2017-11

A Pilot RCT Investigating the Effects of Targeted Compression on Athletes with Pelvic / Groin Pain

Sawle, L

http://hdl.handle.net/10026.1/10617

10.1123/jsr.2017-0097
Journal of Sport Rehabilitation
Human Kinetics

Accepted for publication in the Journal of Sports Rehabilitation. Acceptance date 3/10/2017. https://journals.humankinetics.com/doi/10.1123/jsr.2017-0097

A Pilot RCT Investigating the Effects of Targeted Compression on Athletes with Pelvic / Groin Pain

Leanne Sawle, Jennifer Freeman, Jonathan Marsden.

AFFILIATIONS: [1]Plymouth University, Faculty of Health and Human Sciences, Peninsula Allied Health Centre, Plymouth, Devon, United Kingdom. [2]Cardiff University, School of Engineering. The Parade, Cardiff, Wales.

Context: Athletic pelvic/groin pain is a common yet often challenging problem to both diagnose and manage. A new tool has been developed based on the clinical effects of applied force on the pelvis. Early findings indicate that this customised compression orthosis may have a positive effect upon pelvic/groin pain and performance measures**.**

Objectives: To:

Inform the design and test the practicality of procedures for a future definitively powered randomized controlled trial;

Provide an estimate of the effect size of this orthosis on selected clinical and performance measures.

Design: Pilot randomised controlled trial with participants randomly allocated to an intervention or waiting-list control group

Setting: The training location of each athlete

Participants: 24 athletes with sub-acute and chronic pelvic conditions were proposed to be recruited

Intervention: A customised compression orthosis, delivering targeted compression to the pelvic girdle.

Outcome measures: Measures were the active straight leg raise test, squeeze test, broad jump, and the multiple single-leg hop-stabilization test.

Results: 16 athletes completed the study. The invention group demonstrated moderate to large estimated effect sizes on the squeeze test and active straight leg raise tests (d = 0.6-1.1) whilst wearing the orthosis. Small effect sizes (d = 0.2) were seen on jump distance and the dominant leg balance score. Compared to the control group the intervention group also showed moderate to large estimated effect sizes on the active straight leg raise measures (d = 0.5-09) when wearing sports shorts.

Conclusions: The protocol was feasible. Effect sizes and recruitment/attrition rates suggest that the intervention holds promise and that a future definitive powered RCT appears feasible and is indicated.

INTRODUCTION

The incidence of pelvic/ groin injury is particularly high in sports such as Gaelic (24%)[1], ice hockey (10-11%)[2] and Association Football (49%)[3], and research has highlighted the challenges affecting the diagnosis and management of these injuries [4-6].

Pelvic belts, a form of external pelvic compression [7], are a tool that have demonstrated some success in reducing pain and improving function, on clinical tests such as the squeeze test and active straight leg raise (ASLR) [8,9]. However, the practicality of using belts during performance is limited, and research has begun to consider alternative forms of external pelvic compression. Preliminary research has suggested that pain and/ or function on clinical tests (ASLR and squeeze test force) may be improved by introducing targeted compression in the form of a customised compression orthosis. Subjective data from this study further proposed positive effects upon attributes including power and balance[10] . It has been hypothesised that these effects may be explained by targeted compression influencing the force or form closure deficit associated with this type of injury (providing stability), and/or improving proprioception and muscle function[10].

The use of compression garments as a post exercise adjunct to recovery, have been reported as beneficial for performance recovery and delayed-onset muscle soreness[11,12]. However, there is a paucity of research in the field of compression and injury management. Of the work undertaken in this domain, one study reported that standard compression shorts have been found to significantly reduce pain in athletes with osteitis pubis[13]. Other work found that targeted compression reduced adductor activity in healthy participants, and theorised as reducing the risk of adductor related injury[14].

Research into compression style orthoses has reported mixed findings in terms of enhancing performance attributes; some studies demonstrating improvements in measures such as balance and power, whilst others showing no effect [13,15,16]. Some findings have suggested that compression shorts may influence repetitive performance by reducing muscle oscillations [15], influencing proprioception and delivering athlete perceived improvement effects[16]. Well-fitting compression shorts have demonstrated improvements in the static balance of female athletes, compared to wearing standard shorts[17]

However, little is known about the application of targeted compression, and this warrants further investigation. Whilst acknowledging the limited literature in this domain, there is some evidence that targeted compression may have a role in athletic groin and pelvic injury management [13,14]. It is also possible that a customised targeted compression orthosis, may offer further benefits.

Therefore, to explore the role of compression in injury management, and specifically the use of external pelvic compression in the form of a customised compression orthosis, a randomized controlled trial (RCT) was indicated. However several factors must be determined prior to designing and implementing a full trial, therefore a pilot RCT [18] was undertaken in order to:

Inform the design and test the practicality of procedures for a future definitively powered RCT study [19], by determining:

a. recruitment rate
b. attrition rate
c. presence of adverse events
d. effect size estimate
e. feasibility of using the outcome measures

f. effectiveness of the blinding strategy
g. practicality of the protocol

METHOD

Sampling and Recruitment Strategy

A convenience sample of volunteers was recruited from UK-based sports clubs over one year. The number of males recruited may reflect the fact that that moderate evidence exists supporting a higher risk of this type of injury in male athletes [20].

Table 1 presents the demographical data.

Of the nine athletes allocated to the waiting-list control group, eight had chronic pain; one athlete was identified as having sub-acute pain during screening, but this became chronic pain (> three months) by the time the baseline measures were taken. In the intervention group, all seven athletes had chronic pain. Pain severity ranged from low to moderate across both groups and was influenced by activity; as per the exclusion criteria those exhibiting severe pain (>8/10 on a numerical rating scale [NRS]) did not take part. This was for ethical reasons due to repeated testing.

The uneven numbers in the two groups were due to the minimisation program which was setup for 12 athletes in each group; split evenly across chronic and sub-acute pain.

Table 1 Athlete **demographics**

All athletes were training three or more times per week, and were undertaking both aerobic and anaerobic training. Competition levels ranged from recreational (n = 8) to professional (n = 8).

Eligibility Criteria

Inclusion Criteria:

i. Athletes aged 18 years or above (reactional or professional).

ii. Sub-acute (1-3 months duration) and chronic (>3 months) self-reported pelvic / groin pain presenting during sport or at rest (unilateral or bilateral)

iii. Pelvic / groin pain as confirmed via a screening procedure. For inclusion, positive pain scores had to be determined on at least two of these five tests, as when used in isolation these tests are limited in terms of reliability, but when used together they provide a more reliable approach [21].

