient representative at NHMRC Program Grant meetings was involved in the planning and development of the present study. The burden of participating was not assessed after a participant's involvement, but during recruitment and screening all participants were asked if they were prepared to undergo all of the interventions and outcome measures. The results will be disseminated directly to all participants via email.

Results

Enrolment and Follow-up

Between March 2013 and September 2015, 204 participants were enrolled. Twelve-month follow-up was completed by October 2016 for 63 (/66, 95.5%) participants in the corticosteroid injection group, 65 (/69, 94.2%) in education plus exercise group, and 61 (/69, 88.4%) in the control group (Figure 1). One participant in the education plus exercise group did not receive the intervention and two withdrew, one participant in the control group withdrew, and all participants in the corticosteroid injection group received the intervention. Four participants in the corticosteroid injection group reported seeking physiotherapy or chiropractic treatment by 52 weeks, and two participants in the control group reported having a corticosteroid injection by 52 weeks. Fifteen participants provided only the primary outcome measures via telephone at 52 weeks (7 education plus exercise, 3 corticosteroid injection and 5 no treatment control).

Baseline characteristics were similar in the three groups (Table 1). No participant or practitioner reported a serious adverse event. Reported average weekly adherence of all participants in the

education plus exercise group to the prescribed program, based on percentage of completed exercise sessions reported in the exercise diary, was always >80% (Supplementary Table S2).

Primary Outcomes

At 8 weeks, all groups were different from each other in success rate (GROC) and pain (Figure 2 and 3, Table 2). The 77.3% success rate on the GROC scale for education plus exercise was greater than the 29.4% success rate of control (Risk Difference (95% CI) = 49.1% (34.6 to 63.5)). The 58.5% success rate of corticosteroid injection was also greater than control (29.2% (13.2 to 45.2)). Education plus exercise had a greater success rate than corticosteroid injection (19.9% (4.7 to 35.0)). The Number Needed to Treat (95%CI) for difference in success rate was 2.0 (1.6, 2.9) between education plus exercise and control, 3.4 (2.2 to 7.6) between corticosteroid and control and 5.0 (2.9 to 21.1) between the two interventions. For pain, education plus exercise reported less pain than control (mean difference (95%CI): -2.2 (-2.89 to -1.54)), corticosteroid injection less pain than control (-1.17 (-1.85 to -0.50)) and education plus exercise less pain than corticosteroid injection (-1.04 (-1.72 to -0.37), Table 2).

At 52 weeks, the 78.6% success rate for education plus exercise was better than the 58.3% success rate for corticosteroid injection (20.4% (4.9 to 35.9); NNT(95% CI): 4.9(2.8 to 20.6)) and better than the 51.9% success rate for control (26.8% (11.3 to 42.3); NNT(95%CI): 3.7(2.4 to 8.8)). The success rate for corticosteroid injection was not different from control (6.4% (-10.7, 23.6; 0.46); NNT(95% CI): 15.6(-9.3 to 4.2)). The pain data exhibited a somewhat different effect profile at 52 weeks, with no difference between education plus exercise and corticosteroid injection (MD(95%)CI); -0.26(-1.06 to 0.55)) but with both education plus exercise and corticosteroid injection reporting less pain than control (-1.13 (-1.93 to -0.33)) and -0.87 (-1.68 to -0.07) respectively) (Table 2).

Secondary Outcomes

Results of secondary outcomes are found in Supplementary Table S4. At 8 weeks, education plus exercise was different from control in all secondary outcomes, except for the Active Lag test and Active Australia Questionnaire, which were not different between groups. Corticosteroid injection was also different from control in measures of clinically important pain reduction, function, disability and depression, but not quality-of-life, catastrophizing and self-efficacy. Education plus exercise was better than corticosteroid injection in functional outcomes, quality-of-life, and self-efficacy measures and also had less frequent pain and greater clinically important pain reduction.

