The feasibility, safety, and efficacy of lower limb garment-integrated blood flow restriction training in healthy adults

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ABSTRACT

Objectives: Explore the feasibility of lower-limb garment-integrated BFR-training.
Design: Observational study.
Setting: Human performance laboratory.
Participants: Healthy males with no experience of BFR-training.
Main outcome measures: Feasibility was determined by *a priori* thresholds for recruitment, adherence, and data collection. Safety was determined by measuring BFR torniquet pressure and the incidence of side effects. Efficacy was determined by measuring body anthropometry and knee isokinetic dynamometry. Feasibility and safety outcomes were reported descriptively or as a proportion with 95% confidence intervals (95% CI), with mean change, 95% CIs, and effect sizes for efficacy outcomes.
Results: Twelve participants (mean age 24.8 years [6.5]) were successfully recruited; 11 completed the study. 134/136 sessions were completed (adherence = 98.5%) and 100% of data were collected. There was one event of excessive pain during exercise (0.7%, 95% CI 0.0%, 4.0%), two events of excessive pain post-exercise (1.5%, 95% CI 0.4%, 5.5%), and one event of persistent paraesthesia post-exercise (0.7%, 95% CI 0.0%, 4.0%). Mean maximal BFR torniquet pressure was <200 mmHg. We observed an increase in knee extension peak torque (mean change 12.4 Nm), but no notable changes in body anthropometry.
Conclusions: Lower-limb garment-integrated BFR-training is feasible, has no signal of important harm, and could be used independently.

1. Introduction

Current application of blood flow restriction (BFR)-training involves the partial occlusion of limb vasculature using either a pneumatic cuff or simple tourniquet (e.g., rubber tubing) at the most proximal part of the limb being trained (Patterson et al., 2019; Scott et al., 2015). Most professionals advocate using a pneumatic cuff to standardise limb placement and achieve a defined percentage of arterial occlusion pressure (AOP), with between 40 and 80% advised (Patterson et al., 2019). The pressure required to achieve AOP will vary relative to cuff width, with smaller cuffs requiring higher pressure (Jessee et al., 2016). This is not a realistic expectation outside of a laboratory setting for the majority of BFR users, owing to the required supervision and expensive equipment (£350-£10,000). The need for a defined measurement of a percentage of AOP has recently been questioned, as comparable muscular responses in strength and hypertrophy are reported at varying levels of AOP (Clarkson et al., 2020; Counts et al., 2016). Ensuring the avoidance of total AOP remains an important safety consideration (Clarkson et al., 2020), and simple tourniquets do not allow for this or standardisation of limb placement (Loenneke & Pujol, 2009), making them potentially unsafe and less efficacious (Scott et al., 2015).

BFR-training has been reported as safe in many different populations, with a paucity of minor (muscle soreness) and serious (rhabdomyolysis, thrombosis) side-effects (Nakajima et al., 2006; Patterson et al., 2019). Garment-integrated BFR-training allows for consistent placement of a standardised width cuff and relies on user-defined subjective sub occlusive stimulus, which participants can reproducibly identify (Bell et al., 2018). It is inexpensive and can

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also be used without supervision, increasing its potential application in a variety of settings. Garment-integrated BFR-training has recently been reported as feasible and safe in the upper limb of healthy adults (Dhokia et al., 2022), but this is yet to be established in the lower limb.

Many people are unable to perform high-intensity resistance exercise for logistical and safety reasons, including load compromised individuals (e.g., those with knee osteoarthritis) or those unable to access gym facilities (Hughes et al., 2017). Low-intensity resistance exercise (~30% one-repetition maximum) facilitates muscle strength endurance rather than maximum strength (Kraemer & Ratamess, 2004), but can promote greater strength adaptations and hypertrophy than low-intensity resistance exercise in isolation when combined with BFR-training (Grønfeldt et al., 2020; Lixandrão et al., 2018). Low-intensity resistance exercise combined with BFR-training can also facilitate comparable levels of hypertrophy to high-intensity resistance exercise (~70% one-repetition maximum) (Loenneke & Pujol, 2009; Lowery et al., 2014; Takarada et al., 2000). BFR-training has previously been reported to facilitate hypertrophy and improve functional capacity in both healthy (Grønfeldt et al., 2020) and injured (Ladlow et al., 2018) populations, and six-weeks of upper limb garment-integrated BFR-training significantly increased push ups to volitional failure in healthy adults (Dhokia et al., 2022). The potential for garment-integrated BFR-training to facilitate strength and hypertrophy in the lower-limb is yet to be explored.