Screening Procedure

The following battery of tests were performed; details can be found in previous literature. These tests are appropriate for both unilateral and bilateral pain presentations[8,21,22]:

- Active Straight Leg Raise (ASLR)
- Fabers
- Thigh thrust
- Gaenslens
- Squeeze test

Exclusion Criteria:

Self-reported acute pelvic / groin pain; defined as zero to four-weeks duration, which may be expected have a short resolution period [23].

Neurological, or systemic disease

Pregnancy

Radicular pain

History of pelvic fracture

Inguinal hernia

Severe pain (>8/10 on a NRS)

Trochanteric bursitis

Ruptured muscle

Study Design

A waiting-list control [24], researcher blinded [25], pilot RCT was undertaken after approval from the local (UK-based University) ethics committee. A waiting-list control design was employed for ethical reasons, as all athletes were selected on the premise that they were suffering from ongoing pain. This is considered a useful method for keeping the control athletes engaged with the study[26].

Random allocation with a minimisation procedure was employed to ensure equal distribution of sub-acute and chronic conditions between groups. Athletes in the intervention group used the compression orthosis for a four-week period. Athletes in the control group served as a waiting-list control for a four-week period, before receiving their orthosis.

Recruitment Rate

The recruitment and attrition rates were reported according to CONSORT Guidelines [27].

Sample Size

Twenty-four athletes were proposed to be randomly assigned to the intervention (n=12) or waiting-list control group (n=12), based on the recommendation of 12 in each athlete group for feasibility/pilot work [28] .

Figure 1 summarises the athletes' route through the study.

Figure 1 Athlete **pathway through the study**

After obtaining written informed consent, potential athlete participants were screened, and demographic, pelvic /groin pain history and training data (frequency, duration and type) were recorded. Athletes who met the eligibility criteria were measured for a compression orthosis by the investigator.

One week later (+/- 3 days for flexibility) athletes completed two sets of baseline measures wearing sports shorts and loose-fitting track pants over the top (provided). The use of track pants was to standardise dress, and to ensure blinding of the investigator at later dates.

Athletes were also fitted for their customised orthosis, and given usage and care instructions. The study administrator's details were provided for any future compression orthosis queries, and the orthosis held by the administrator until after the randomisation process.

Randomisation Procedure

The administrator randomly allocated the athlete to the groups using a web-based system (minim http://www-users.york.ac.uk/~mb55/guide/minim.htm). A minimisation algorithm was used to ensure balance between the groups on the basis of injury chronicity (1-3 months versus > 3 months). Allocation concealment was employed to blind the investigator to the randomisation process [29]. The administrator informed athletes of their group allocation, posted the diaries to record training frequency, duration and type, treatment and compression orthosis usage, and sent the compression orthosis to the intervention group.

Allocation Concealment during Outcome Measurement

A compression orthosis may have an orthotic effect[30], only seen when the orthosis is in situ. Long term use of the compression orthosis may also result in improvements in the outcome measures even when it as not worn; a "carryover effect". To measure these potential effects the intervention group were assessed with and without the compression orthosis. For the intervention group, one assessment was completed when wearing the compression orthosis and another with shorts. Athletes in the control group were assessed twice with shorts. As there is a potential order effect the order of the testing (orthosis versus shorts) was randomised to account for effects such as fatigue or exacerbation of symptoms with testing.

The administrator randomised the wearing of the orthosis, completed paper slips recording this information, and sealed them in opaque envelopes labelled with the athlete's name, study number and the measurement session number. These were sent to the investigator prior to each test date so that they could hand the sealed envelope to the participant at the start of each session. Envelopes were also prepared for those in the waiting-list control group; the contents asked these athletes to wear shorts for both assessments. Athletes were asked to verbally confirm that the envelope that they had been given was sealed and had their name on it and the measurement session (week two, four or six) via a digital recorder.

Blinding

A criticism regarding the reporting of blinding in studies, is that many studies do not test the effectiveness of their blinding strategy [25]. Therefore, athletes wore track pants to conceal what they were wearing, and at week two, photographs were taken of athletes from the torso down at the start of assessment one and assessment two. To determine the effectiveness of the investigator blinding procedure, at the end of the study eight individuals were independently asked to identify whether a participant was wearing a compression orthosis or not from looking at the photographs. Further, at the end of the measurement sessions at week two, four and six the investigator completed a form indicating what they felt the athlete was wearing.

Groups

Intervention Group

Athletes were asked to wear their orthosis for normal training/ sport / physiotherapy input for a four-week “intervention” period and complete daily diaries to record usage, training, sport and physiotherapy input throughout this period.

Waiting-List Control Group

Athletes were asked to continue normal training/ performance/ physiotherapy input and record this in their daily diaries for a four-week period. After this time, the control group received the orthosis by post from the administrator.

Timing and Purpose of Assessments

Outcome measures were recorded at week one (baseline), week two, week four and week six, and athletes were assessed twice (assessment one and assessment two), separated by 10 minutes of rest. The outcome measures were undertaken in a standardised order, and performed as described below.

The measures taken at baseline, when all athletes wore sports shorts for both assessments give an indication of the stability of the outcome measures over time. This was checked using intraclass correlation coefficients (ICCs) and Bland Altman plots.

To maximise recruitment testing was conducted in the athletes' clubs/sports centres using portable equipment to fit in around the athlete's schedule. To minimise the effects of external cues such as audience and environmental effects, athletes were tested in the same environment with only the investigator present.

Outcome Measures

Primary Outcome Measure

Squeeze test – Athletes with longstanding groin pain have shown significantly ($p = <0.01$) lower squeeze test force values than healthy controls [31]. This suggests that this test is appropriate for measuring the deficits associated with this type of pain. It has also shown excellent inter and intra tester reliability in athletes with and without groin pain (ICC ≥ 0.90)[32].

From a supine position (hips and knees at 0°) athletes were asked to squeeze their legs together as hard as possible. This position has shown higher force output [33], and minimal variability [34]. Maximal force output was measured using a padded load cell (SGA Applied Weighing, Reading, UK) placed between the medial femoral condyles, an oscilloscope (HPSI 40i handheld pocket scope, Velleman Instruments, Taiwan) and an amplifier (Applied Weighing, Reading, UK). The voltage recorded was converted into Newtons.

Secondary Outcome Measures

A familiarisation session was built into the start of the baseline testing session, so that athletes became aware of how to complete each test. Athletes had the tests verbally explained to them, could view the tests, look at photographs of the tests being performed, read simple instructions, and practice once on each leg.

The Active Straight Leg Raise (ASLR)

Previous findings showed that the ASLR test produced low pain scores in a similar sample of athletes [9], therefore the original ASLR protocol which records difficulty in completing the test [35] was also used. Research has also indicated that increased difficulty with the ASLR is reflected in higher pain scores on the test [36].

In terms of reliability, its test retest reilability in post-partum posterior pelvic pain patients is excellent (ICC 0.87). Although reliability values are not available for athletes, the test has been used with athletes (from a variety of team and individual based sports) with groin pain [8,37].