By 52 weeks, there were no differences between education plus exercise and corticosteroid injection in any secondary outcomes except that education plus exercise had less frequent pain. Education plus exercise had better clinically important pain reduction, function and quality-of-life and less frequent pain than control. Corticosteroid injection differed from control on clinically important pain reduction, function (LHPQ), catastrophizing and depression.

Discussion

As hypothesized, there was greater patient rated global improvement and lower pain intensity in the short-term (8 weeks) following education plus exercise and corticosteroid injection for gluteal tendinopathy than there was with the no-treatment control. In addition, we found that outcomes were greater for education plus exercise compared to injection at 8 weeks. The hypothesis for the long term outcome (52 weeks) was only partially upheld with patient rated improvement being greater for education plus exercise than injection, whereas there was no difference in pain intensity between the two treatments.

In proposing to implement these findings into clinical practice, there are a number of limitations and strengths of the study to be considered. Participants with gluteal tendinopathy were specifically selected on the basis of clinical diagnosis and MRI confirmation, with other musculoskeletal

complaints (such as low back pain or hip osteoarthritis) excluded, and the interventions in the trial were designed specifically to address gluteal tendinopathy. Pragmatically, it is common for clinicians to encounter patients with multiple conditions, which would usually also be addressed in their management. MRI confirmation is not always available or affordable, however there is evidence that some of the clinical diagnostic tests used in this study's selection process have high diagnostic utility when referenced to MRI (10), thus use of these tests could improve confidence in selecting appropriate patients for which to apply treatments from this clinical trial. Differences in number of sessions and time spent with practitioners between the different groups may influence outcomes, however, these interventions are designed to reflect conventional management protocols, and requirements and investment of time for each group are implicitly unbalanced. All physiotherapy and radiology clinics were community based, and treatments were generally well accepted by participants as demonstrated by the high retention rates and no major adverse events. Although blinded to study hypotheses, participants were not blinded to the treatments, which may have resulted in bias when completing the patient rated outcome measures, particularly as one group was a no treatment control. The potential for Type 1 error due to multiple comparisons must also be considered. Adjustment to the significance level was not made, but p-values for all comparisons are provided (22). Thus, the results concerning the secondary time points and outcomes may be considered exploratory. Notwithstanding this, it should be noted that p-values for the three primary comparisons would continue to be labelled as statistically significant when Bonferroni corrections for three pair-wise comparisons were applied post-hoc.

Few other studies have addressed the conservative management of gluteal tendinopathy with exercise and education compared to corticosteroid injection. The results from this study regarding the corticosteroid injections concur with the only other comparable randomised trial in gluteal tendinopathy, where CSI provided short-term (12 weeks) but not longer term (52 weeks) benefits

compared with usual care (4). These outcomes are also broadly consistent with trials involving tendinopathies at other sites (23, 24). Regarding the exercise and education program, this study showed that it was better than control (wait and see) at all time points, demonstrating that it is effective for the management of gluteal tendinopathy. A novel finding that was not hypothesised was the greater benefit of education plus exercise over corticosteroid injection on all primary outcomes at 8 weeks. This is in contrast with a previous clinical trial involving home-based exercise for gluteal tendinopathy (5), which reported a significantly lower success rate of only 7% for exercise compared to the 75% success rate for CSI at 1 month. By 4 months the success rate in the exercise group was 41%, which did not differ from the 51% success rate in the injection group. The success rates for education and exercise in the current study were much higher, 58% to 74% over 4 to 12 weeks. This may be due to the fact that the present study addressed the principles of tendon load management and specifically targeted the function of the gluteus minimus and medius muscles with the prescribed exercise program, whereas the home exercise program in the previous study included exercises that did not specifically target the gluteus medius and minimus muscles, or control the degree of tendon loading (especially compression load) for the gluteal musculotendinous complex, with limited exercise supervision (5).

