

Gluteal Loading Versus Sham Exercises to Improve Pain and Dysfunction in Postmenopausal Women with Greater Trochanteric Pain Syndrome: A Randomized Controlled Trial

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Abstract

Objectives: The aim of the current study was to determine the effects of education with targeted or sham exercise on pain and function in postmenopausal women with greater trochanteric pain syndrome (GTPS).

Background: Conservative management of GTPS is poorly described, and to date, there have been no studies on education with exercise as an intervention for GTPS. Ninety-four postmenopausal women with GTPS were recruited to participate in this study.

Materials and Methods: Participants were randomized to receive one of two 12-week exercise programs (GLOBE vs. sham). Participants received education on avoiding tendon compression with appropriate activity modification. The Victorian Institute of Sport Assessment-Gluteal tendon (VISA-G) was examined at baseline, 12, and 52 weeks. Secondary outcomes included hip pain and function questionnaires (Hip dysfunction and Osteoarthritis Outcome Score (HOOS), Oxford Hip Score (OHS), and Lateral Hip Pain questionnaire), a global rating of change in symptom questionnaire, and a quality of life measure (Assessment of Quality of Life [AQoL]-8D). Differences between groups were analyzed using intention to treat with analysis of covariance, per-protocol analysis, and responder analysis.

Results: Responders to the GLOBE intervention had significantly better VISA-G, HOOS, OHS, and lateral hip pain questionnaire scores compared to responders in the sham group. However, intention to treat analyses showed no between-group differences for the GLOBE intervention and sham exercise groups. Significant improvement in VISA-G score was found for both programs at 12- and 52-weeks time points ($p < 0.001$).

Conclusion: Lack of treatment effect was found with the addition of an exercise program to a comprehensive education on GTPS management. The improved outcomes of the responders in the GLOBE group indicate that there may be a subgroup of patients with a GTPS diagnosis that benefit from a GLOBE intervention program.

Keywords: postmenopausal, women, tendinopathy, GTPS, exercise, rehabilitation

Introduction

GREATER TROCHANTERIC PAIN syndrome (GTPS) is a common complaint in primary healthcare, particularly in women aged between 45 and 63 years.¹ The condition involves pathology of the gluteus medius and minimus tendons (gluteal tendinopathy) and/or trochanteric bursa (trochanteric bursitis).²⁻⁵ Those with the condition commonly

describe intermittent or continuous pain at, or around, the greater trochanter of the femur while sitting, stair climbing, walking, and lying on their side.⁶ GTPS has negative implications on employment and quality of life, which mimic that experienced by people with severe hip osteoarthritis (OA) awaiting hip arthroplasty.⁷ The reported incidence of GTPS is 1.8 per 1000 patients per year in primary care,¹ and the prevalence rate of GTPS is 23.5% in women at risk of knee

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OA⁸ and 54% in recipients of renal transplants.⁹ In comparison, the prevalence of hip OA is 26% in females over 55 years.¹⁰

The conservative management of GTPS is poorly described, despite the plethora of studies on injection therapy, shockwave, and surgical interventions for the lateral hip region.¹¹ To date, there have been no studies on education as an intervention for GTPS, and study by Rompe et al.¹² is the only study to investigate the use of an exercise program for the management of GTPS. Rompe et al.¹² compared exercise therapy with corticosteroid injection and shock wave therapy and found that exercise therapy was less effective for self-reported pain and recovery levels than corticosteroid injection at 1 month follow-up, but was superior at the 15-month follow-up, indicating longer-term benefits. It is possible that in the short term, some exercises used by Rompe et al.¹² (piriformis and iliotibial band stretching) may have aggravated the condition by increasing tendinous compression, and by the 15-month follow-up, participants had stopped completing potentially provocative exercises. This limitation will be addressed in the current study using GLoBE exercise and education on posture and activity modification, to reduce compression of the gluteal tendons.

Since exercise has been reported to be the best intervention for other lower limb tendons (Achilles¹³ and patellar tendinopathy¹⁴), a similar treatment algorithm for the gluteal tendons may be effective in reducing pain and dysfunction. Both eccentric and heavy slow resistance exercise have been shown to be beneficial^{15,16} for rehabilitating tendon conditions. More recently, isometric contractions have been reported to target both peripheral and central pain drivers by releasing cortical inhibition and reducing tendon pain immediately and for 45 minutes postintervention in the laboratory¹⁷ and during in-season training in those suffering with patellar tendinopathy.¹⁸ The effect of exercise on pain or dysfunction associated with GTPS requires investigation.

The aim of the current study was to determine the effects of education with targeted or sham exercise on pain and function in postmenopausal women with GTPS.

Materials and Methods

Design

This was a participant-blinded, single-arm randomized controlled trial (RCT) with 12-week (primary outcome time point) and 52-week follow-up. Clinical assessment of participants was undertaken at La Trobe University, Melbourne, Australia. The trial received ethical approval from the La Trobe University Human Ethics Committee (14-055). All participants provided written informed consent.

This study was a component of a larger 2 × 2 factorial RCT registered on the Australian New Zealand Clinical Trial Registry (ACTRN12614001157662).¹⁹ That larger study involved education, exercise, and menopausal hormone therapy interventions. Participants who were not eligible for the larger 2 × 2 trial or not willing to participate due to the use of hormone therapy participated in this single-arm trial.

Participants

Study participants were recruited from Victorian (Australia) gymnasiums, local medical and allied health profes-

sional clinics, pharmacies, community noticeboards, sporting clubs, as well as women's associations and via social media. Participants had to be postmenopausal (>52 weeks of menstrual cessation), have lateral hip pain reproduction in three of five pain provocation tests,²⁰ and have sufficient English skills to read and complete the questionnaires and consent to the requirements of the study. If both hips were symptomatic, the most painful side (as reported by the participant) was evaluated in the study.

Participants were excluded if they had an injection into the hip region in the previous 12 weeks (platelet-rich plasma, autologous blood injection, or corticosteroid injection), a history of hip trauma or surgery on the affected side, or any other musculoskeletal, neurological, and cardiorespiratory condition/s affecting their ability to participate in the study.

Randomization and blinding

Participants were randomized into either an intervention group (GLoBE: Gluteal La Trobe University exercise program) or a control group (sham exercise). A block randomization schedule was generated using a web-based randomization program (www.randomisation.com) by an external investigator, who had no contact with participants throughout the duration of the trial. The external researcher directly communicated to the treating physiotherapist implementing the exercise intervention. Participants were blinded to group allocation, but were aware that education was consistent across the groups. Success of blinding was measured 1 week after randomization. Data analysts and outcome measure assessors were blinded to group allocation. Due to the nature of the interventions, physiotherapists could not be blinded to the treatment group so were trained to ensure equal provision of care and motivation for both groups.

Education

An education booklet was provided to all participants. It detailed activities to avoid (climbing stairs, walking up hills, and hip adduction across midline) and correct sitting (hips positioned higher than knees, no crossing legs), standing (equal weight-bearing through lower limbs), and lying postures (no side lying) to reduce compressive tendon load. Participants were instructed during the first physiotherapy visit and throughout the trial to apply these principles to all activities of daily living, recreation, and sport.

Interventions

The intervention was implemented by 23 physiotherapists registered with the Australian Health Practitioner Regulation Agency (AHPRA) with a minimum of 2 years' musculoskeletal experience. Physiotherapists were provided 3 hours of standardized training by the primary author in the exercise and education protocols, incorporating theory and practical sessions. Participants undertook a 10–15 minute home exercise program twice daily for 12 weeks. The exercise program was initiated by a physiotherapist then reviewed and progressed at 4, 8, and 12 weeks. Participants were asked to refrain from undertaking any other treatment on their affected hip (e.g., massage and acupuncture), but were encouraged to maintain their normal non-aggravating activities. The participants were asked not to have any injections into the hip for

the duration of the treatment intervention (12 weeks). No restriction on use of oral or topical anti-inflammatories or analgesia and ice/heat was implemented.