From a supine position on a plinth, athletes were asked to raise their right leg (knee in extension) to a bar positioned 20cm above the plinth. Athletes were asked to rate their pain at completion of the test using a numerical rating scale (NRS) of zero to ten (zero = no pain, ten = worst pain imaginable). Athletes were also asked to self-score the difficulty of this task using a rating of zero to five (zero = no difficulty; five = extremely difficult). This was repeated with the left leg.

The Broad Jump

The broad jump test of power [38] has been reported as demonstrating excellent test re-test reliability (ICC = 0.97) [39]. Athletes were asked to jump forwards over a mat, taking off from a two-footed stance and using their arms to propel themselves forward, landing with their feet close together. The landing spot was recorded using a chalked mark, and a right-angled tool (a hinged wooden bar) was used to measure from the landing mark, to the measuring tape fixed to the length of the mat. The protocol described by Almuzaini and Fleck [39] was followed, and the jump was repeated three times with the furthest distance recorded as their score.

Functional Balance

The Multiple Single-Leg Hop-Stabilisation test (MSLHST) has been used as a functional, dynamic measure of athletic balance [40], as due to its forward, transverse and diagonal movements, it tests balance across multi-movement planes. It has demonstrated good to excellent test re-test reliability in an active population (ICC = 0.85; CI 0.61-0.95)[41].

Athletes were asked to jump from a standardised unipedal stance to and from 10 squares placed at distances determined by their height. The test incorporated periods of landing and statically maintaining a unipedal stance, giving athletes a balance and landing score for each of the 10 squares. The protocol reported by Riemann et al.[40] was used, and the test was undertaken on both the dominant and non-dominant leg. Leg dominance was defined as the leg with which the athlete prefers to kick with [40], usually the right leg, therefore the left leg takes a pivotal role in providing stability [42].

Statistical Analysis

Results were reported according to CONSORT Guidelines [27].

To establish whether outcome measure scores could be averaged at baseline and for the two assessments per measurement session taken by the waiting-list control group, test retest reliability was examined where it was not already known in this patient group. ICCs (2,1) and Bland-Altman plots were used.

Fisher's Exact test was used to assess the effectiveness of the blinding procedures. It is a test used to analyse 2 x 2 contingency tables, and is advised for use with small sample sizes [43]. Blinding is considered effective if no significant difference is seen between the responses given (incorrect and correct; $p = 0.05$).

Descriptive statistics were used, as recommended for pilot studies where a powered sample has not been employed [44]. Effect sizes were calculated (Cohen's d) and interpreted as being small = ≥ 0.2, <0.5, medium = ≥ 0.5 or large = ≥ 0.8 [45]. The formula for calculating effect sizes using Cohen's d is shown below (M = mean; SD = standard deviation).

$$d = \frac{M_1 - M_2}{SD_{\text{pooled}}}$$

An intention-to-treat approach to the descriptive analysis was employed in order to include data from all athletes randomized to a group, ignoring anything that occurs post randomisation [46]. The last measure carried forward technique was used in order to deal with any missing data from athletes dropping out during the study, and provided a conservative estimate of their performance had they continued [47].

Criteria to proceed to full RCT

In order to determine feasibility [19], the following criteria was required:

1. The attrition rate is <20% across the length of the study [48].
2. The proposed number of athletes (n=24) could be recruited over a 12-month period.

RESULTS

The CONSORT diagram (figure 2) shows the numbers of athletes recruited, allocated to each group, and completing the study. T tests showed no significant difference between the groups in terms of age, training, height or weight ($P = >0.05$).

Figure 2 The CONSORT diagram showing the flow of athletes **through the study**

Reliability

ICCs and Bland Altman plots indicated that it was appropriate to average the waiting-list control group measures, and the baseline measures for both groups across assessment 1 and 2. This decision was justified by the ASLR ICC values indicating good to excellent reliability and precision (0.90-0.96; CI = 0.73-0.98). Bland Altman plots showed that the majority of the difference in test retest values stayed within 2SD. The decision to average the other outcome measures was based upon their historical intra-rater reliability.

Effect Sizes

Table 2 presents Cohen's d effect sizes representing the standardised mean difference in the scores of the intervention group compared to the waiting-list control group, at each stage of the study. Table 3 shows descriptive statistics i.e. standardised mean differences and 95% confidence intervals.

Table 2 The effect sizes (d) for each outcome measure at each stage of the study

Table 3 The mean difference (in bold) and 95% confidence intervals for the mean difference, from baseline to assessment week two, four and six for each outcome measure and for each condition

Blinding

Eight individuals were asked to decide whether participants were wearing a compression orthosis or not by looking at photographs taken during the week two measurements. The responses were grouped as being either correct or incorrect. Fisher's Exact test indicated that there was no significant difference between the groups ($p = 0.4$).

For the investigator's blinding check of effectiveness Fisher's Exact test showed that this result was not significant ($p = 1$); blinding was effective.

DISCUSSION

Athletic pelvic/ groin pain is often a challenge both diagnostically, and from a management perspective[5]. Findings have suggested that the use of external pelvic compression in the form of a customised compression orthosis, may offer a tool for supporting the multi-modal management of these injuries[10]. However before implementing a full trial, a pilot RCT [18] was needed to inform the design and test the practicality of procedures for a future definitively powered RCT study [19]. These findings have been reviewed.

Recruitment and Attrition Rates

Of the intended 24 athletes, only 16 athletes (males = 13) were randomly assigned to groups and tested. Although the CONSORT diagram highlights the problem of ineligibility, it does not show that another 11 information packs were requested and received by interested athlete participants. This suggested that sufficient numbers were available, but that the 12-month study duration may have been an issue. Future work must consider time constraints, and how to improve the recruitment rate. Once recruited the attrition rate was zero demonstrating that once enrolled in the study, athletes were engaged enough to continue. It may also reflect that the attrition rate was not influenced by factors such as illness and other injuries.

Adverse Effects

No adverse effects were reported.

Feasibility of Procedures and Outcome Measures

Testing procedures proved to be successful in terms of logistics, practicality of outcome measures and data collection. The measures were straightforward to administer and athletes reported no difficulties in completing them. There was no missing data.

Blinding Effectiveness

The blinding procedures proved effective, and suggested that this method of blinding would be appropriate for future work.

Summary of Outcome Measure Effect Sizes

The results show that the compression orthosis had varying effects on a range of outcomes in athletes with chronic pelvic / groin pain. In general, wearing the compression orthosis demonstrated moderate to large effects on clinical measures, and negligible to small effects upon performance measures. These findings were considered and compared to the results of compression studies, however the use of customised, targeted compression differs, and thus stands as a unique concept.