The early success rate of the education and exercise program, compared to CSI and control may emphasize the importance of a sound evidence-based rationale for condition specific management of gluteal tendinopathy. Contemporary evidence suggests that optimal treatment for tendinopathies requires a program that targets the underlying pathology of tendinopathy using education for load management and exercise (6). The education plus exercise program had a dual focus: to educate the participant to avoid movements and positions that compress the gluteus medius and minimus tendons (the tendons implicated in gluteal tendinopathy) against the greater trochanter (7, 25) and to progressively condition and strengthen the gluteal muscles in a specific manner to improve load-

bearing capacity of the musculotendinous unit (Supplementary Table S1). Adequate supervision to enable progression and correction of form, as well as to directly address concerns and questions about the education information is likely to be important for delivery of education plus exercise programs (26) and the relative benefits reported herein. Although better than CSI at 8 weeks, there were mixed findings for the hypothesis of longer-term benefits of education plus exercise over CSI at 52 weeks. Success (GROC), quality of life (EQ-5D) and pain frequency, but not pain intensity or other gluteal tendinopathy specific measures (e.g. VISA-G, LHPQ, hip abduction muscle torque) indicated that education plus exercise was better than CSI. As a global impression of a participant's perception of their hip condition over time, the GROC might reflect less frequent pain and better quality-of-life rather than pain intensity and gluteal tendinopathy-specific measures of disability. Given that measures of muscle strength were not different at 8 weeks, the mechanism underpinning the benefits of education plus exercise might well reside more in the education aspect of the program. The education component involved 14 sessions with a physiotherapist spread over 8 weeks during which there was an emphasis on avoidance of postures and movements that compress the tendons against the greater trochanter as well as appropriately controlling and gradually progressing tendon loads. All of these could plausibly influence modifiable factors and contribute to feeling globally improved with less frequent hip pain and better quality-of-life when compared to the corticosteroid injection and control. Notwithstanding, the strengthening exercises might have also contributed to improved motor control (which was not measured), direct analgesic effects and/or improved tendon structure (27, 28), without measurable increase in strength, and this may have underpinned benefits from the education regarding load management.

Considering the favourable outcomes of an education and exercise program in both the short and long term, further research might be well directed towards establishing the degree of contribution of specific education alone about the condition itself, tendon loading principles and appropriate strategies for self management, and whether this may be a viable, cost-effective approach to early

management and prevention of progression and recurrences. Understanding and knowledge of appropriate management strategies may engender a greater sense of self-efficacy and control over the condition, leading to improved quality of life.

Conclusion

In GT, education plus exercise and corticosteroid injection resulted in higher rates of patient-reported global improvements and lower pain intensity at 8 weeks, compared to no treatment. Education plus exercise was also better than injection. Education plus exercise exhibited better global improvement than injection at 52 weeks, but with no difference in pain intensity between groups. These results support use of education plus exercise for gluteal tendinopathy, while corticosteroid injection might have utility in the short-term.

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RM had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Competing Interests

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare support from the NHMRC Program Grant only for the submitted work (see above); no financial relationships with any organisations that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

What is already known on this topic

- Corticosteroid injections are commonly used for treatment of tendinopathy, with good short-term but poor long-term outcomes.
- Exercise is recommended for tendinopathies, but there are no randomised controlled trials of its effects in gluteal tendinopathy.

What this study adds

- This randomised controlled trial provides evidence that education and exercise produce greater pain relief and global improvement than corticosteroid injection or no treatment by 8 weeks.
- Over one year, the rates of improvement remain higher for education plus exercise than injection.
- Education plus exercise for gluteal tendinopathy confers better short and long term outcomes, whereas corticosteroid injection might only have short-term utility.

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Table 1. Baseline descriptive characteristics given as the mean (standard deviation), median (1st, 3rd quartile) or number (percentage) for the education plus exercise (EDX), corticosteroid injection (CSI) and no treatment control groups.