GLoBE exercise protocol

Participants received a four-stage exercise program, involving isometric loading of the gluteus medius and minimus, and kinetic chain (quadriceps and calf muscle) strengthening exercises (Fig. 1). Stage 1 commenced with an isometric hip hitch hold (up to 40 seconds) in standing, whereby the participant, holding onto a wall or chair for balance, hitched their unaffected leg up off the ground (~1 cm) while keeping both knees in full extension, loading the contralateral/affected gluteal tendons without compression. In stages 2 and 3, the hip hitch was integrated with a dynamic movement progression, adding toe taps and then hip swings, respectively. The most advanced exercise in the gluteal series was a single leg wall squat (stage 4). Quadriceps strengthening commenced with a double leg ¼–½ squat (stage 1), sit to stand exercise with feet even, and progression to split stance variation (stage 2 and 3) and step-ups (stage 4). Calf strengthening involved double leg calf raises (stage 1), calf raises with toe taps (stage 2), and progressed onto single leg calf raises (stage 3 and 4). Participants were instructed to complete 2–4 sets of 5–15 repetitions of the prescribed dynamic exercises, depending on the individual participants' level of function and stage of the program

(see Supplementary Data; Supplementary Data are available online at www.liebertpub.com/jwh for exercise booklet and trial registry ACTRN12614001157662 for full dosage instructions and specific criteria to determine when the subjects were ready to progress to the next stage of the program).

Sham exercise protocol

Participants received a four-stage sham exercise program (Fig. 2) that predominately involved seated exercises not aimed at therapeutic loading of the gluteal tendons or strengthening of the kinetic chain (variations of seated gluteal activation exercises, seated knee extension, and seated calf raises). Dosage instructions for all exercises reflected those of the GLoBE program dynamic exercises.

Outcome measures

Outcomes were assessed at baseline, 12, and 52 weeks. The timing of baseline testing varied from the original protocol—baseline outcome measures were collected post randomization. The primary outcome measure was the VISA-G (Victorian Institute of Sport-Gluteal tendon) questionnaire,²¹ a gluteal tendon outcome measure that quantifies pain with tendon loading, with a higher score representing less pain and dysfunction. This questionnaire contains a visual analog score for “usual” pain, four questions related to pain, one question related to difficulty with moving after sitting, and two activity related questions. A further five questionnaires were used as

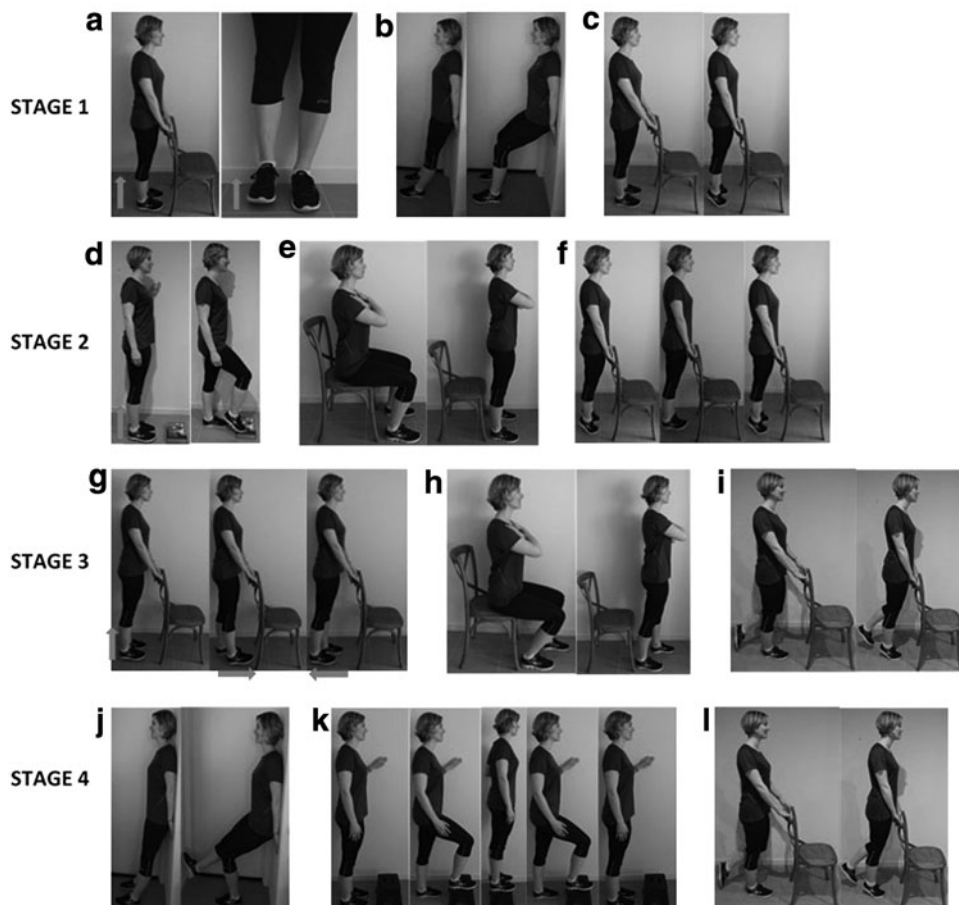


FIG. 1. GLoBE exercise program stages 1–4: (a) hip hitch; (b) double leg wall squat; (c) double leg calf raises; (d) Hip hitch with toe tap; (e) sit to stand; (f) calf raises with toe taps; (g) hip hitch with hip swing, vertical red arrow indicates a hip hitch so that the foot is ~1 cm off the ground, horizontal arrow indicates direction of hip swing; (h) sit to stand with split stance; (i) single leg calf raises; (j) single leg squat; (k) step up; (l) single leg calf raise.

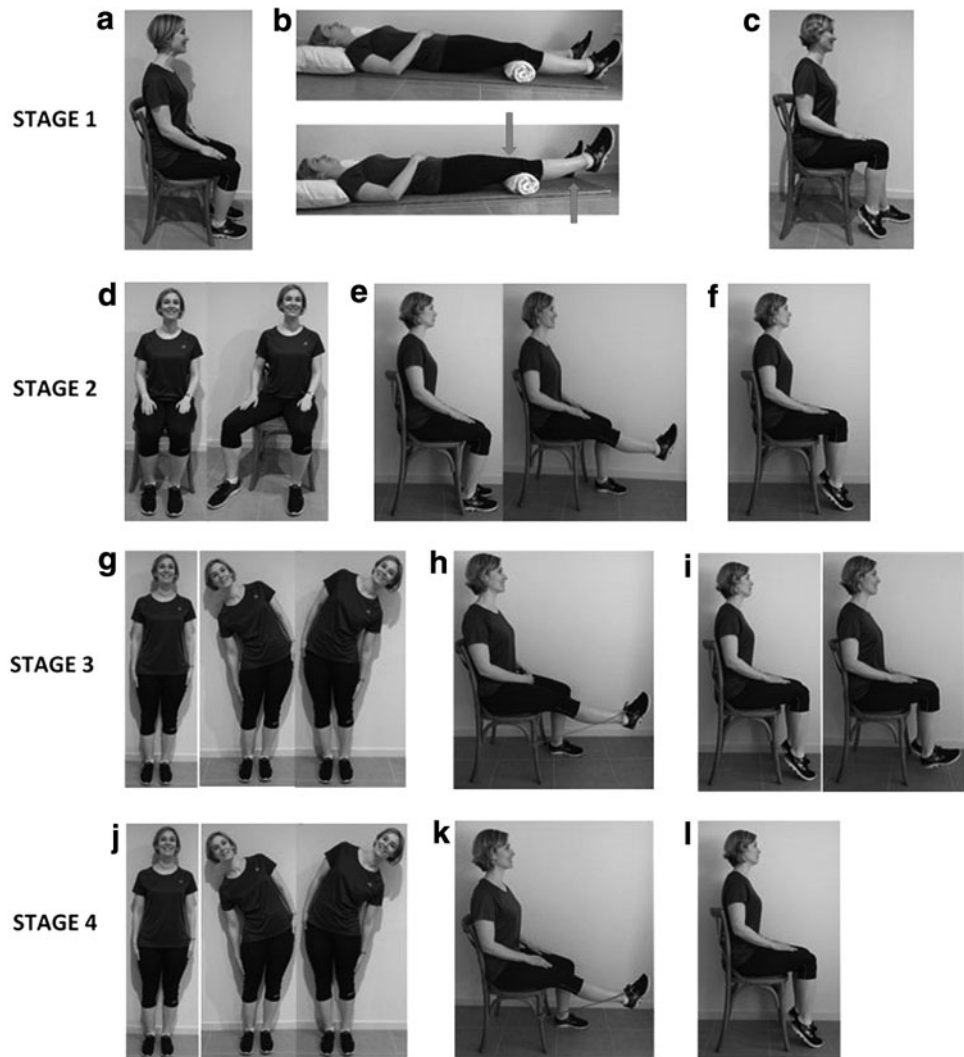


FIG. 2. Sham exercise program stages 1–4: (a) seated gluteal squeezes; (b) quadriceps over fulcrum; (c) seated single leg calf raises; (d) seated hip abduction; (e) seated knee extension no resistance; (f) seated double leg calf raises; (g) standing lateral flexion; (h) seated knee extension with *red* Theraband resistance; (i) seated calf raise with toe taps; (j) standing lateral flexion; (k) seated knee extension with *green* Theraband resistance; (l) double leg calf raise with pulses up and down.

secondary outcome measures to assess hip pain and dysfunction, perceived improvement, and quality of life: Oxford Hip Score (OHS),²² global rating of change questionnaire (–7 to +7 Likert score), Assessment of Quality of Life (AQoL), Hip dysfunction and Osteoarthritis Outcome Score (HOOS),²³ and the Lateral Hip Pain Questionnaire.²⁴ Participant adherence to the exercise program was assessed using an exercise diary that was filled out by the participant after each home exercise session.