Clinical Measures

At week six, those allocated to the intervention demonstrated reduced pain and less difficulty in undertaking the ASLR, and, increased squeeze test force (d = 0.6 to 1.1) compared to those in the waiting-list control group.

Moderate to large effect sizes (d= 0.5 to 0.8) were seen on the ASLR measures when the intervention group were tested wearing sports shorts, indicating a possible carryover effect from orthosis use. The ASLR difficulty scores showed larger effect sizes (d = 1.1) than pain on ASLR (d = 0.6 to 0.9), supporting its appropriateness in this patient group [8], and suggesting that other factors can influence performance difficulty. For example, increased pelvic mobility has been identified as a factor associated with higher ASLR scores [35]. This suggests those with more pelvic joint mobility find the ASLR test more difficult. In consensus with other research [36], increased difficulty with the ASLR corresponded to higher pain scores on the test.

The large effect on squeeze test force (d = 0.8) present at week four and week six, concurs with the effects of external pelvic compression on athletes with adduction-related groin pain [8]. The findings from the intervention group wearing sports shorts indicates that this effect was associated only with wearing the orthosis. This may suggest a splinting or orthotic effect based on the use of an aid which demonstrates an effect only whilst it is in use. This could be explored with a longer intervention period to establish if a carryover effect becomes evident. Effects upon the ASLR support previous work in patients with chronic pelvic pain finding less ASLR difficulty with compression [49]. There is also support for the findings of compression orthoses reducing pain in athletes with osteitis pubis [13]. However, the practicality of this compression orthosis, and its customised fit, may offer an improved method of applying targeted compression.

Performance Measures

Small effect sizes were seen on the broad jump and non-dominant leg MSLHST ($d = 0.2$ to 0.3 respectively) when wearing the orthosis. A negligible effect was seen on the dominant leg ($d=0.1$).

Studies into compression shorts have shown contradictory findings on balance and power tests in healthy and patient populations. Whereas static unipedal balance has been seen to significantly improve ($p = <0.05$) when well-fitting compression shorts have been worn [17], other findings demonstrated that compression shorts worn by healthy participants showed no significant effect ($p = 0.9$) upon static balance [50]. However, the static nature of this test may not have been athletically challenging or adequately responsive for a patient population.

In an athletic population with pelvic and groin pain, athletes with osteitis pubis showed a trend towards improved functional stability [13]; single leg squat ($p = 0.08$); effect size of $d = 0.2$. This finding was for the left leg and may have indicated improved performance on the leg commonly required to provide stability for the dominant leg to perform. This finding might have partly explained the pilot RCT finding of a small effect seen in the non-dominant leg MSLHST score ($d = 0.3$), but minimal improvement seen on the dominant leg ($d = 0.1$). Due to bilateral pain reported in all athletes, and the ASLR mean differences and SD showing no difference between right and left leg pain scores, the effect of site of pain is unknown. It has been suggested that leg dominance should be considered in terms of the nature of the task, with the right leg dominating in activities requiring manipulation, for example kicking, whereas the left leg dominates in postural control activities [42]. The small improvement in the non-dominant or postural control leg, may have indicated that the targeted pelvic compression led to small but identifiable improvements in the dynamic balance of athletes with pelvic / groin pain.

Field tests of power have also produced mixed findings in healthy athletes, from no significant effect of compression upon vertical jump height [50], to customised compression shorts demonstrating significant improvements in countermovement vertical jump height ($p = 0.015$)[15]. Whilst compression shorts did not improve maximal vertical jump power, a significant effect upon repeated jump performance was reported [16]. Mean power output on repeated jumps ($n = 10$) significantly improved when compression shorts were worn [16]. Compression leggings have also been shown to improve repeated sprint performance in healthy female athletes. Although there was no effect seen on haemodynamic or physiological measures, an influence upon proprioception was suggested [51]. This might have been due to the stimulation of the neuromuscular system. Gluteal muscle kinesiotaping has been found to increase explosive power as measured by a field test [52].

This pilot RCT concurs with previous findings that wearing targeted compression shorts shows some improvement in power, but contributes new preliminary knowledge that this finding has been observed in athletes with pelvic / groin pain, and by using a customised approach.

Intervention Assessment Points

The effect sizes at different stages of the intervention period showed variable results. Week two improvements in the intervention group whilst wearing control shorts, may have indicated an immediate carryover. It is also possible that this was the influence of being allocated to the intervention group, and behaving accordingly.

However, the data varies over time; performance in the intervention group appears to have been detrimentally affected in the earlier assessment sessions before showing improvement at the latter assessments. One possible explanation may be that athletes underwent a period of adjustment to wearing the orthosis, and that there was variability in how they responded; possibly influenced by their expectations. It may also have been the result of increased discomfort caused by factors including the compression orthosis, increased training loads and changes in their condition. Early outcome measures may have been influenced by the level of pain at the start of the study, particularly in a population with varying pain mechanisms, and sites of pain [4]. Attempts were made to balance injury chronicity in both groups by way of a minimisation procedure. However, in view of the chronic nature of all participants, future work might wish to use a minimisation procedure to allocate athletes according to pain levels. Apprehension when undertaking measures for the first time may also have led to a tentative technique.

Although the performance measures showed small effect sizes, there may have been a learning effect, indicated by the control group also showing some improvements. Whilst effort was made to limit this by having a familiarisation session at baseline, balance studies have reported learning effects [40,53]. This may also have indicated an improvement in their condition.

Pain Provocation Tests

Athlete responses to the five pain provocation tests ranged from two, to five positive outcomes. This figure was higher when bilateral pain responses are observed, and concurred with other studies finding bilateral and multiple sites of pain [8]. As none of the athletes presented with truly unilateral pain, the presence of bilateral pain might be indicative of those presenting with chronic pain. It is therefore not known if unilateral pain would have influenced the results.

As is expected with an inclusion criteria designed to identify athletes with any pelvic /groin pain; pain presentations varied in terms of the site(s) of pain [4]. It is also possible that this might have influenced the results, especially if positive pain responses were more evident in one group. However, there was an evenly matched spread in the number of positive pain responses across both groups. Therefore, it is suggested that this reflected the very nature of this injured population, and that pain presentations had a limited effect on the results. Despite this, future work should consider the number of positive pain responses as a minimisation factor.

Recruitment

Future work requires an essential change to recruitment strategies. Sources of recruitment proved to be effective in generating interest from prospective athletes, but not in recruiting them into the study. This could have been due to the time commitment involved. Once the participant information pack was received 11 potential athletes were lost for reasons including work commitments. Of those recruited, ineligibility and the time/ resources available reduced the number of athletes completing the study. Having co-investigators may have helped, and been more efficient timewise when multiple athletes were being tested.