Characteristic	All participants (n=204)	EDX (n=69)	CSI (n=66)	Control (n=69)
Site				
Brisbane	99 (48.5%)	32 (46.4%)	33 (50.0%)	34 (49.3%)
Melbourne	105 (51.5%)	37 (53.6%)	33 (50.0%)	35 (50.7%)
Age years	54.8 (8.8)	54.8 (8.1)	55.3 (9.4)	54.5 (9.1)
Female	167 (81.9%)	56 (81.2%)	57 (86.4%)	54 (78.3%)
Height m	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)	1.7 (0.1)
Weight kg	75.9 (15.3)	75.9 (14.4)	74.4 (14.6)	77.3 (16.7)
BMI kg/m^2	27.4 (5.1)	27.7 (4.8)	27.0 (5.1)	27.6 (5.5)
Waist girth cm	88.6 (13.4)	87.7 (12.4)	88.9 (13.3)	89.2 (14.5)
Hip circumference cm	104.6 (10.1)	104.2 (8.3)	104.0 (10.0)	105.5 (11.8)
Hormonal status				
Premenopausal	43 (21.1%)	16 (23.2%)	15 (22.7%)	12 (17.4%)
Perimenopausal	24 (11.8%)	7 (10.1%)	5 (7.6%)	12 (17.4%)
Postmenopausal	93 (45.6%)	31 (44.9%)	36 (54.5%)	26 (37.7%)
Unknown	7 (3.4%)	2 (2.9%)	1 (1.5%)	4 (5.8%)
N/A	37 (18.1%)	13 (18.8%)	9 (13.6%)	15 (21.7%)
Main occupation[a]				
Manager/professional	120 (59.1%)	36 (52.9%)	41 (62.1%)	43 (62.3%)
Tradesperson/clerical worker	55 (27.1%)	24 (35.3%)	17 (25.8%)	14 (20.3%)
Transport, sales, service	16 (7.9%)	6 (8.8%)	3 (4.5%)	7 (10.1%)
No paid job	11 (5.4%)	2 (2.9%)	4 (6.1%)	5 (7.2%)
Don't know	1 (0.5%)	0 (0.0%)	1 (1.5%)	0 (0.0%)
Education level				
<3 yrs High school	2 (1.0%)	0 (0.0%)	1 (1.5%)	1 (1.4%)
3+ yrs High school	41 (20.1%)	21 (30.4%)	7 (10.6%)	13 (18.8%)
Some tertiary training	45 (22.1%)	12 (17.4%)	18 (27.3%)	15 (21.7%)
Graduated from uni/polytech.	53 (26.0%)	13 (18.8%)	22 (33.3%)	18 (26.1%)
Any post-graduate study	63 (30.9%)	23 (33.3%)	18 (27.3%)	22 (31.9%)
Marital status				