The primary aim of the study was therefore to explore the feasibility of garment-integrated BFR-training in the lower limb of healthy male adults. Secondary aims were to explore the safety and efficacy signals of garment-integrated BFR-training in the lower limb. We anticipated that lower limb garment-integrated BFR-training would be feasible and safe, and demonstrate efficacy signals, with findings that will help inform the design of future larger scale studies in healthy and clinical populations.

2. Methods

We conducted an observational feasibility and safety cohort study.

Ethical approval

The University of Essex ethics subcommittee one granted ethical approval (ETH2122-0167).

2.1. Participants

We recruited a convenience sample of male participants, with eligibility confirmed and informed consent provided prior to study commencement using a customised Qualtrics survey (Qualtrics, Seattle, USA). We sought 12 male participants in line with guidelines and previously published feasibility studies (Dhokia et al., 2022; Julious, 2005; Neal et al., 2018). Participants were eligible if they were aged ≥18, currently in good health, injury-free in their lower limbs, and willing to complete two BFR-training sessions per week for six-weeks. Participants were ineligible if they had a family history of any blood clotting disorder, deep vein thrombosis (DVT), pulmonary embolism (PE), previous surgery in the past six-weeks, a prior diagnosis of rhabdomyolysis, haemorrhagic or thrombotic stroke, or any prior experience with BFR-training.

We required participants to attend two separate data collection sessions, before and after six-weeks of BFR-training. Participants began their BFR-training period within seven days of their initial data collection session. The second visit took place within seven days of participants completing their BFR-training period. We

provided participants with an appropriately sized lower limb garment with integrated BFR (Hytro Limited, London, UK) that uses two standardised 5 cm elastane straps at the most proximal part of each thigh as a tourniquet. The strap is secured with a Velcro mechanism (YKK Fastening Corp, Tokyo, Japan; see Fig. 1) and allows for a standardised compression stimulus using a system of five levels in roman numerals (1/2/3/4/5; 1 = minimal compression, 5 = maximal compression) with a standardised distance of 2 cm between each level.

2.1.1. Demographics

Eligible participants self-reported their age (in years) and physical activity level using the Tegner scale; a reliable and valid measure that reflects the average physical activity levels of recruited participants by combining both work and sports activities (Barber-Westin & Noyes, 2010).

2.2. Feasibility outcomes

Feasibility outcomes were chosen with reference to recently published feasibility studies with comparable methodologies (Dhokia et al., 2022; Neal et al., 2018).

We defined successful recruitment *a priori* as a maximum of three months to recruit 12 participants.

We defined successful adherence *a priori* as a minimum of 80% of prescribed sessions completed by each participant.

We defined successful data collection *a priori* as a minimum of 80% data capture.

2.3. Safety outcomes

We determined safety by monitoring for evidence of important harm using the cumulative incidence of side effects that could indicate an adverse event (e.g., DVT or PE) during and after BFR-training (Dhokia et al., 2022). To provide more insight into factors potentially affecting safety outcomes, and better interpret any incidence of side effects, we also measured the mean pressure exerted on the limb by each BFR strap setting prior to BFR-training commencement. We set an *a priori* ceiling of 200 mmHg to reflect the common pressures used in existing BFR studies with 5 cm cuff widths (Loenneke et al., 2012).

2.3.1. BFR strap pressure

We initially measured the pressure exerted (mmHg) by the integrated BFR strap at each level. We collected these data, and subsequent efficacy outcome data for the dominant limb only, defined as the limb that participants would use to kick a ball (Neal et al., 2018). In an incremental order and beginning with the lowest level, external strap pressure was recorded by placing an air bladder between the garment and the lateral aspect of a

Fig. 1. Garment-integrated BFR with Velcro mechanism.

participant's thigh, directly underneath the strap. An air-pressure transducer (Kikuhime, Meditrade, Soro, Denmark) was attached to a 30 × 38 mm oval bladder, made from 3 mm polyurethane foam, and connected to the transducer via silicone tubing, which has a 1% coefficient of variation (Partsch & Mosti, 2010). Participants stood upright with feet shoulder width apart during all measurements. For each pressure level (1–5), three repeated measures were obtained at 1-min intervals and a mean calculated.