Limitations

Although the intention was to recruit athletes with sub-acute and chronic pain, only the latter were recruited. Therefore, the results should be only considered in the context of a future study into chronic athletic pelvic / groin pain, and suggests it is more appropriate to focus upon recruiting athletes with chronic pain. It is also noted that using a mixed sample of professional and recreational athletes is a confounding factor. The training / competition demands on the professional athletes may have influenced pain.

This was also a partially blinded study which may have been influenced by demand characteristics [54]. Athletes knew which group they have been assigned to, and may have adopted behaviour which they consider the investigator is demanding from them. This may have led to those wearing the compression orthosis trying hard to improve their performance to “please” the investigator. This may explain some of the positive effects seen at week two, when the compression orthosis was initially provided. At week two, even wearing shorts led to improvements in the intervention group (ASLR pain and difficulty scores). As the order of testing was randomised this cannot be explained fully by an instantaneous “carry-over effect,” as not all participants would have worn the orthosis first. Despite this possible bias, double-blinding was rejected because the effects of other compression shorts [13,16] would not allow for a true control. Therefore the reporting of blinding procedures was made transparent, and its effectiveness tested [25].

Contribution to Knowledge

This pilot study has provided preliminary evidence to demonstrate the potential for employing a novel method of applying targeted compression to the pelvic girdle. Based on moderate to large improvement effects on clinical tests (ASLR and the squeeze test), and small improvement effects upon performance measures (balance and power), it is suggested that this unique compression orthosis may offer a practical tool to support the difficult management of chronic athletic pelvic / groin pain.

Clinical Implications

There may also be scope to explore the use of this compression orthosis in the prevention of pelvic / groin injury. Based on the findings of decreased adductor and biceps femoris activity with compression in both healthy and pelvic pain groups[14,55], and the risks associated with increased and asymmetric activation, there may be a preventive role for this orthosis. As previous pelvic / groin injury is a risk factor for further injury [56], this group of athletes would be appropriate to consider for orthotic use.

The possibility of a compression orthosis associated thermal effect upon performance should also be considered. Studies have reported that compared to control shorts compression shorts can significantly increase skin temperature during exercise (~1 degree centigrade) [57], and that there is a relationship between increased skin temperature and increased muscle temperature [15]. It has also been shown that during short duration exercise neuromuscular function can be affected by muscle temperature; functions such as nerve conduction velocity improving with higher temperatures. Improved performance has been also observed on vertical jump tests of power after the lower limbs have been heated [58]. This suggests that it may be appropriate to explore the use of this compression orthosis after warm up exercise, as this may show different effects to tests undertaken immediately after donning the orthosis.

CONCLUSIONS

The aims of this pilot RCT were partly achieved. Although the intended number and chronicity distribution of athletes was not reached, this may be addressed in the future by employing more focused recruitment drives (for example with Gaelic Football), extending the recruitment period and focusing upon athletes with chronic pain. The criteria of an attrition rate < 20% was achieved. The protocol itself was feasible, and blinding of the investigator was effective, but the use of co-investigators would be more time effective and essential for facilitating better recruitment.

The effect sizes and recruitment/dropout rates suggest that the intervention holds promise as a tool to support the multi-modality approach to pelvic / groin injury management. Based upon these findings and the actions proposed to address recruitment, a future definitively powered RCT appears feasible and is indicated.

References

1. Glasgow P, Webb M, McNicholl C. *Report of Gaelic groin think tank: prevention and management of chronic groin pain in Gaelic Football.* Newtownabbey: Sports Institute Northern Ireland in association with Ulster Council GAA; 2011.
2. Tyler TFS, H.J.; Gerhardt, M.B.; Nicholas, S.J. Groin injuries in sports medicine. *Sports Health.* 2010;2(3):231-236.
3. Thorborg K, Rathleff MS, Petersen P, Branci S, Hölmich P. Prevalence and severity of hip and groin pain in sub-elite male football: a cross-sectional cohort study of 695 players. *Scand J Med Sci Spor.* 2017;27(1):107-114.
4. Ficek K, Rzepka R, Orawczyk T, Zotnierczyk Z. Groin pain in athletes - clinical experience. *J Hum Kinet.* 2008;19:141-148.
5. Ekçi B, Beyzadeoglu T. Groin pain in athletes - sports hernia and osteitis pubis. In: Canonico S, ed. *Inguinal Hernia [online]*. Vol 10.5772/58621 Intech. 111-123 Available: http://www.intechopen.com/books/export/citation/EndNote/inguinal-hernia/groin-pain-in-athletes-sports-hernia-and-osteitis-pubis [Accessed 6/2/2015]; 2014.
6. Serner A, van Eijck CH, Beumer BR, Hölmich P, Weir A, de Vos R-J. Study quality on groin injury management remains low: a systematic review on treatment of groin pain in athletes. *Br J Sports Med.* 2015;49:818. http://bjsm.bmj.com/content/49/12/813.full. Accessed 12/2/ 2015.
7. Arumugam A, Milosavljevic S, Woodley S, Sole G. Effects of external pelvic compression on form closure, force closure, and neuromotor control of the lumbopelvic spine – a systematic review. *Manual Ther.* 2012;17(4):275-284.
8. Mens J, Inklaar H, Koes BW, Stam HJ. A new view on adduction-related groin pain. *Clin J Sport Med.* 2006a;16(1):15-19.

9. Sawle L, Freeman J, Marsden J, Matthews MJ. Exploring the effect of pelvic belt configurations upon athletic lumbopelvic pain. *Prosthetics and Orthotics International.* 2013;37(2):124-131.

10. Sawle L, Freeman J, Marsden J. The use of a dynamic elastomeric fabric orthosis (DEFO) in supporting the management of athletic pelvic and groin injury. *J Sports Rehabil.* 2016;25:101-110.

11. Beliard S, Chauveau M, Moscatiello T, Cros F, Ecarnot F, Becker F. Compression garments and exercise: no influence of pressure applied. *J Sports Sci Med.* 2015;14(1):75-83.

12. Hill J, Howatson G, van Someren K, Leeder J, Pedlar C. Compression garments and recovery from exercise-induced muscle damage: a meta-analysis. *Br J Sports Med.* 2013.

13. McKim KR, Taunton JE. The Effectiveness of compression shorts in the treatment of athletes with osteitis pubis. *NZ J Sport Med.* 2001;29:70-73.

14. Chaudhari AMW, Jamison ST, McNally MP, Pan X, Schmitt LC. Hip adductor activations during run-to-cut manoeuvres in compression shorts: implications for return to sport after groin injury. *J Sport Sci.* 2014;32(14):1333-1340.