In addition, at the 52-week follow-up, participants were asked a series of questions regarding their pain level (increased, decreased, or no change in pain since the study), and whether they had undertaken new or continued management strategies following the 12-week education and exercise program (injection therapy, surgery, and study exercises). Success of blinding was assessed at the end of week 1 by asking participants to indicate which group they believed they were allocated to.

Sample size

Based on the VISA-G questionnaire,²¹ using standard deviation (SD) of 13.35 and a mean difference of 10.68, a fully

powered trial would require 52 participants (26 per group) to detect a moderate standardized mean difference of 0.8 (assuming 80% power, an alpha level of 0.05, and a 15% dropout rate).^{21,25}

Statistical analysis

Statistical analysis was undertaken using statistical software (SPSS version 21, IBM SPSS, Inc., Chicago, IL), and intention to treat principles, per-protocol analysis, and responder analysis were applied. A linear mixed model was undertaken on dependent variables (questionnaires), adjusting for baseline values and for intention to treat and per-protocol analyses. If age, height, mass, or body mass index (BMI) was significantly different between groups, measured using independent *t*-tests, they were included as covariates in the analyses. This was to determine the difference between and within groups for primary and secondary outcomes. A responder analysis, adjusting for covariates of BMI and baseline scores, was undertaken to determine if significant differences in patient reported outcome measure scores existed between groups of responders. Participants who reported a global rating of change of +5 or more at the 12-month time point were considered “responders,” and the relative risk of

responding to treatment was calculated. Categorical outcomes (continuation of exercises, pain level, injection therapy, and hip surgical intervention) at the 52-week time point were compared using a chi square test, and where the expected count was less than five in more than 20% of cells, the Fisher's exact test score was recorded.

To establish the magnitude of differences, effect sizes were calculated for each group comparison using standardized mean differences (SMDs) and 95% confidence intervals (CIs).²⁶ An effect size threshold of 0.2, 0.5, and 0.8 was considered small, medium, and large, respectively.²⁷ Global rating of change scores across groups was compared using a Mann-Whitney U test. Baseline participant characteristics were analyzed using independent samples *t*-tests, and categorical data were analyzed using chi squared. The effectiveness of blinding was recorded as the total number of the cohort that remained unaware of their group allocation at the end of week 1, and participant adherence was calculated as a percentage of completed exercise sessions.

Results

Between March 2013 and September 2014, 178 women were screened, 94 met the selection criteria and were invited to participate in the study, and 94 consented to participate (Fig. 3). Forty-six participants were randomized to the GLoBE intervention exercise program and 48 to the sham exercise program.

The trial was completed in December 2016, 52 weeks after the completion of the last participant's 12-week exercise program. A total of 13 participants withdrew from the study (8 in GLoBE group and 5 in sham group), and 86.6% were followed up at 12 weeks and at 52 weeks. At the end of week 1, all participants in the GLoBE and sham groups remained blinded. No participant was aware of the group allocation and reported being "unsure" if they were in the intervention or sham group. The sham exercise group was significantly heavier in weight and BMI at baseline (Table 1). At week 12, only half of the GLoBE participants were able to progress to stage 4 of the program.

Intention to treat analysis: Treatment effectiveness for the primary outcome measure, the VISA-G, and for secondary outcome measures, the HOOS, OHS, and AQoL

Ten participants had baseline scores brought forward to their 12- and 52-week follow-up for intention to treat analysis. Four participants (GLoBE×3, sham×1) withdrew after randomization and before completing baseline scores and were excluded from the analysis.²⁸ Results were adjusted for baseline questionnaire scores and BMI (Table 1). No between-group differences were identified for primary and secondary outcome measures at 12 and 52 weeks. Significant improvements in outcomes were identified for both groups at the 12- and 52-week time points, with the exception of the lateral hip pain questionnaire (LHPQ) sports subsection (Table 2).

Per protocol analysis: Treatment effectiveness for the primary outcome measure, the VISA-G and for secondary outcome measures, the HOOS, OHS, and AQoL

In total, 38 GLoBE participants and 43 Sham participants were included in the analysis. No between-group differences

were identified for the VISA-G, HOOS, OHS, and AQoL questionnaires for either protocol. Significant improvements in outcomes ($p < 0.01$) were found for both GLoBE and sham interventions from baseline to 12- and 52-week time points for all outcomes except the sports subsection on the LHPQ (12-week follow-up for both groups and 52-week follow-up for GLoBE group) (Appendix 1).

Treatment effectiveness: self-reported measure, the Global Rating of Change

GLoBE participants reported being "quite a bit better" (median [interquartile range]: 5.0 [2.0–7.0]) and sham group, "moderately better" 4.0 (2.0–7.0) at 12 weeks. At the 52-week follow-up both groups reported being "quite a bit better" (GLoBE: 5.0 [0.5–7.0] and sham: 5.0 [0.75–7.0]). There was no significant between-group difference in global rating of change score at 12-week ($p = 0.340$) and 52-week ($p = 0.746$) time points. There was no significant difference between groups in the number of responders (GLoBE, 20/37; sham, 24/43; relative risk [CI] = 0.969 [0.650–1.443]).

Responder analysis: Treatment effectiveness for the primary outcome measure, the VISA-G, and for secondary outcome measures, the HOOS, OHS, and AQoL

A responder analysis was performed for participants reporting a global rating of change of +5 or more (Table 3). Significant between-group differences favoring the GLoBE intervention were identified for all outcomes at the 12-week (moderate-to-large effects, 0.5–1.0) and 52-week (low-to-moderate effects, 0.2–0.7) follow-up, except the lateral hip pain questionnaire sports subsection at 12 weeks and AQoL at all time points. Significant within-group differences were found for the GLoBE intervention for all outcomes except the lateral hip pain questionnaire sports subsection at 12 and 52 weeks. Significant within-group differences were also found for the sham intervention, except for the lateral hip pain questionnaire at the 52-week time point.

Fifty two-week variables

No differences in 52-week variables of pain level, menopausal hormone therapy use, surgical intervention, injection therapy, or continuation of research study exercises were found between the groups (Table 4).

Adverse events

During the study, two participants reported increasing lateral hip pain that did not ease during the 12-week intervention period (one participant from each group). One reported that her increase in pain was attributed to the exercises, and the other attributed her lateral hip pain from a sudden increase in activity levels while travelling overseas. Despite this, both completed the program, and 12- and 52-week outcome measures were collected and included in the analysis.