Married/civilly united	143 (70.1%)	50 (72.5%)	47 (71.2%)	46 (66.7%)
Living with significant other	20 (9.8%)	7 (10.1%)	5 (7.6%)	8 (11.6%)
Divorced/separated	27 (13.2%)	8 (11.6%)	8 (12.1%)	11 (15.9%)
Widowed	3 (1.5%)	1 (1.4%)	0 (0.0%)	2 (2.9%)
Single	11 (5.4%)	3 (4.3%)	6 (9.1%)	2 (2.9%)
Living status				
Alone	22 (10.8%)	7 (10.1%)	9 (13.6%)	6 (8.7%)
Partner/spouse only	95 (46.6%)	31 (44.9%)	31 (47.0%)	33 (47.8%)
Partner & child/ren	81 (39.7%)	31 (44.9%)	25 (37.9%)	25 (36.2%)
Children only	6 (2.9%)	0 (0.0%)	1 (1.5%)	5 (7.2%)
Dominant leg[b] Right	174 (87.4%)	55 (82.1%)	61 (93.8%)	58 (86.6%)
Study hip - Right	105 (51.5%)	36 (52.2%)	33 (50.0%)	36 (52.2%)
Unilateral symptoms	157 (77.0%)	55 (79.7%)	46 (69.7%)	56 (81.2%)
Symptom duration months	24 (8,48)	24 (9,60)	18 (8,36)	24 (9,44)
Symptom duration				
2-6 months	24 (11.8%)	5 (7.2%)	11 (16.7%)	8 (11.6%)
6-12 months	51 (25.0%)	21 (30.4%)	16 (24.2%)	14 (20.3%)
>12 months	129 (63.2%)	43 (62.3%)	39 (59.1%)	47 (68.1%)
Mechanism of onset				
Insidious onset	178 (87.3%)	58 (84.1%)	58 (87.9%)	62 (89.9%)
Change in activity	15 (7.4%)	8 (11.6%)	5 (7.6%)	2 (2.9%)
Slip/fall	9 (4.4%)	2 (2.9%)	3 (4.5%)	4 (5.8%)
Other	2 (1.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)
Pain NRS 0-10	4.9 (1.0)	4.8 (1.0)	4.8 (1.0)	4.9 (1.2)
LHPQADL 0-100	45.7 (16.3)	45.2 (17.4)	46.4 (15.1)	45.6 (16.6)
PSFS AvScore 0-10	4.6 (1.9)	4.5 (2.1)	4.5 (2.0)	4.0 (1.6)
EQ-5D Index 0-1	0.7 (0.1)	0.7 (0.1)	0.7 (0.1)	0.7 (0.2)
PCS 0-52	13.6 (9.0)	13.4 (10.1)	13.7 (8.2)	13.6 (8.7)
PHQ 0-20	4.7 (4.4)	4.5 (4.0)	4.6 (4.1)	5.0 (5.2)
VISA-G 0-100	59.9 (12.5)	60.2 (13.1)	59.3 (11.1)	60.2 (13.4)
PSEQ 0-60	47.7 (9.3)	47.3 (9.2)	47.9 (9.1)	47.8 (9.6)
AAQ mins	462.5 (428.6)	434.4 (424.6)	368.8 (313.4)	580.2 (500.8)
Gluteal muscle torque Nm/kg	0.8 (0.3)	0.8 (0.3)	0.8 (0.3)	0.8 (0.3)

Active Lag degrees	10.4 (6.4)	10.0 (6.6)	10.6 (6.4)	10.7 (6.2)

[a]missing for 1 participant in group 1

[b]missing for 2 participants in each of groups 1 and 3, and for 1 participant in group 2.

NRS= Numeric Rating Scale, LHPQADL= Lateral Hip Pain Questionnaire Activities of Daily Living score, PSFSAvScore = Patient Specific Functional Scale Average Score, EQ-5D= European Quality of Life-5D questionnaire, PCS= Pain Catastrophising Scale total score, PHQ= Patient Health Questionnaire total score, PSEQ= Pain Self Efficacy Questionnaire, AAQ – Active Australia Questionnaire – Total time spent in overall activity in the past week.

Table 2 – Primary outcome measures. Number of participants reporting improvements on the GROC scale (rate of success) for each group, with between groups Risk Differences (RD), p-Values and Numbers Needed to Treat (NNT) and respective 95% confidence intervals (CI) at each time point. Mean (SD) Pain over the past week (0 – 10 point NRS) for each group and between groups adjusted mean difference (95% CI; p-value) at each time point. Wk – Weeks after start of intervention; GROC-Global Rating of Change scale; EDX-Education and Exercise group; CSI- Corticosteroid Injection; CON - No Treatment Control group; RD- Risk Difference; 95%CI- 95% confidence interval; NNT- Numbers needed to treat; SD – Standard Deviation; NRS= Numeric Rating Scale; # pairwise comparisons addressing pre-specified hypotheses