15. Doan BK, Won YH, Newton RU, et al. Evaluation of a lower-body compression garment. *J Sport Sci.* 2003;21:601-610.

16. Kraemer WJ, Bush JA, Newton RU, et al. Influence of a compression garment on repetitive power output before and after different types of muscle fatigue. *Sports Med, Training and Rehab.* 1998;8(2):163-184.

17. Michael JS, Dogramaci SN, Steel KA, Graham KS. What is the effect of compression garments on a balance task in female athletes? *Gait & Posture.* 2014;39(2):804-809.

18. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*. 2010;10: 67:67. http://www.biomedcentral.com/1471-2288/10/67. Accessed 20/1/2013.

19. Thabane L, Ma J, Chu R, et al. A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology*. 2010;10(1):1-10.

20. Orchard JW. Men at higher risk of groin injuries in elite team sports: a systematic review. *Br J Sports Med.* 2015;49(12):798-802.

21. Stuber KJ. Specificity, sensitivity, and predictive values of clinical tests of the sacroiliac joint: A systematic review of the literature. *The Journal of the Canadian Chiropractic Association.* 2007;51(1):30-44.

22. Vleeming A, Albert HB, Ostgaard HC, Sturesson B, Stuge B. European guidelines for the diagnosis and treatment of pelvic girdle pain. *European Spine Journal.* 2008;17(6):794-819.

23. Hagglund M, Walden M, Ekstrand J. Injuries among male and female elite footballers. *Scand J Med Sci Spor.* 2009;19(6):819-827.

24. Elliott SA, Brown JSL. What are we doing to wait list controls? *Behaviour Research &Therapy.* 2002;40(9):1047-1052.

25. Schulz KF, Grimes DA. Blinding in randomised trials: hiding who got what. *The Lancet.* 2002;359(9307):696-700.

26. Dempster M. *A Research Guide for Health and Clinical Psychology.* Palgrave Macmillan; 2011.

27. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Medicine.* 2010;8(18):1-9.

28. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics.* 2005;4:287-291.

29. Wood A, White I, Thompson S. Are missing outcome data adequately handled? A review of published randomized controlled trials in major medical journals. *Clin Trials.* 2004;1:368 - 376.

30. Kottink AIR, Oostendorp LJM, Buurke JH, Nene AV, Hermens HJ, Ijzerman MJ. The Orthotic Effect of Functional Electrical Stimulation on the Improvement of Walking in Stroke Patients with a Dropped Foot: A Systematic Review. *Artif Organs.* 2004;28(6):577-586.

31. Nevin F, Delahunt E. Adductor squeeze test values and hip joint range of motion in Gaelic football athletes with longstanding groin pain. *J Sci Med Sport.* 2014;17(2):155-159.

32. Malliaras P, Hogan A, Nawrocki A, Crossley K, Schache A. Hip flexibility and strength measures: reliability and association with athletic groin pain. *Br J Sports Med.* 2009;43(10):739-744.

33. Hanna CM, Fulcher ML, Raina Elley C, Moyes SA. Normative values of hip strength in adult male association football players assessed by handheld dynamometry. *J Sci Med Sport.* 2010;13:299-303.

34. Hölmich P, Hölmich LR, Berg AM. Clinical examination of athletes with groin pain: an intraobserver and interobserver reliability study. *Br J Sports Med.* 2004;38:446-451.

35. Mens JMA, Vleeming A, Schniders CJ, Stam HJ, Ginai AZ. The active straight leg raise test and mobility of the pelvic joints. *European Spine Journal.* 1999;8:468-473.

36. Palsson TS, Hirata RP, Graven-Nielsen T. Experimental pelvic pain impairs the performance during the active straight leg raise test and causes excessive muscle stabilization. *Clin J Pain.* 2015;31(7):642-651.

37. Jansen JA, Mens JM, Backx FJ, Stam HJ. Changes in abdominal muscle thickness measured by ultrasound are not associated with recovery in athletes with longstanding groin pain associated with resisted hip adduction. *Journal of Orthopaedic and Sports Physical Therapy.* 2009;39(10):724-732.

38. Markovic G, Dizdar D, Jukic I, Cardinale M. Reliability and factorial validity of squat and countermovement jump tests. *J Strength Cond Res.* 2004;18(3):551-555.

39. Almuzaini KS, Fleck SJ. Modification of the standing long jump test enhances ability to predict anaerobic performance. *J Strength Cond Res.* 2008;22(4):1265-1272.

40. Riemann B, Caggiano NA, Lephart SM. Examination of a clinical method of assessing postural control during a functional performance task. *J Sports Rehabil.* 1999;8:171-183.

41. Sawle L, Freeman J, Marsden J. Intra-rater reliability of the multiple single-leg hop-stabilization test and relationships with age, leg dominance and training. *Int J Sports Phys Ther.* 2017;12(2):190-198.

42. Velotta J, Weyer J, Ramirez A, Winstead J, Bahamonde R. Relationship between leg dominance tests and type of task. *Portugese Journal of Sports Sciences.* 2011;11(2):1035-1038.

43. Freeman JV, Julious SA. The analysis of categorical data. *Scope.* 2007;16(1):18-21.

44. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.

45. Cohen J. *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. Hillsdale: Lawrence Erlbaum Associates; 1988.

46. Gupta SK. Intention-to-treat concept: a review. *Perspect Clin Res.* 2011;2(3):109-112.
47. Streiner D, Geddes J. Intention to treat analysis in clinical trials when there are missing data. *Evidence Based Mental Health.* 2001;4(3):70-71.
48. Bhakta BB. Management of spasticity in stroke. *Brit Med Bull.* 2000;56(2):476-485.
49. Beales DJ, O'Sullivan PB, Briffa NK. The effects of manual pelvic compression on trunk motor control during an active straight leg raise in chronic pelvic girdle pain subjects. *Man Ther.* 2010;15(2):190-199.
50. Bernhardt T, Anderson GS. Influence of moderate prophylactic compression on sport performance. *J Strength Cond Res.* 2005;19(2):292-297.
51. Born DP, Holmberg HC, Goernert F, Sperlich B. A novel compression garment with adhesive silicone stripes improves repeated sprint performance - a multi-experimental approach on the underlying mechanisms. *BMC Sports Sci Med Rehabil.* 2014;6:21.
52. Mostert-Wentzel K, Swart JJ, Masenyetse LJ, et al. Effect of kinesio taping on explosive muscle power of gluteus maximus of male athletes: original research. *South African Journal of Sports Medicine.* 2012;24(3):75-80.
53. Hertel J, Miller JS, Denegar CR. Intratester and intertester reliability during the star excursion balance tests. *J Sport Rehabil.* 2000;9:104-116.
54. Kirk RE. *Experimental Design: Procedures for the Behavioral Sciences.* 2nd ed. Pacific Grove: Brooks/Cole; 1982.
55. Jung HS, Jeon HS, Oh DW, Kwon OY. Effect of the pelvic compression belt on the hip extensor activation patterns of sacroiliac joint pain patients during one-leg standing: a pilot study. *Man Ther.* 2013;18(2):143-148.
56. Whittaker JL, Small C, Maffey L, Emery CA. Risk factors for groin injury in sport: an updated systematic review. *Br J Sports Med.* 2015;49:803-809.