Participant adherence

There was no significant difference in adherence levels between groups over the 12-week period ($p = 0.97$). The mean percentage of exercise completion for GLoBE exercise

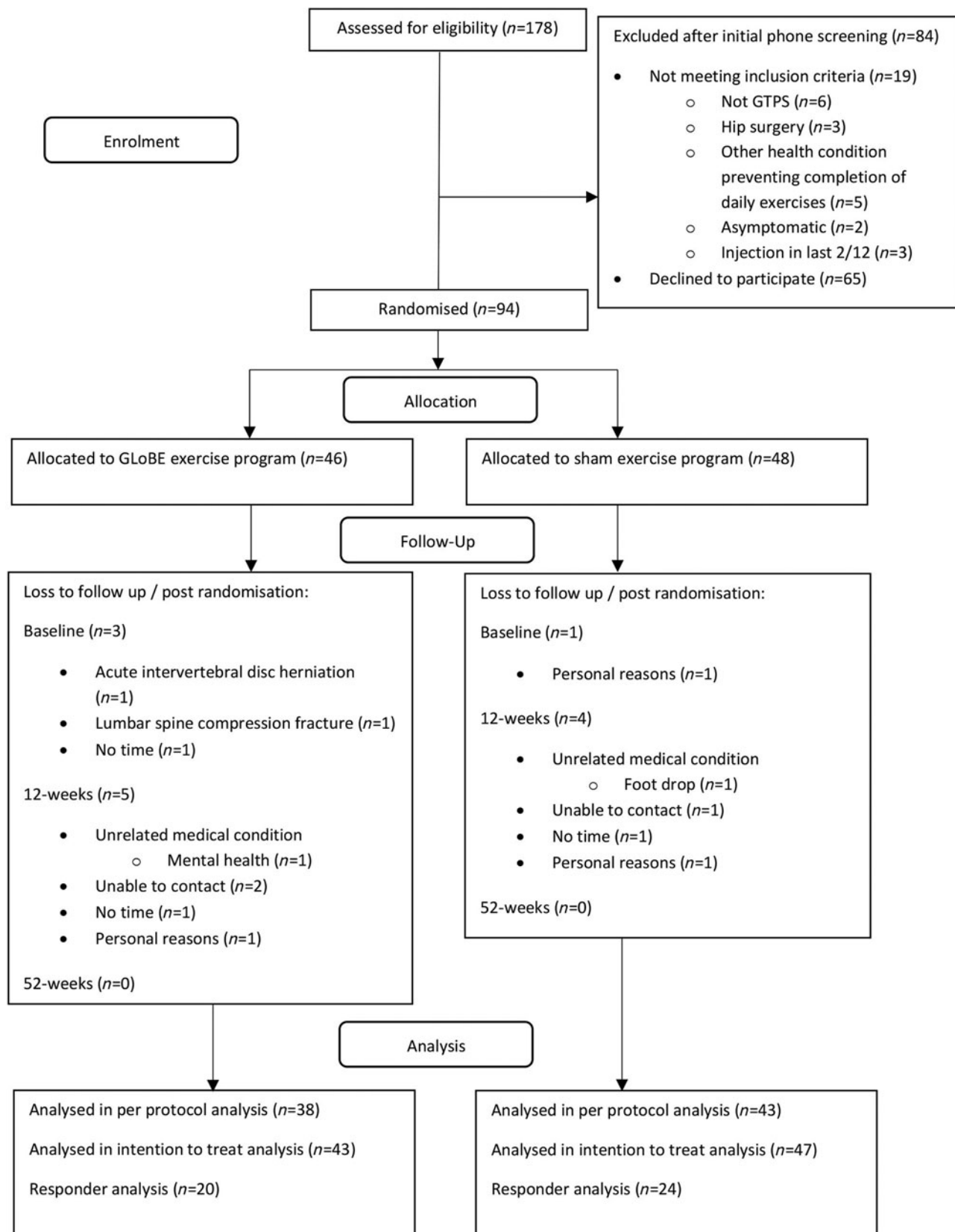


FIG. 3. Flow of participants throughout the study.

TABLE 1. CHARACTERISTICS

Baseline variables	GLoBE (n = 46)	Sham (n = 48)	p
	Mean (SD)	Mean (SD)	
Age	61.14 (6.70)	62.53 (8.92)	0.771
Height	164.40 (6.10)	163.09 (6.60)	0.415
Mass	71.83 (12.80)	81.92 (20.04)	0.006
BMI	26.57 (4.69)	30.83 (7.18)	0.002
VISA-G Score	61.60 (10.91)	53.83 (17.33)	0.018
Side affected (left/right)	23/20	25/22	0.803 ^a

^aChi squared test.

BMI, body mass index; SD, standard deviation; *n*, number included in analysis; Bold, significant finding.

group was 75.80% (SD = 23.49) and sham exercise group was 75.99% (SD = 25.35). Similarly, both groups completed their morning and evening exercises to an equivalent level, with no significant differences identified: morning exercises GLoBE 79.35% (SD = 21.33), sham 85.3% (SD = 16.61) $p = 0.96$; evening exercises GLoBE 76.1% (SD = 23.7), sham 81.6% (SD = 17.2), $p = 1.00$.

Discussion

Significant within-group improvements in pain, function, and quality of life measures were identified for both GLoBE and sham interventions from baseline to 12 and 52 weeks; however, the type of exercise intervention did not affect results.

Within-group improvements for both GLoBE and sham interventions in all analyses may reflect the importance of education in the management of GTPS. Education was consistent between groups and focused on decreasing compression of the gluteal tendons over the greater trochanter. Mechanical compression has been reported to cause adaptive changes in tendon with the formation of fibrocartilage, increased proteoglycan production,²⁹ and increased cross-sectional area.³⁰ Similarly, compressive and tensile load, in isolation, but more importantly in combination, can have negative implications for pathology resulting in pain³¹ and dysfunction. Thus, a reduction in these loads should result in pain relief and increased function.

No studies have evaluated the benefits of an education program in the management of GTPS. However, education to avoid aggravating activities has been recommended as a management strategy for the condition³² and is being used in ongoing RCTs.^{19,33} Education principles were discussed with each participant and were applied to their specific activities of daily living, sport, and recreation. This may have enabled easy translation and uptake of these strategies and contributed to a reduction in pain and symptoms. Education and advice on activities of daily living may have provided this group of postmenopausal women with enough pain relief to undertake activities at a sufficient level of function and improve quality of life (AQoL). However, it remains unclear if these improvements were solely due to the education, whether in fact the sham exercises contributed to this improvement or it was improvement over time, regardless of intervention. Without a wait-and-see group the influence of

time cannot be estimated; however, since almost half the cohort were no better (no change in pain) at 52 weeks, the impact of time may not be particularly relevant in this population. This reflects the chronic recalcitrant nature of the condition. Thus, it is likely that the education underpinned the improvements that were seen, rather than this being due to the natural recovery of the condition. This is especially true in GTPS where simple lifestyle amendments can impact on pain, perhaps more so than other conditions such as hip OA. Future research could involve a comparison with an education only group and/or a change over time group.

The effect of placebo on significant within-group changes cannot be underestimated. It has been found that open-label placebo treatment reduces pain and disability in chronic low-back pain sufferers, compared to usual treatment over a 3-week period.³⁴ Although GTPS participants were blinded to group allocation in this study, they were made aware of the potential to receive an exercise program not targeting rehabilitation of GTPS alongside education. Furthermore, both interventions were delivered by a qualified physiotherapist in a clinical setting, with equal enthusiasm for the program.

The primary structure contributing to nociceptive input could alter the response to exercise intervention. Since the cause of tendon pain is not known³⁵ and the pathophysiology of GTPS is poorly understood, it is plausible that responders in the GLoBE group had primary tendon pathology known to benefit from isometric exercise.¹⁷ Comorbidities in other structures around the hip (*e.g.*, labral tear, chondropathy) could impact on the response to the exercise programs. Responders to the GLoBE exercise and education program had significantly greater improvements in their outcome measures compared with the responders in the sham exercise and education program. This may indicate that there is a subgroup of people with GTPS who respond better (improved pain and function) to a GLoBE exercise program with education than with a sham exercise program with education. Further analysis of subgroup characteristics using the current data was not undertaken since adequately powered responder analysis requires a greater sample size to allow for dichotomizing continuous variables and to identify characteristics of subgroups.^{36,37} Heterogeneity within a group of participants can diminish the likelihood of significant treatment effects³⁸ as only a certain proportion of the group will be responsive to the given treatment intervention. This has been shown in low-back pain disorders³⁹ and patellofemoral joint pain⁴⁰ whereby targeted interventions for subgroups have been effective in reducing pain and dysfunction and recommended in hip chondropathy studies.⁴¹ With adequate power for subgroup analysis, the level of pain and disability at baseline, personal, and pathophysiological factors could be examined to determine likely responsiveness to treatment intervention.

The GLoBE exercise intervention was designed with the intention to load the gluteal tendons in functional positions without causing compression. Interestingly, only two participants in the GLoBE exercise program were unable to complete the hip hitch exercise at the first appointment due to increased lateral hip pain and instead were prescribed an alternative bilateral standing isometric abduction exercise until they were able to resume the GLoBE intervention protocol. This indicates that the majority of postmenopausal women with GTPS can tolerate standing isometric hip exercises at first presentation.