Participants were subsequently asked to pull the BFR strap as tight as possible with the assistance of a researcher, which reflected maximal compression stimulus and 10/10 on a perceived compression rating scale (Dhokia et al., 2022). We then asked participants to release their BFR strap to a self-perceived 70% compression stimulus (7/10 on a perceived compression rating scale), previously reported to be a reliable method for identifying sub occlusive pressures (Bell et al., 2018). Participants were then informed that this was the desired compression stimulus for their initial BFR-training session, which they could also subsequently identify by using the numerical scale on the garment.

2.3.2. Questionnaire

We instructed participants to record and report any post-exercise response that was atypical for them that could reflect thrombosis, ischaemia, or rhabdomyolysis (Table 1) (Brandner et al., 2018). Participants completed a safety questionnaire after each BFR-training session and attended a weekly virtual meeting with a research assistant to report any side effects that occurred during the preceding week. We also instructed participants to report anything of immediate concern to the primary investigator via email or telephone.

2.4. Efficacy signal outcomes

2.4.1. Body composition

Height and body mass (Seca, model 770, Germany), measured with participants dressed in light sports clothing with shoes removed, were used to calculate body mass index (BMI). Thigh girth was measured according to the International Society for the Advancement of Kinanthropometry guidelines (Norton, 2019) and high inter-rater reliability (intraclass correlation coefficient [ICC] = 0.99; standard error of measure [SEM] = 0.49 cm) has previously been reported (Whitney et al., 1995).

Body composition was assessed using whole-body dual-energy x-ray absorptiometry (DEXA) scans (Hologic Horizon W, Hologic Inc., Marlborough, MA, USA), using the Hologic APEX software version 5.6.0.5. Participants were instructed to eat normally on the day of their scan but were provided the opportunity to void their bladder prior to their scan, and wore underwear with a provided hospital gown. Participants were positioned in supine along the mid-line of the DEXA table, their arms by their side and palms facing down, with the legs shoulder width apart and internally rotated, and the feet taped together at the metatarsophalangeal joint to maintain a fixed position throughout the duration of the

scan (Bilsborough et al., 2014). A single DEXA operator who conducted all scans manually corrected the automated separation of body regions, ensuring that the arms were separated at the acromio-humeral joints and the legs were separated at the pelvic-femoral joints (Nana et al., 2015) The DEXA scanner was stable on daily phantom quality assessment (coefficients of variation = 0.22%). Analysis of the DEXA scans were used to quantify whole body fat mass (kg), lean mass (kg) and leg (left + right leg combined) fat mass and lean mass. Precision error was previously determined at the host institution. Root mean square coefficient of variance and least significant change (LSC) for repeat measurement (n = 23) at the 95% confidence interval was 0.94% and 1.44 kg, respectively, for total lean tissue mass, 1.83% and 1.21 kg, for total fat mass, 3.76% and 1.73 kg for leg lean mass, and 4.68% and 1.22 kg for leg fat mass.

2.4.2. Knee muscle strength

Data were collected with a Biodex System 4 isokinetic dynamometer (Biodex, Shirley, New York) at 100 Hz. The dynamometer was calibrated as per the manufacturer's procedures prior to data collection. Participants were seated on the dynamometer, the popliteal fossa approximately 5 cm off the edge of the chair, the lateral epicondyle of the dominant knee aligned with the lever-arm axis-of-rotation, and the nondominant limb hanging freely. The torso, pelvis, and dominant limb were secured using straps. The dynamometer's knee attachment was adjusted so the lower edge of the shank strap was just above the proximal margin of the medial malleolus.