Wk	EDX	CSI	CON	EDX vs CON		CSI vs CON		EDX vs CSI	
GROC – n success/total				**RD (95% CI; p Value)**	**NNT (95% CI)**	**RD (95% CI; p Value)**	**NNT (95% CI)**	**RD (95% CI; p Value)**	**NNT (95% CI)**
4	37/64	38/66	13/66	38.8 (23.7, 54.0; <0.001)	2.6 (1.9, 4.2)	38.0 (22.9, 53.0; <0.001)	2.6 (1.9, 4.4)	0.9 (-15.9, 17.6; 0.92)	115.5 (5.7, -6.3)
8	51/66	38/65	20/68	49.1 (34.6, 63.5; <0.001)[#]	2.0 (1.6, 2.9)[#]	29.2 (13.2, 45.2; <0.001)[#]	3.4 (2.2, 7.6)[#]	19.9 (4.7, 35.0; 0.010)	5.0 (2.9, 21.1)
12	43/58	39/65	21/64	39.9 (24.2, 55.7; <0.001)	2.5 (1.8, 4.1)	26.0 (9.7, 42.3; 0.002)	3.8 (2.4, 10.3)	13.9 (-2.4, 30.3; 0.094)	7.2 (3.3, -41.9)
26	45/61	34/64	23/61	37.0 (20.9, 53.1; <0.001)	2.7 (1.9, 4.8)	15.4 (-1.4, 32.3; 0.073)	6.5 (-70.9, 3.1)	21.6 (5.5, 37.7; 0.008)	4.6 (2.7, 18.1)
52	51/65	36/63	31/60	26.8 (11.3, 42.3; <0.001)	3.7 (2.4, 8.8)	6.4 (-10.7, 23.6; 0.46)	15.6 (-9.3, 4.2)	20.4 (4.9, 35.9; 0.010)[#]	4.9 (2.8, 20.6)[#]
Pain -Mean (SD)				**Mean difference (95% CI; p-value)**		**Mean difference (95% CI; p-value)**		**Mean difference (95% CI; p-value)**	
4	2.7 (1.6)	2.4 (2.0)	4.1 (1.9)	-1.4 (-2.02, -0.73; <0.001)		-1.8 (-2.43, -1.17; <0.001)		0.4 (-0.21, 1.07; 0.19)	
8	1.5 (1.5)	2.7 (2.4)	3.8 (2.0)	-2.2 (-2.89, -1.54; <0.001)[#]		-1.2 (-1.85, -0.50; <0.001)[#]		-1.0 (-1.72, -0.37; 0.003)	
12	1.7 (1.7)	2.5 (2.1)	3.6 (2.2)	-1.7 (-2.41, -0.95; <0.001)		-1.1 (-1.82, -0.40; 0.002)		-0.6 (-1.32, 0.17; 0.13)	
26	1.8 (1.9)	2.6 (2.2)	3.1 (2.4)	-1.2 (-2.00, -0.37; 0.005)		-0.6 (-1.38, 0.26; 0.18)		-0.6 (-1.41, 0.16; 0.12)	
52	2.1 (2.2)	2.3 (1.9)	3.2 (2.6)	-1.1 (-1.93, -0.33; 0.006)		-0.9 (-1.68, -0.07; 0.034)		-0.3(-1.06, 0.55; 0.53)[#]	

Figure Titles and Legends

Figure 1 – Participant Flow Chart.

Flow of participants throughout trial – Enrolment, randomisation, treatment and follow-up.

UTA- Unable to attend; UTC- Unable to contact; LBP- Low back pain; LHP- Lateral Hip Pain; CSI-Corticosteroid Injection; OA- Osteoarthritis; Sx- Symptoms; Jt- joint; MRI- Magnetic Resonance Imaging; KL- Kellgren Laurence scale; DNA- Did not attend; SIJ- Sacroiliac joint; ITB- Iliotibial Band; Pts Rx- patients treated; Med- Median score; Min- Minimum number; Max- Maximum number; Ax- Assessment ; EDX – Education and Exercise

Figure 2 – Primary outcome measure – Global Rating of Change (GROC)

Frequency counts for all categories of the Global Rating of Change (GROC) outcome at each follow up time point indicating success in blue (very much better to moderately better). EDX – Education and Exercise; CSI – Corticosteroid injection; CON – No treatment control

Figure 3 – Primary outcome measure – Pain Intensity

Pain in the last week for each group over time, as reported on a Pain Numeric Rating Scale (NRS) from 0 to 10, where 0=”No pain” and 10= “Worst pain”. EDX= Education plus Exercise group; CIS= Corticosteroid Injection group. ; CON – No treatment control group