TABLE 2. GLOBE AND SHAM BETWEEN-GROUP AND WITHIN-GROUP DIFFERENCES AND AN INTENTION TO TREAT ANALYSIS USING BASELINE SCORES AND BODY MASS INDEX AS COVARIATES

Outcome (weeks)	Time of measurement (weeks)	Unadjusted mean score (SD)	Adjusted between-group difference ^a (95% CI)	Adjusted SMD ^a (95% CI)	p	GLoBE	Sham	Within-group mean difference (95% CI)	p	Sham
Primary outcome measure										
VISA-G (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip)										
	0	43/47 61.6 (10.9)	53.8 (17.3)							
	12	43/47 73.1 (17.3)	64.1 (18.4)	0.9 (-6.3 to 8.2)	0.799	11.8 (7.0–16.7)		10.9 (5.5–16.3)	<0.001	
	52	43/47 76.0 (17.4)	70.5 (21.6)	-2.7 (-10.0 to 4.6)	0.466	13.1 (8.3–18.0)		15.8 (10.5–21.2)	<0.001	
Secondary outcome measures										
HOOS: Pain subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a less painful hip)										
	0	43/47 61.8 (15.3)	58.5 (15.7)							
	12	43/47 74.8 (17.5)	68.8 (18.9)	3.1 (-3.5 to 9.8)	0.357	13.4 (9.0–17.8)		10.3 (5.4–15.3)	<0.001	
	52	43/47 75.6 (17.0)	74.4 (18.1)	-2.6 (-9.3 to 4.1)	0.445	13.1 (8.6–17.5)		15.7 (10.7–20.6)	<0.001	
HOOS: Symptom subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less symptomatic hip)										
	0	43/47 74.3 (13.9)	67.5 (14.7)							
	12	43/47 82.4 (13.5)	73.3 (17.1)	2.7 (-5.0 to 10.5)	0.495	8.9 (4.1–13.8)		6.3 (0.5–12.1)	0.034	
	52	43/47 80.9 (13.7)	77.4 (19.7)	-2.0 (-9.7 to 5.6)	0.598	7.1 (2.2–12.0)		9.2 (3.4–15.0)	0.002	
HOOS: ADL subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher ADL functioning)										
	0	43/47 69.8 (16.2)	62.9 (17.2)							
	12	43/47 80.58 (16.3)	72.9 (18.9)	0.8 (-7.2 to 8.9)	0.837	11.1 (5.5–16.7)		10.3 (4.5–16.0)	0.001	
	52	43/47 83.0 (14.9)	78.2 (18.0)	-1.9 (-9.9 to 6.1)	0.637	13.1 (7.5–18.7)		15.1 (9.3–20.9)	<0.001	
HOOS: Sport subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip)										
	0	43/47 54.5 (22.0)	47.0 (24.9)							
	12	43/47 69.7 (20.7)	61.2 (23.5)	1.4 (-7.6 to 10.3)	0.759	15.6 (9.2–22.1)		14.2 (8.0–20.5)	<0.001	
	52	43/47 69.5 (20.2)	66.3 (35.3)	-4.1 (-13.1 to 4.9)	0.373	14.4 (7.9–20.9)		18.5 (12.3–24.8)	<0.001	
HOOS: QoL subscale (Score from 0 to 100; 100 = a normal hip; a higher score indicates better QoL)										
	0	43/47 51.2 (17.8)	45.5 (20.7)							
	12	43/47 62.1 (20.5)	56.0 (22.0)	0.7 (-7.0 to 8.4)	0.860	11.4 (5.8–16.9)		14.2 (8.0–20.5)	<0.001	
	52	43/47 65.0 (19.3)	65.4 (21.8)	-4.8 (-12.5 to 2.9)	0.220	13.8 (8.2–19.4)		18.5 (12.2–24.8)	<0.001	
OHS (Score from 0 to 48, 48 = a normal hip; a higher score indicates a higher functioning and less painful hip)										
	0	43/47 31.9 (6.3)	29.3 (7.4)							
	12	43/47 37.5 (7.2)	34.0 (8.8)	0.9 (-2.0 to 3.8)	0.538	5.8 (4.0–7.6)		4.9 (2.7–7.1)	<0.001	
	52	43/47 38.7 (6.9)	36.4 (8.8)	-0.3 (-3.1 to 2.6)	0.863	6.6 (4.8–8.5)		6.9 (4.7–9.1)	<0.001	

(continued)

TABLE 2. (CONTINUED)

Outcome (weeks)	Time of measurement (weeks)	Unadjusted mean score (SD)		Adjusted between-group difference ^a (95% CI)	Adjusted SMD ^a (95% CI)	p	Within-group mean difference (95% CI)		
		GLoBE	Sham				GLoBE	Sham	p
LHPQ: ADL subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower ADL functioning)									
	0	43/47	46.6 (18.1)	49.2 (20.0)					
	12	43/47	32.2 (20.0)	38.6 (23.5)	-4.9 (-12.6 to 2.9)	0.288	-15.1 (-20.1 to -10.2)	-10.3 (-16.2 to -4.3)	0.001
	52	43/47	28.7 (21.8)	26.9 (21.2)	3.3 (-4.5 to 11.1)	0.450	-17.7 (-22.6 to -12.7)	-20.9 (-26.8 to -15.0)	<0.001
LHPQ: Sport subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower functioning and more painful hip during sport)									
	0	43/47	81.2 (28.1)	76.4 (31.8)					
	12	43/47	72.7 (38.5)	73.1 (36.9)	-6.0 (-6.5 to 23.0)	0.270	-8.7 (-19.5 to 2.0)	-2.7 (-13.0 to 7.5)	0.602
	52	43/47	73.8 (38.2)	59.0 (43.5)	8.3 (-20.8 to 8.7)	0.423	-8.2 (-19.0 to 2.5)	-16.5 (-26.8 to -6.2)	0.002
AQL (Score from 0.00 to 1.0, 1.0 = full health; 0.0 = death-equivalent health state)									
	0	43/47	0.7 (0.2)	0.7 (0.2)					
	12	43/47	0.7 (0.2)	0.7 (0.2)	-0.006 (-0.051 to 0.038)	0.796	0.035 (0.0008-0.072)	0.042 (0.013-0.070)	0.005
	52	43/47	0.7 (0.2)	0.8 (0.2)	-0.030 (-0.075 to 0.015)	0.186	0.036 (0.0003-0.071)	0.066 (0.037-0.094)	<0.001

^aLinear mixed model analysis, adjusted for baseline scores and BMI. SMD, standard mean difference; 95% CI, 95% confidence interval; Bold, significant finding; HOOS, Hip dysfunction and Osteoarthritis Outcome Score; OHS, Oxford Hip Score; AQL, Assessment of Quality of Life; LHPQ, lateral hip pain questionnaire; ADL, activities of daily living.

TABLE 3. GLOBE AND SHAM BETWEEN-GROUP AND WITHIN-GROUP DIFFERENCES. A RESPONDER ANALYSIS USING BASELINE SCORES AND BODY MASS INDEX AS COVARIATES