Sagittal plane range-of-motion limits were set to allow 90-0° extension-flexion range-of-motion. The knees' 0° position (anatomical position, extension range-of-motion limit) was determined with visual estimation, which is reliable for experienced practitioners (Hancock et al., 2018). Next, the 90° flexion range-of-motion limit was set using the dynamometer's digital goniometer. The limb was weighed, and participants instructed to extend and flex the knee with no resistance to ensure correct participant-dynamometer configuration. Thigh strap tension was checked to ensure it was not restricting quadriceps girth expansion during knee extension. Velocity of assessment was set at $60° \cdot sec^{-1}$. Reciprocal extension-flexion concentric-concentric muscle actions were sampled. The range-of-motion, velocity, and muscle action parameters were chosen to be consistent with common procedures for knee isokinetic dynamometry with uninjured participants (Calmels et al., 1997; Sakuraba & Ishikawa, 2009).

Participants performed two warm up trials for familiarisation consisting of five sub-maximal repetitions at 50% perceived maximum voluntary effort (MVE), a 2-min recovery, followed by five repetitions at 100% MVE. Participants were then provided with 2-min rest, given a "3, 2, 1, Go!" countdown, before performing five reciprocal extension-flexion measured trials at 100% MVE. Participants were permitted to hold the dynamometer handles and strong verbal encouragement was provided. Data were gravity corrected automatically by the dynamometer's software (Biodex Advantage Software, Biodex, Shirley, New York). Immediately after the measured trials, the graphical output of the isokinetic curve was visually inspected for any aberrancy and the text file output was reviewed to verify that participants achieved a minimum range-of-motion of 85-5° knee flexion/extension and a maximum velocity of at least $55° \cdot sec^{-1}$ for each extension-flexion cycle (Clark et al., 2022). If graphical or text file outputs were unsatisfactory, the procedure was discarded, the participant given 2-min rest, and a new procedure performed. Data were windowed to ensure peak torque (PT) values (Newton-metres [Nm]) were extracted from constant-velocity portions of an assessment (Baltzopoulos et al., 2012). Reliability for knee extension-flexion isokinetic peak

Table 1
Side effects monitored for the duration of the BFR-training programme.

SIDE EFFECTS DURING EXERCISE	SIDE EFFECTS POST EXERCISE
Excessive pain (subjective severity)	Excessive pain (subjective severity)
Chafing/abrasions	Shortness of breath
Bruising/pressure marks	Whole limb swelling
	Chafing/abrasions
	Bruising/pressure marks
	Persistent paraesthesia/tingling
	Anaesthesia/loss of sensation

torque has been reported (ICC = 0.97, SEM = 4.8–4.9%) (Pincivero et al., 1997). Absolute PT (Nm) and normalised PT (Nm/kg = absolute peak torque [Nm] ÷ body mass [kg]) values were used for analyses.

2.5. BFR-training programme

We instructed participants to follow a six-week lower limb BFR-training programme of two sessions per week and twelve sessions in total. Each BFR-training session involved three exercises; body weight squats, glute bridges, and calf raises, selected as low load exercises that participants could complete independently without the need for specialist facilities or equipment. We instructed participants to adhere to a previously published protocol (Patterson et al., 2019); completing four sets of each exercise (maximum 30/15/15/15 repetitions), with a 30-s rest interval between sets and a 2 min rest interval between exercises. We instructed participants to apply their BFR straps to both thighs prior to commencing an exercise, keeping them secured for all four sets (i.e., maximum 75 repetitions), before releasing at the start of the 2-min rest interval between exercises to allow for reperfusion (Patterson et al., 2019). If participants reached volitional failure prior to the prescribed number of repetitions in a set, we instructed them to record their number of successful repetitions. Participants were instructed to tighten their BFR straps to a perceived compression stimulus of 70% (7/10 on a numerical rating scale) for their initial session and could progress to higher perceived compression stimulus over the remainder of the sessions if tolerable.

2.6. Statistical analysis

We collated data using a customised spreadsheet (Microsoft Excel, Microsoft, Washington, USA). We calculated the cumulative incidence (%) of side effects by dividing the number of events by the total number of completed BFR-training sessions multiplied by 100. We calculated cumulative session adherence (%) by dividing the number of completed sessions by the total number of prescribed sessions multiplied by 100.