57. Venckunas T, Trinkunas E, Kamandulis S, Poderys J, Grunovas A, Brazaitis M. Effect of lower body compression garments on hemodynamics in response to running session. *Scientific World Journal.* 2014;353040:353040. http://www.hindawi.com/journals/tswj/2014/353040/. Accessed 15/2/2015.

58. Racinais S, Oksa J. Temperature and neuromuscular function. *Scand J Med Sci Spor.* 2010;20(s3):1-18.

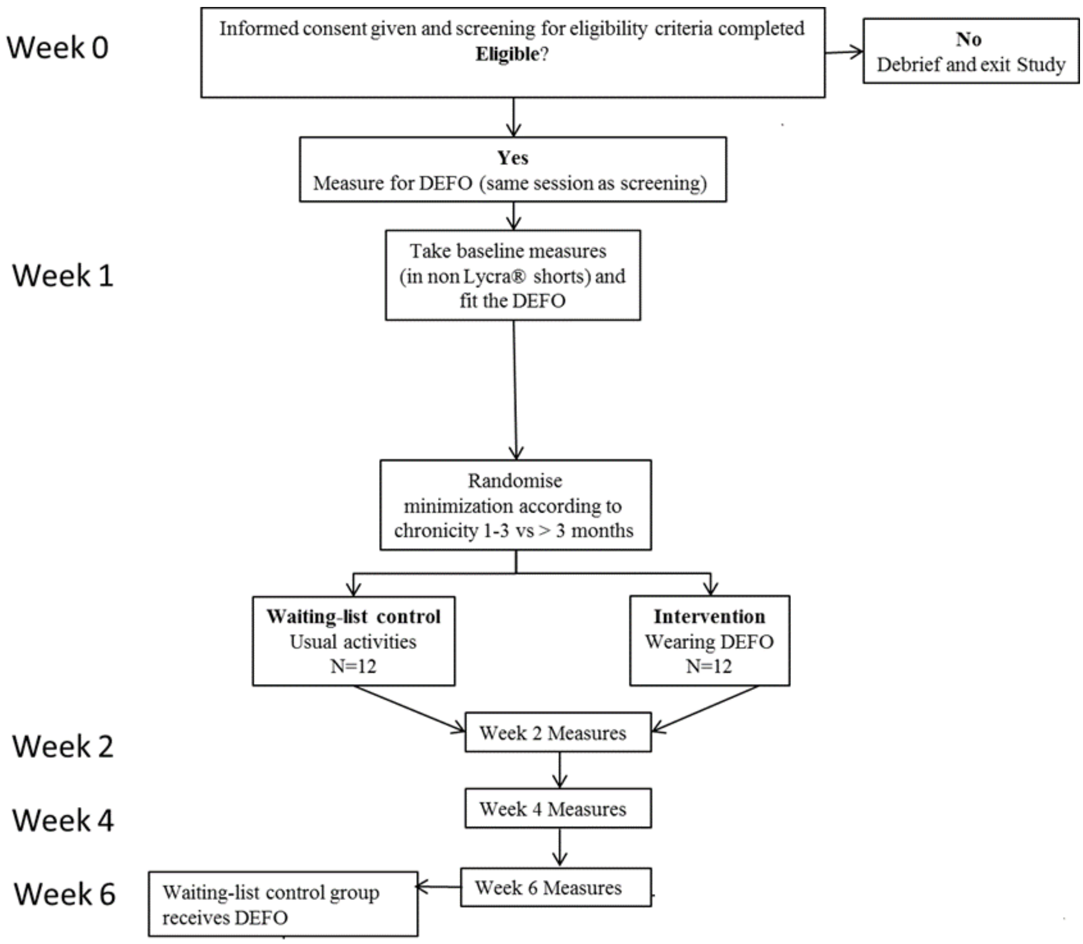

Figure 1 Athlete pathway through the study

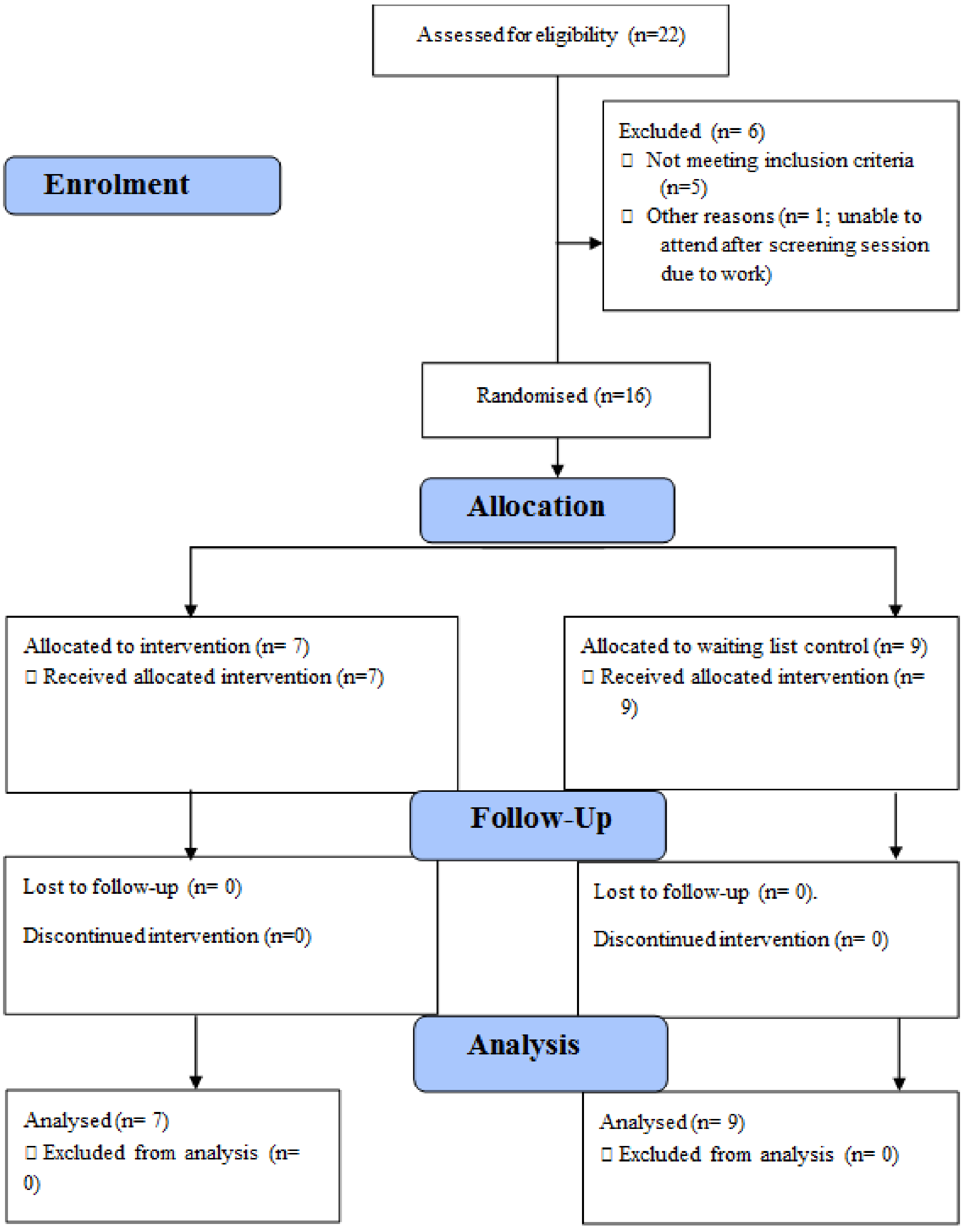

Figure 2 The CONSORT diagram showing the flow of participants through the study

	Waiting-List Control Group (n = 9)	**Intervention Group (n = 7)**
Gender	Male = 6	Male = 7
Leg Dominance	Right = 8	Right = 7
Mean Age in years +/-SD (range)	30.7 +/- 9.3 (22-48)	26 +/- 5.3 (23-36)
Mean Height in cm +/- SD (range	179 +/- 6.2 (167-190.5)	180 +/- 8 (164.8-186.5)
Mean Weight in kg +/- SD (range)	73.2 +/- 15 (56.4-93.4)	80.5 +/- 7.8 (66.2-88.7)

Table 1 Athlete demographics

	Week 2		Week 4		Week 6	
Outcome Measure	**Compression Orthosis Effect Size (d)**	**Sport Shorts Effect Size (d)**	**Compression Orthosis Effect Size (d)**	**Sport Shorts Effect Size (d)**	**Compression Orthosis Effect Size (d)**	**Sport Shorts Effect Size (d)**
Dominant Leg ASLR NRS Score	0.4	0.2	0.7^	0.4	0.6^	0.5^
Dominant Leg ASLR Score	0.7^	0.3	0.8 *	0.4	1.1*	0.7^
Non-Dominant Leg ASLR NRS Score	0.6^	0.8*	0.8*	0.6^	0.9*	0.8*
Non-Dominant Leg ASLR Score	0.7^	0.6^	0.2	0.6^	1.1*	0.8*
Squeeze Test Force (N)	- 0.1	0.0	0.8*	0.6^	0.8*	-0.5
Broad Jump Distance (cm)	0.1	-0.1	0.2	0.1	0.2	0.1
Dominant Leg MSLHST Score	- 0.1	0.1	0.2	0.5^	0.1	-0.4
Non-Dominant Leg MSLHST Score	0.1	-0.3	0.8*	0.7^	0.3	0.0

Table 2 The effect sizes (d) for each outcome measure at each stage of the study.

NRS refers to the numerical rating scale; MSLHST refers to the functional balance test

*Denotes a large effect size; ^ signifies a moderate effect size