Time of Outcome measurement (weeks)	Number included (GLOBE/Sham)	Unadjusted mean score (SD)	Adjusted between-group difference ^a (95% CI)	Adjusted SMD ^a (95% CI)	p	Within-group mean difference (95% CI)	p	Sham
Primary outcome measure								
GLOBE Sham								
VISA-G (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip)								
0	20/24	63.5 (10.1)	58.7 (19.4)					
12	20/24	86.0 (11.9)	72.1 (15.1)	14.0 (-6.7 to 9.5)	<0.001	20.2 (12.0-28.3)	<0.001	14.0 (6.6-21.4)
52	20/24	88.0 (10.2)	78.4 (18.5)	26.4 (19.1-33.6)	<0.001	19.8 (11.6-27.94)	<0.001	26.38 (19.0-33.8)
Secondary outcome measures								
HOOS: Pain subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a less painful hip)								
0	20/24	68.3 (12.0)	61.6 (15.3)					
12	20/24	87.7 (11.0)	79.6 (15.2)	25.7 (19.3-32.1)	<0.001	19.5 (12.5-26.4)	<0.001	16.3 (9.5-23.1)
52	20/24	89.8 (10.8)	84.4 (10.7)	16.3 (9.9-22.7)	<0.001	20.0 (13.0-26.9)	<0.001	25.7 (18.9-32.5)
HOOS: Symptom subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less symptomatic hip)								
0	20/24	80.0 (9.8)	71.9 (12.9)					
12	20/24	90.0 (9.0)	83.1 (11.7)	9.8 (3.2-16.4)	0.004	13.0 (6.2-19.7)	<0.001	9.8 (2.7-16.8)
52	20/24	89.6 (8.0)	87.8 (10.6)	8.8 (2.3-15.4)	0.009	9.5 (2.7-61.2)	0.007	8.8 (1.8-15.9)
HOOS: ADL subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher ADL functioning)								
0	20/24	72.3 (14.0)	68.5 (18.1)					
12	20/24	91.1 (8.7)	84.3 (12.4)	13.7 (5.6-21.6)	0.001	17.3 (8.7-26.0)	<0.001	13.7 (5.5-21.8)
52	20/24	94.6 (6.9)	88.7 (10.0)	12.8 (4.8-20.7)	0.002	14.5 (5.8-23.1)	0.001	4.6 (4.6-20.9)
HOOS: Sport subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip)								
0	20/24	56.9 (19.0)	54.8 (23.3)					
12	20/24	82.2 (14.8)	74.7 (15.5)	15.1 (6.7-23.6)	0.001	26.6 (17.8-35.5)	<0.001	15.1 (6.3-23.9)
52	20/24	83.5 (14.0)	78.1 (15.5)	23.8 (15.3-32.3)	<0.001	25.2 (16.4-34.1)	<0.001	23.8 (15.0-32.6)
HOOS: QoL subscale (Score from 0 to 100; 100 = a normal hip; a higher score indicates better QoL)								
0	20/24	54.2 (20.7)	50.1 (19.7)					
12	20/24	79.1 (14.1)	65.4 (15.6)	13.6 (5.8-21.5)	0.001	19.9 (10.7-29.1)	<0.001	13.6 (6.0-21.2)
52	20/24	82.7 (14.4)	78.4 (14.4)	29.9 (22.1-37.7)	<0.001	23.1 (13.9-32.3)	<0.001	29.9 (22.3-37.5)

(continued)

TABLE 3. (CONTINUED)

Outcome measurement (weeks)	Time of measurement (weeks)	Number included (GLOBE/Sham)	Unadjusted mean score (SD)	Adjusted difference ^a (95% CI)		Adjusted SMD ^a (95% CI)	Within-group mean difference (95% CI)		
				GLOBE	Sham		GLOBE	Sham	p
Primary outcome measure									
OHS (Score from 0 to 48, 48 = a normal hip; a higher score indicates a higher functioning and less painful hip)									
	0	20/24	34.8 (4.9)	32.6 (6.8)					
	12	20/24	42.6 (3.9)	39.6 (6.4)	7.0 (4.5–9.5)	1.3 (0.6–1.9)	8.3 (5.7–11.0)	7.0 (4.1–9.8)	<0.001
	52	20/24	44.3 (3.6)	41.6 (5.1)	11.1 (8.6–13.6)	2.4 (1.7–3.2)	9.4 (6.8–12.1)	11.1 (8.2–14.0)	<0.001
LHPQ: ADL subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower ADL functioning)									
	0	20/24	41.9 (14.2)	45.3 (19.3)					
	12	20/24	15.8 (11.0)	24.3 (16.7)	-15.2 (-23.0 to -7.4)	-1.0 (-1.7 to -0.4)	-20.4 (-28.0 to -12.8)	-15.2 (-23.6 to -6.9)	0.001
	52	20/24	9.9 (8.2)	16.6 (15.2)	-32.3 (-40.0 to -24.6)	-2.5 (-3.3 to -1.8)	-26.0 (-33.6 to -18.4)	-32.3 (-40.6 to -24.1)	<0.001
LHPQ: Sport subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower functioning and more painful hip during sport)									
	0	20/24	76.1 (27.4)	79.1 (34.0)					
	12	20/24	54.9 (44.7)	72.4 (39.2)	-1.1 (-17.9 to 15.8)	-0.03 (-0.6 to 0.6)	-14.6 (-35.4 to 6.2)	-1.01 (-16.8 to 14.7)	<0.001
	52	20/24	57.4 (43.4)	41.3 (43.0)	-29.5 (-46.3 to -12.7)	-0.7 (-1.3 to -0.1)	11.8 (-32.6 to 9.0)	-29.5 (-45.3 to -13.7)	0.891
AQoL (Score from 0.00 to 1.0, 1.0 = full health; 0.0 = death—equivalent health state)									
	0	20/24	0.77 (0.15)	0.80 (0.14)					
	12	20/24	0.86 (0.09)	0.85 (0.10)	0.04 (-0.01 to 0.10)	0.5 (-0.1 to 1.1)	0.07 (0.00–0.14)	0.044 (0.001–0.087)	0.044
	52	20/24	0.89 (0.08)	0.87 (0.10)	0.10 (-0.08 to 0.15)	1.1 (0.5–1.7)	0.07 (0.00–0.14)	0.038 (0.005–0.141)	<0.001

^aLinear mixed model, adjusted for baseline scores and BMI. Bold, significant finding.

HOOS, Hip dysfunction and Osteoarthritis Outcome Score; OHS, Oxford Hip Score; AQoL, Assessment of Quality of Life; LHPQ, lateral hip pain questionnaire; ADL, activities of daily living.

TABLE 4. FIFTY TWO-WEEK VARIABLES

52-week variables		GLoBE (n = 38)	Sham (n = 43)	Chi squared
		n/37 ^a (%)	n/43(%)	
Continuation of exercises	Yes	18 (48.6)	17 (39.5)	0.413
	No	19 (51.4)	26 (60.5)	
Injection therapy	None	30 (81.1)	36 (83.7)	0.776 ^b
	CSI	6 (16.2)	7 (16.3)	
	PRP/ABI	1 (2.7)	0 (0)	
Pain level	Increased	4 (10.8)	4 (9.3)	0.763 ^b
	Decreased	16 (43.2)	22 (51.2)	
	No change	17 (45.9)	17 (39.5)	
Hip surgical intervention	Yes	0 (0)	1 (2.3)	1.00 ^b
	No	37 (100)	42 (97.7)	

^aData lost for one GLoBE participant.

^bFisher's exact test used because expected count <5 in more than 20% of cells.

n, number included in analysis; CSI, corticosteroid injection; PRP, Platelet Rich Plasma; ABI, Autologous Blood Injection.

Limitations

No guidelines exist on the most effective exercises for gluteal tendon rehabilitation, with only one published article in this area.¹² However, the prescription of exercises in this study was based on clinical expertise and prior electromyographic studies.⁴² Sham exercises were chosen based on their perceived inability to load the tendon; however, biomechanical and electromyographic analysis has not been undertaken on these exercises.

This study used patient-reported outcome measures to determine changes in hip pain and function at 12 and 52 weeks following the intervention. For a more thorough evaluation of the effects of each individual program, physical outcome measures (muscle strength and objective functional tests) may be considered important to investigate the specificity required in therapeutic exercise and also provide direction for mechanistic studies. Similarly, it would have been beneficial to collect data on participation in sport, physical activity, and duration of GTPS symptoms, to detect the benefits of each exercise program in particular subgroups. Results did not control for medication use (therapeutic or medicinal), but randomization may account for this potential confounder.

Due to the pragmatic nature of the study, it was more cost effective and time efficient to collect baseline data at the first physiotherapy appointment, rather than before randomization as outlined in the protocol.¹⁹ Consequently, baseline measures were not received for four participants, and these participants were excluded from the intention to treat analysis.

The use of 23 physiotherapists to implement the intervention made it difficult to ensure that each clinician adhered to the exercise protocol, potentially affecting results. However, auditing clinical notes, standardized training, and prescription of exercises based on provided booklets aimed to ensure consistent treatment administration.

Future research

This single-arm trial may indicate that education is largely responsible for within-group changes; however, a wait and see approach is required to assess whether improvements in both groups are attributable to the natural history of the

condition. A subgroup of participants in the study further responded to GLoBE exercise therapy in addition to education. Research to identify these patients would assist clinicians to implement appropriate management strategies for individual rehabilitation. It is possible that there are exercises, not yet researched, that are more effective at reducing GTPS pain and dysfunction than those identified in this study. Thus, comparison of the GLoBE exercise program with other exercise programs is important to consider. Furthermore, only half of the globe group progressed to the end of the program by 12 weeks. So an analysis of level was reached and change in pain and function could be investigated.