We did not perform dependent sample t-tests or calculate p-values because of the potential for type II error and to avoid giving the impression of robust findings from a feasibility design. For DEXA measures, mean change between pre and post values were compared with the LSC at 95% confidence to establish whether changes can be attributed to the participant or the machine noise. For isokinetic data, baseline normalised PT was calculated using body mass at the baseline timepoint and follow up normalised PT was calculated using body mass at the follow up time point. We used Shapiro-wilk to determine if secondary efficacy outcome data (follow up − baseline) were normally distributed; calculating mean change, associated standard deviation (SD), and 95% CI (Tomczak & Tomczak, 2014). We also calculated effect sizes using Hedges' *g* owing to our sample of < 20; interpreted as trivial (<0.2), small (0.2–0.49), medium, (0.5–0.79) and large (≥0.8) (Tomczak & Tomczak, 2014). All efficacy data analyses were undertaken in SPSS 27 (IBM Corporation, Armonk, New York). Slope graphs were produced using the Estimation Stats application (https://www.estimationstats.com) and were estimated using five thousand bootstrap samples (Ho et al., 2019).

3. Results

3.1. Participants

We recruited 12 participants and 11 (91.7%) completed the study (Table 2). One participant withdrew because of a posterior cruciate ligament injury sustained during an incident unrelated to the BFR-training protocol. This participant completed 4/12 (33.3%) pre-scribed BFR-training sessions and is therefore included in our feasibility and safety analyses, but not our efficacy analyses. Cohort descriptive data are presented in table two. Ten participants were right-leg dominant, and two participants were left leg dominant.

3.2. Feasibility outcomes

3.2.1. Recruitment

We successfully recruited and enrolled 12 participants in 39 days (i.e., <3 months), commencing on January 17, 2022 and ceasing on February 25, 2022.

3.2.2. Adherence

134/136 sessions were successfully completed (98.5%, 95% CI 94.8%, 99.6%). Two individual participants each missed a single session.

3.2.3. Data collection

Full data sets were collected from 11/11 participants (100.0%, 95% CI 74.1%, 100.0%).

3.3. Safety outcomes

3.3.1. Side effects

One participant reported a single event of excessive pain during exercise (0.7%, 95% CI 0.1%, 4.0%). One participant reported two events of bruising/pressure marks post-exercise (1.5%, 95% CI 0.4%, 5.5%). One participant reported a single event of persistent paraesthesia post-exercise (0.7%, 95% CI 0.1%, 4.0%). No other side effects were reported, and no participant went on to experience an adverse event.

3.3.2. BFR strap pressure

The mean exerted pressure for each strap setting is presented in Table 3. The maximum mean pressure exerted was 178.2 ± 12.5 mmHg, achieved at strap setting five.

3.4. Efficacy signal outcomes

3.4.1. Body composition (Fig. 2a–d)

From baseline to follow up, mean body mass, mean whole body fat mass, and mean whole body lean mass all increased with effect sizes that were trivial (Table 4). Mean leg fat mass and mean leg lean mass both decreased with effect sizes that were trivial (Table 4).

3.4.2. Knee muscle strength (Fig. 3a–d)

From baseline to follow up, mean knee extension peak torque and mean knee flexion peak torque both increased with effect sizes that were small and trivial, respectively (Table 4). Mean knee extension normalised peak torque increased with a small effect size whilst mean knee flexion normalised peak torque was virtually unchanged with a trivial effect size (Table 4).

4. Discussion

This study aimed to explore the feasibility, safety, and efficacy of garment-integrated BFR-training in the lower limb of healthy male adults. Consistent with our expectations, we identified garment-integrated BFR-training to be feasible, with no evidence of important harm, and led to an increase in knee extension peak torque and normalised peak torque.

Table 2
Baseline descriptive data (n = 12).

	Age (yr)	Height (cm)	Body mass (kg)	BMI (kg/m^2)	Thigh girth (cm)	Tegner scale
Mean (SD)	24.8 (6.5)	178.7 (7.2)	81.0 (9.8)	25.4 (2.5)	57.2 (4.3)	7.3 (1.9)

yr = years; cm = centimetres; kg = kilograms; BMI = body mass index; kg/m^2 = kilograms per square metre; SD = standard deviation.

Table 3
BFR strap pressure data (n = 12).