	Intervention Group Mean Difference and 95% Confidence Intervals						Waiting-List Control Group Mean Difference and 95% Confidence Intervals		
	DEFO			Sport Shorts			Sport Shorts		
Measures	**Week Two**	**Week Four**	**Week Six**	**Week Two**	**Week Four**	**Week Six**	**Week Two**	**Week Four**	**Week Six**
Dominant Leg ASLR NRS Score	**1.1** -1.4 3.6	**1.3** -0.9 3.4	**1.2** -1.0 3.3	**0.8** -1.6 3.1	**1.0** -1.3 3.2	**1.1** -1.1 3.3	**0.4** -0.8 1.7	**0.3** -1.0 1.5	**0.2** -1.4 1.8
Dominant Leg ASLR Mens Score	**0.6** -0.4 1.7	**0.6** -0.4 1.7	**0.8** -0.1 1.7	**0.4** -0.7 1.4	**0.4** -0.8 1.5	**0.5** -0.4 1.4	**0.1** -0.5 0.7	**0.0** -0.8 0.7	**0.0** -0.6 0.7
Non-Dominant Leg ASLR NRS Score	**1.2** -1.2 3.5	**1.4** -0.8 3.6	**1.3** -1.0 3.5	**1.4** -0.8 3.6	**1.1** -1.1 3.3	**1.1** -1.0 3.3	**0.2** -1.0 1.3	**0.2** -0.8 1.3	**-0.3** -1.9 1.4
Non-Dominant Leg ASLR Mens Score	**0.5** -0.6 1.6	**0.1** -1.4 1.6	**0.7** -0.3 1.7	**0.4** -0.8 1.6	**0.4** -0.7 1.5	**0.4** -0.7 1.5	**-0.2** -0.9 0.6	**-0.1** -0.8 0.6	**-0.2** -1.1 0.6
Squeeze Test Force	**-5.6** -72.5 61.4	**43.6** -30.3 117.4	**86.8** 21.6 152.0	**-1.3** -73.1 70.5	**27** -47.9 101.8	**-0.8** -52.0 50.4	**0.7** -70.1 71.5	**-9.7** -78.1 58.7	**32.4** -42.8 107.6

Broad Jump Distance	**3.6** -36.1 43.2	**9.9** -29.4 49.1	**11.8** -26.1 49.7	**-4.4** -43.7 34.8	**5.8** -38.9 50.4	**9.2** -33.9 52.2	**0.0** -39.0 39.0	**2.3** -39.2 43.8	**4.0** -37.8 45.9
Dominant Leg MSLHST Error Score	**-1.5** -20.0 17.0	**0.9** -16.9 18.7	**10.9** -6.9 28.7	**2.5** -14.2 19.2	**6.2** -10.3 22.7	**3.1** -13.7 19.8	**1.2** -20.6 23.1	**-1.9** -18.8 25.4	**9.1** -11.2 29.3
Non-Dominant Leg MSLHST Error Score	**5.3** -10.1 20.7	**10.7** -4.3 25.7	**10.6** -4.3 25.4	**-2.3** -20.6 16.0	**9.0** -11.2 29.2	**6.6** -14.9 28.1	**3.3** -20.6 16.7	**-3.8** -25.2 17.5	**6.5** -11.7 24.7

Table 3. **The mean difference (in bold) and 95% confidence intervals for the mean difference, from baseline to assessment week two, four and six for each outcome measure and for each condition**

722