Conclusion

A lack of treatment effect was found with the addition of an exercise program (GLoBE targeted exercise or sham exercise) to a comprehensive education on GTPS management. Both groups resulted in improvements at 12 and 52 weeks, with no significant differences found between groups using intention to treat analysis. Responders in the GLoBE group improved to a greater degree than responders in the sham exercise group. This highlights that diagnostic subgroups likely exist in GTPS and that further work on the classification of GTPS is warranted.

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Authors' Contribution

All authors have participated sufficiently in the conception and design of this work and the analysis of the data, as well as

the writing of the article to take public responsibility for its content. Authors declare that the article is original, and its essential substance, tables, or figures have not been previously published in part or in whole.

Author Disclosure Statement

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References

- Lieverse A, Bierma-Zeinstra S, Schouten B, Bohnen A, Verhaar J, Koes B. Prognosis of trochanteric pain in primary care. *Br J Gen Pract* 2005;55:199–204.
- Fearon A, Scarvell J, Cook J, Smith P. Does ultrasound correlate with surgical or histologic findings in greater trochanteric pain syndrome? A pilot study. *Clin Orthop Relat Res* 2010;468:1838–1844.
- Kingzett-Taylor A, Tirman PF, Feller J, et al. Tendinosis and tears of gluteus medius and minimus muscles as a cause of hip pain: MR imaging findings. *Am J Roentgenol* 1999;173:1123–1126.
- Kong A, Van der Vliet A, Zadow S. MRI and US of gluteal tendinopathy in greater trochanteric pain syndrome. *Eur Radiol* 2007;17:1772–1783.
- Pfirrmann CW, Notzli HP, Dora C, Hodler J, Zanetti M. Abductor tendons and muscles assessed at MR imaging after total hip arthroplasty in asymptomatic and symptomatic patients. *Radiology* 2005;235:969–976.
- Gordon E. Trochanteric bursitis and tendinitis. *Clin Orthop Relat Res* 1961;20:193–202.
- Fearon, Cook JL, Scarvell JM, Neeman T, Cormick W, Smith PN. Greater trochanteric pain syndrome negatively affects work, physical activity and quality of life: A case control study. *J Arthroplasty* 2014;29:383–386.
- Segal NA, Felson DT, Torner JC, et al. Greater trochanteric pain syndrome: Epidemiology and associated factors. *Arch Phys Med Rehabil* 2007;88:988–992.
- Demant AW, Kocovic L, Henschkowski J, et al. Hip pain in renal transplant recipients: Symptomatic gluteus minimus and gluteus medius tendon abnormality as an alternative MRI diagnosis to avascular necrosis. *Am J Roentgenol* 2007;188:515–519.
- Australian Institute of Health and Welfare 2010. A snapshot of arthritis in Australia 2010. Arthritis series no. 13. Cat. no. PHE 126. Canberra: AIHW.
- Del Buono A, Papalia R, Khanduja V, Denaro V, Maffulli N. Management of the greater trochanteric pain syndrome: A systematic review. *Br Med Bull* 2012;102:115–131.
- Rompe JD, Segal NA, Cacchio A, Furia JP, Morral A, Maffulli N. Home training, local corticosteroid injection, or radial shock wave therapy for greater trochanter pain syndrome. *Am J Sports Med* 2009;37:1981–1990.
- Ganderton C, Cook J, Docking SI, Rio E, Van Ark M, Gaida JE. Achilles tendinopathy: Understanding the key concepts to improve clinical management. *Australas Musculoskelet Med* 2015;19:12–18.
- Rudavsky A, Cook J. Physiotherapy management of patellar tendinopathy (jumper's knee). *J Physiother* 2014;60:122–129.
- Alfredson H, Pietilä T, Jonsson P, Lorentzon R. Heavy-load eccentric calf muscle training for the treatment of chronic Achilles tendinosis. *Am J Sports Med* 1998;26:360–366.
- Beyer R, Kongsgaard M, Hougs Kjær B, Øhlenschläger T, Kjær M, Magnusson SP. Heavy slow resistance versus eccentric training as treatment for Achilles tendinopathy. *Am J Sports Med* 2015;43:1704–1711.
- Rio E, Kidgell D, Purdam C, et al. Isometric exercise induces analgesia and reduces inhibition in patellar tendinopathy. *Br J Sports Med* 2015;49:1277–1283.
- Ark Mv, Cook J, Docking S, et al. 14 Exercise programs to decrease pain in athletes with patellar tendinopathy in-season: A RCT. *Br J Sports Med* 2014;48(Suppl 2):A9–A10.
- Ganderton C, Semciw A, Cook J, Pizzari T. Does menopausal hormone therapy (MHT), exercise or a combination of both, improve pain and function in post-menopausal women with greater trochanteric pain syndrome (GTPS)? A randomised controlled trial. *BMC Womens Health* 2016;16. DOI: 10.1186/s12905-016-0311-9.
- Ganderton C, Semciw A, Cook J, Pizzari T. De-mystifying the clinical diagnosis of lateral hip pain in women. *J Womens Health* 2017;26. DOI: <https://doi.org/10.1089/jwh.2016.5889>.
- Fearon AM, Ganderton C, Scarvell JM, et al. Development and validation of a VISA tendinopathy questionnaire for greater trochanteric pain syndrome, the VISA-G. *Man Ther* 2015;20:805–813.
- Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg* 1996;78:185–190.
- Klässbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score: An extension of the Western Ontario and McMaster universities osteoarthritis index. *Scand J Rheumatol* 2003;32:46–51.
- The University of Queensland. Lateral Hip Pain Questionnaire 2016. Available at: https://static-content.springer.com/esm/.../12891_2016_1043_MOESM1_ESM.pdf Last accessed February 13, 2018.
- Carlin JB, Doyle LW. Statistics for clinicians 7: Sample size. *J Paediatr Child Health* 2002;38:300–304.
- Centre for Evaluation and Monitoring Durham University. Effect size calculator. Available at: www.cemcentre.org/evidencebased-education/effect-size-calculator Accessed January 18, 2017.
- Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale: Lawrence Erlbaum, 1988.
- Deke J, Puma M. Coping with Missing Data in Randomized Controlled Trials In: Health HaHSOoA, ed., 2013:1–9. <https://www.hhs.gov/ash/oah/sites/default/files/ash/oah/oah-initiatives/for-grantees/assets/copingwithmissingdata.pdf>
- Vogel KG, Koob TJ. Structural specialization in tendons under compression. *Int Rev Cytol* 1989;115:267–293.
- Soslowky LJ, Thomopoulos S, Esmail A, et al. Rotator cuff tendinosis in an animal model: Role of extrinsic and overuse factors. *Ann Biomed Eng* 2002;30:1057–1063.
- Cook J, Purdam C. Is compressive load a factor in the development of tendinopathy? *Br J Sports Med* 2012;46:163–168.
- Grimaldi A, Fearon A. Gluteal tendinopathy: Pathomechanics and implications for assessment and management. *J Orthop Sports Phys Ther* 2015;45:910–922.
- Mellor R, Grimaldi A, Wajswelner H, 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;17:196.
- Carvalho C, Caetano JM, Cunha L, Rebouta P, Kaptchuk TJ, Kirsch I. Open-label placebo treatment in chronic low back pain: A randomized controlled trial. *Pain* 2016;157:2766–2772.