Strap setting				
1	2	3	4	5
Mean (SD; mmHg)				
60.4 (9.6)	81.9 (14.4)	118.9 (11.2)	158.0 (14.0)	178.2 (12.5)

SD = standard deviation, mmHg = millimetres of mercury.

Table 4
Mean change, 95% CIs and effect sizes for efficacy data (n = 11).

	Pre mean (SD)	Post mean (SD)	Mean change (SD)	Mean change 95% CI	Effect size
Body mass (kg)	80.9 (10.2)	81.5 (10.2)	0.6 (1.6)	−1.68, 0.43	0.06
Whole body fat mass (kg)	20.3 (2.7)	20.5 (1.9)	0.1 (1.2)	−0.69, 0.94	0.09
Whole body lean mass (kg)	58.6 (7.9)	59.1 (8.5)	0.5 (1.0)	−0.16, 1.22	0.06
Leg fat mass (kg)	7.5 (1.0)	7.3 (5.2)	−0.2 (0.5)	−0.54, 0.14	−0.05
Leg lean mass (kg)	20.3 (3.0)	20.0 (3.0)	−0.3 (0.6)	−0.68, 0.10	−0.10
Knee extension peak torque (Nm)	243.1 (45.6)	255.5 (50.6)	12.4 (18.1)	0.19, 24.5	0.26
Knee extension normalised peak torque (Nm/kg)	3.0 (0.3)	3.1 (0.3)	0.1 (0.2)	−0.27, 0.04	0.33
Knee flexion peak torque (Nm)	125.8 (30.0)	126.9 (31.2)	1.2 (13.1)	−9.93, 7.63	0.04
Knee flexion normalised peak torque (Nm/kg)	1.5 (0.2)	1.5 (0.2)	0.0 (0.1)	−0.09, 0.09	0.00

kg = kilograms; Nm = Newton meters; Nm/kg = Newton meters per kilogram of body mass; SD = standard deviation; CI = confidence interval.
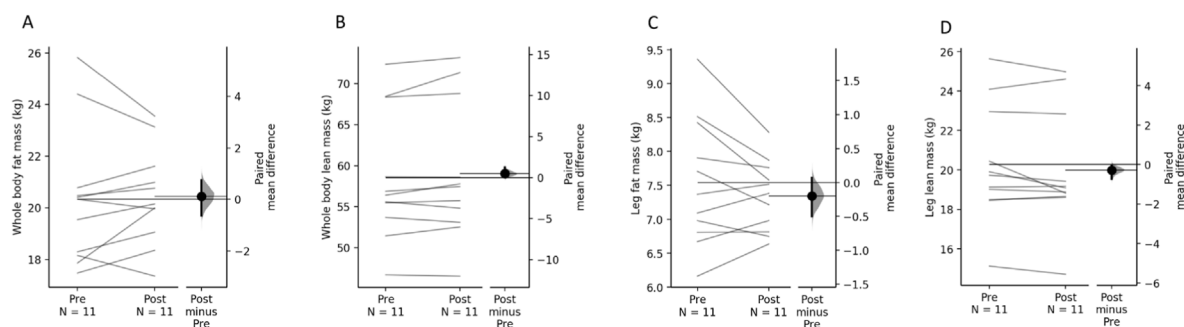

Fig. 2. Paired mean difference plots for body composition outcomes. Fig. 2. The paired mean difference between pre and post, (A) whole body fat mass, (B) whole body lean mass, (C) leg fat mass and (D) leg lean mass, is shown in the above Gardner-Altman estimation plot. Both groups are plotted on the left axes as a slopegraph and each paired set of observations is connected by a line. The paired mean difference is plotted on a floating axes on the right as a bootstrap sampling distribution. The mean difference is depicted as a dot; the 95% confidence interval is indicated by the ends of the vertical error bar.
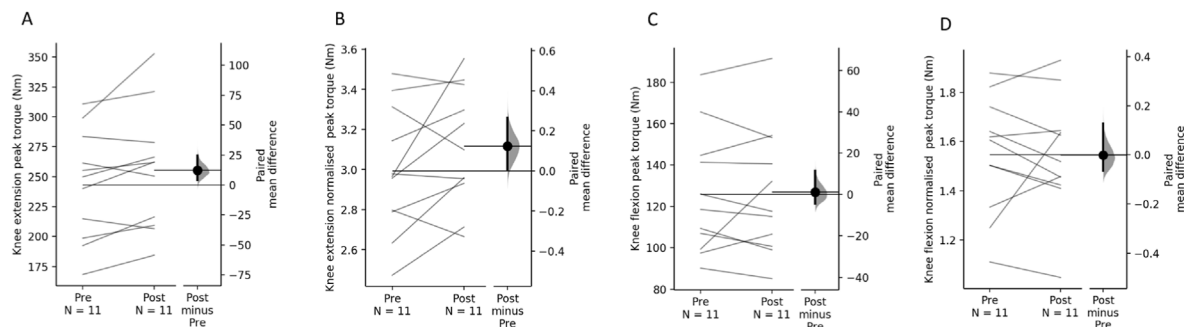

Fig. 3. Paired mean difference plots for knee muscle strength outcomes. Fig. 3. The paired mean difference between pre and post, (A) knee extension peak torque, (B) knee extension normalised peak torque, (C) knee flexion peak torque and (D) knee flexion normalised peak torque, is shown in the above Gardner-Altman estimation plot. Both groups are plotted on the left axes as a slopegraph and each paired set of observations is connected by a line. The paired mean difference is plotted on a floating axes on the right as a bootstrap sampling distribution. The mean difference is depicted as a dot; the 95% confidence interval is indicated by the ends of the vertical error bar.

4.1. Feasibility

We satisfied all three of our *a priori* defined feasibility outcomes. We recruited the minimum number of required participants within three months and obtained complete data sets from them all. The participant who failed to complete the study did so because of a traumatic knee injury sustained playing a contact sport, leading to his withdrawal. Adherence to the garment-integrated BFR protocol used was high (98.5%); comparable to the adherence rate reported in our recent upper limb garment-integrated BFR study (Dhokia et al., 2022), and by other BFR-training feasibility studies in clinical populations (Jonsson et al., 2021). The two missed sessions by independent participants were explained by illness (SARS-CoV-2) and fatigue (post-unrelated exercise), respectively. We are confident that garment-integrated BFR-training for the lower limb can be scaled up and investigated using a randomised controlled trial involving laboratory collected data.

4.2. Safety

We identified no signal of important harm when applying garment-integrated BFR-training to the lower limb of healthy adult males. The cumulative incidence of side effects during and after BFR-training was low and mean maximal BFR strap pressure was below our *a priori* defined ceiling of 200 mmHg (Table 3). One participant reported excessive muscle soreness during exercise. Muscle soreness during and after low load resistance exercise combined with BFR-training is common (Patterson et al., 2019) and may persist for up to 72 h (Brandner et al., 2018). The single event of persistent paraesthesia post-exercise lasted for 25 min only and did not reoccur but could be explained by narrower cuff widths leading to greater discomfort in some users (Estebe et al., 2000). Nerve conduction velocity has previously been reported to be unaffected by four weeks of low intensity resistance exercise combined with BFR-training (Loenneke et al., 2011). Bruising was reported as a side effect by 13% of BFR practitioners in a recent worldwide survey (Patterson & Brandner, 2018). The two events of pressure marks reported by a single participant lasted for 1 h only and occurred in the first two weeks of the programme; reflecting a normal response to wearing a compression garment (Sanders et al., 1995).

A maximum of 80% AOP is advocated when combining BFR-training with resistance exercise to minimise the potential for more serious side effects (Patterson et al., 2019). Whilst the pressure required to achieve total arterial occlusion will vary by limb size and cuff width (Jessee et al., 2016), a mean pressure of 241.5 mmHg was recently reported to fully occlude the lower limb in standing with an 11.5 cm cuff (Hughes et al., 2018). We defined an *a priori* ceiling of 200 mmHg based on previous studies using 5 cm cuffs (Loenneke et al., 2012), with our mean maximal exerted pressure falling comfortably below this. One participant exceeded this ceiling (211.0 mmHg), but upon reflection they were placed in an incorrectly sized garment (thigh girth = 56.7 cm; garment size = small), as participants with similar thigh girths were placed in medium garments and achieved lower mean maximal pressures. We are therefore confident that garment-integrated BFR-training for the lower limb has no signal of important harm and could be used without supervision. Maximal cuff pressures are unlikely to exceed 80% AOP when the garment is sized correctly.