35. Rio E, Moseley L, Purdam C, et al. The pain of tendinopathy: Physiological or pathophysiological? *Sports Med* 2013;44:9–23.
36. Altman DG, Royston P. The cost of dichotomising continuous variables. *Br Med J* 2006;332:1080.
37. Deyi BA, Kosinski AS, Snapinn SM. Power considerations when a continuous outcome variable is dichotomized. *J Biopharm Stat* 1998;8:337–352.
38. Delitto A. Research in low back pain: Time to stop seeking the elusive “magic bullet”. *Phys Ther* 2005;85:206–208.
39. Hahne AJ, Ford JJ, Surkitt LD, et al. Specific treatment of problems of the spine (STOPS): Design of a randomised controlled trial comparing specific physiotherapy versus advice for people with subacute low back disorders. *BMC Musculoskelet Disord* 2011;12:104.
40. Selfe J, Janssen J, Callaghan M, et al. Are there three main subgroups within the patellofemoral pain population? A detailed characterisation study of 127 patients to help develop targeted intervention (TIPPs). *Br J Sports Med* 2016;50:873–880.
41. Kemp JL, Makdissi M, Schache AG, Pritchard MG, Pollard TCB, Crossley KM. Hip chondropathy at arthroscopy: Prevalence and relationship to labral pathology, femoroacetabular impingement and patient-reported outcomes. *Br J Sports Med* 2014;48:1102–1107.
42. Ganderton C, Pizzari T, Cook J, Semciw A. A comparison of gluteal muscle activity during isometric and dynamic exercises in older women. *J Orthop Sports Phys Ther* 2017;47:914–922.

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APPENDIX 1. GLOBE AND SHAM BETWEEN GROUP AND WITHIN GROUP DIFFERENCES

Time of Outcome measurement (weeks)	Number included (GLOBE/Sham)	Unadjusted mean score (SD)	Adjusted SMD (95%CI)	Adjusted between group difference (95%CI)	p-value	ES	GLOBE	Sham	p-value	Sham	p-value
Primary outcome measure											
VISA-G (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip)											
0	38/43	63.5 (9.7)	55.4 (15.3)	-0.6 (-1.1 to -0.2)			14.2 (8.9 to 19.5)	12.5 (6.8 to 18.1)	<0.0001		<0.0001
12	38/43	77.1 (16.8)	66.5 (15.6)	0.1 (-0.3 to 0.5)	0.668	0.7	17.0 (11.3 to 22.6)	17.0 (11.3 to 22.6)	<0.0001		<0.0001
52	38/43	79.8 (14.9)	69.8 (19.0)	-0.0 (-0.5 to 0.4)	0.853	0.6					
Secondary outcome measures											
HOOS: Pain subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a less painful hip)											
0	38/43	63.8 (14.2)	59.1 (13.5)	-0.3 (-0.8 to 0.1)			15.2 (11.0 to 20.7)	12.0 (6.7 to 17.1)	<0.0001		<0.0001
12	38/43	78.9 (15.8)	70.6 (17.8)	0.2 (-0.3 to 0.6)	0.357	0.5	16.9 (11.7 to 22.0)	16.9 (11.7 to 22.0)	<0.0001		<0.0001
52	38/43	78.1 (15.8)	73.7 (16.6)	-0.1 (-0.5 to 0.4)	0.788	0.3					
HOOS: Symptom subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less symptomatic hip)											
0	38/43	75.5 (13.1)	67.7 (13.7)	-0.6 (-1.0 to -0.1)			9.0 (4.3 to 15.0)	7.6 (1.5 to 13.7)	<0.0001		0.016
12	38/43	84.5 (13.2)	75.3 (16.5)	0.1 (-0.4 to 0.5)	0.739	0.6	9.7 (3.8 to 14.13)	9.7 (3.7 to 15.8)	0.001		0.002
52	38/43	84.2 (11.1)	77.1 (19.1)	0.0 (-0.4 to 0.5)	0.971	0.5					
HOOS: ADL subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher ADL functioning)											
0	38/43	72.1 (16.0)	64.1 (14.9)	-0.5 (-1.0 to -0.1)			12.6 (6.9 to 18.24)	12.1 (6.2 to 18.0)	<0.0001		<0.0001
12	38/43	84.9 (13.3)	76.0 (16.5)	0.0 (-0.4 to 0.4)	0.803	0.6	16.9 (10.1 to 22.8)	15.9 (10.1 to 21.8)	<0.0001		<0.0001
52	38/43	84.3 (15.2)	78.8 (17.2)	0.1 (-0.4 to 0.5)	0.917	0.3					
HOOS: Sport subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates a higher functioning and less painful hip during sport)											
0	38/43	58.0 (22.2)	44.6 (21.9)	-0.6 (-1.1 to -0.2)			17.6 (10.8 to 24.5)	16.3 (9.7 to 22.9)	<0.0001		<0.0001
12	38/43	74.9 (18.7)	63.7 (21.8)	0.0 (-0.4 to 0.5)	0.794	0.6	20.3 (13.7 to 26.9)	20.3 (13.7 to 26.9)	<0.0001		<0.0001
52	38/43	72.9 (19.2)	65.9 (23.3)	-0.2 (-0.6 to 0.3)	0.489	0.3					
HOOS: QoL subscale (Score from 0 to 100, 100 = a normal hip; a higher score indicates better QoL)											
0	38/43	52.5 (18.4)	47.6 (20.1)	-0.3 (-0.7 to 0.2)			12.7 (6.7 to 18.6)	12.4 (6.8 to 18.0)	<0.0001		<0.0001
12	38/43	66.6 (20.8)	60.0 (18.5)	0.1 (-0.4 to 0.5)	0.96	0.3	16.1 (10.1 to 22.1)	20.3 (14.7 to 25.9)	<0.0001		<0.0001
52	38/43	69.3 (18.9)	65.3 (20.6)	-0.2 (-0.7 to 0.2)	0.30	0.2					
OHS (Score from 0 to 48, 48 = a normal hip; a higher score indicates a higher functioning and less painful hip)											
0	38/43	32.6 (5.1)	30.2 (6.6)	-0.4 (-0.8 to 0.1)			6.5 (4.5 to 8.5)	5.7 (3.4 to 8.0)	<0.0001		<0.0001
12	38/43	39.0 (6.2)	35.9 (7.5)	0.1 (-0.3 to 0.6)	0.626	0.5	7.9 (5.9 to 9.84)	7.5 (5.2 to 9.8)	<0.0001		<0.0001
52	38/43	39.7 (6.4)	36.8 (7.9)	0.1 (-0.4 to 0.5)	0.811	0.4					
LHPQ: ADL subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower ADL functioning)											
0	38/43	45.4 (19.1)	47.4 (15.7)	0.1 (-0.3 to 0.6)			-19.9 (-25.4 to 14.4)	-15.9 (-22.5 to -9.4)	<0.0001		<0.0001
12	38/43	25.2 (17.4)	32.6 (18.7)	-0.2 (-0.7 to 0.2)	0.338	0.4	-22.0 (-27.3 to -16.6)	-23.8 (-29.9 to -17.7)	<0.0001		<0.0001
52	38/43	23.3 (19.6)	26.7 (19.8)	0.1 (-0.4 to 0.5)	0.679	0.2					
LHPQ: Sport subscale (Score from 0 to 100, 0 = a normal hip; a higher score indicates lower functioning and more painful hip during sport)											
0	38/43	83.9 (24.3)	72.7 (34.0)	-0.4 (-0.8 to 0.1)			-10.1 (-22.6 to 2.3)	-3.4 (-15.0 to 8.15)	0.109		0.559
12	38/43	71.7 (40.2)	62.8 (41.8)	-0.2 (-0.6 to 0.3)	0.438	0.2	-9.6 (-21.8 to 2.6)	-18.9 (-30.0 to -7.7)	0.12		0.001
52	38/43	70.3 (39.0)	52.7 (41.8)	0.2 (-0.2 to 0.7)	0.266	0.4					
AQoL (Score from 0.00 to 1.0, 1.0 = full health; 0.0 = death-equivalent health state)											
0	38/43	0.8 (0.2)	0.7 (0.2)	-0.3 (-0.7 to 0.1)			0.1 (0.0 to 0.9)	0.1 (<0.1 to 0.1)	0.017		0.004
12	38/43	0.8 (0.1)	0.8 (0.2)	-0.1 (-0.5 to 0.4)	0.977	0.0	0.1 (0.0 to 0.9)	0.1 (<0.1 to 0.1)	0.016		0.001
52	38/43	0.8 (0.1)	0.8 (0.2)	-0.1 (-0.6 to 0.3)	0.333	0.0					

A per protocol analysis using baseline scores and BMI as covariates.

Bold = significant finding.^aLinear mixed model analysis, adjusted for baseline scores and BMI.

HOOS, Hip dysfunction and Osteoarthritis Outcome Score; OHS, Oxford Hip Score; AQoL, Assessment of Quality of Life; LHPQ, lateral hip pain questionnaire; ADL, activities of daily living; SD, standard deviation; SMD, standard mean difference; 95%CI, 95% confidence interval; ES, effect size.