4.3. Efficacy signals

No change in whole body nor lower limb body composition was observed in the current study. Mean change in whole body and lower limb measures were below the LSC for all DEXA derived results, indicating that any small changes are likely attributable to

chance. It is plausible that the BFR-training duration (twelve sessions across six weeks) and exercise stimulus was insufficient to augment body composition changes beyond the required LSC. In support of this, eight weeks of whole body BFR-training, comprised of upper and lower body BFR-training (total of 20 sessions) produced an increase in whole body, arm and leg lean mass in healthy adults obtained via DEXA (Brandner et al., 2019). With feasibility established, future research should look to investigate the efficacy of lower-body garment-integrated BFR-training in an adequately powered trial with an appropriate control, study duration and AOP monitored throughout to adhere to guidelines of <80% (Patterson et al., 2019).

Mean knee extension peak torque increased by 12.4 Nm (Table 4) from baseline to follow up. Given the reported SEM for isokinetic knee extension peak torque is 4.8% (Pincivero et al., 1997), which equates to a mean of 12.3 Nm for our post-training mean knee extension peak torque data (Table 4), the mean increase of 12.4 Nm may not be genuine despite the apparent pre-to post-training small effect size (Table 4). The same consideration applies to the findings for the mean change of knee extension normalised peak torque because its calculation requires the peak torque as the numerator. This could be explained by the BFR-training stimulus used in this study being too low to result in meaningful changes in strength. As evidenced by the lower bound of the 95% CIs (Table 4), some participants' knee extension and knee flexion normalised peak torque values decreased during the study. Both the lower effect size and the negative signs for the lower bounds of the 95% CIs for the normalised peak torque data occurred because some participants' body mass increased during the study whilst others decreased; this is evidenced by the 95% CIs for the body mass mean change being above and below zero, respectively (Table 4). Researchers should therefore consider with care whether non-normalised or normalised values are used for analysis of any change in knee muscle strength following BFR-training.

4.4. Interpretation

A priori thresholds for recruitment, adherence, and data collection were all met, meaning that a future larger scale trial is feasible. We did not investigate the feasibility of randomisation in this study, and a future trial should have appropriate stop/go criteria should initial randomisation prove infeasible. Garment-integrated BFR-training demonstrated no signal of important harm in the lower limb of healthy male adults, and it is plausible that this outcome is generalisable to wider populations. Future trials should confirm this ahead of commencement if investigating a different population (e.g., young healthy females, older adults).

4.5. Limitations

We did not include a control group in our study as this was not part of our aim, but it is therefore impossible to discern if any observed effects are the direct result of BFR-training. We did not control for the intensity of the completed BFR-training protocol, and it may be that the training protocol, completed intensity, or training duration was insufficient for a group of young healthy males to achieve changes in body composition or muscle strength. We did not determine an individualised limb occlusion pressure for each participant, and instead interpreted the maximum pressure achieved by the garment for each participant relative to an *a priori* threshold of 200 mmHg. We did not control for dietary intake prior to DEXA scanning and follow up scans may have taken place at a different time of day to the baseline scans, which may account for the absence of change in body composition.

5. Conclusions

Garment-integrated BFR-training is feasible in the lower limb of healthy males and could proceed to a future trial with stop/go criteria for randomisation and can be combined with low load resistance exercise using existing BFR-training protocols. There was no signal of important harm in the investigated young and healthy male cohort, and exerted strap pressures are likely to fall below 80% AOP, making independent use possible. The efficacy of garment-integrated BFR-training and its equivalence or superiority to existing BFR-training methods requires confirming in future adequately powered trials.

Ethical approval

Ethical approval was sought and subsequently granted by University of Essex ethics subcommittee one (ETH2122-0167).

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Declaration of competing interest

Dr Warren J. Bradley is the chief technical officer of Hytro Ltd. All other authors have no competing interests to declare.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ptsp.2023.01.006.

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