

The Safety, Feasibility, and Efficacy of Upper Limb Garment-integrated Blood Flow Restriction Training in Healthy Adults

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Research

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Abstract

Background

Blood flow restriction training (BFR) has been demonstrated to increase muscle hypertrophy and strength, but has logistical and cost barriers. Garment-integrated BFR has the potential to reduce these barriers, by lowering equipment demands and cost at point of access. The primary aim of the study was to explore the safety and feasibility of garment-integrated BFR in the upper limb of healthy adults, with a secondary aim of exploring efficacy.

Methods

Participants who were active, otherwise healthy and had no previous experience with BFR, were sought. Eligible participants completed a five-week garment-integrated BFR programme that involved completing two sessions per week. Safety was determined by recording adverse events and by monitoring arterial occlusion pressure using a pulse oximeter. Feasibility was determined by measuring recruitment, adherence to the garment-integrated BFR programme and data collection. Efficacy was determined by measuring push-ups to volitional failure, arm girth, and number of prescribed repetitions completed. Adverse events were counted and reported as a percentage of the cohort. Adherence was calculated as a percentage of successfully completed sessions of the prescribed total. Mean change, 95% confidence intervals and associated effect sizes were calculated for efficacy outcomes.

Results

28 participants were included and 27 successfully completed the study. Minimal adverse events were reported; one incident of localised bruising (0.36%) and three incidences of excessive pain during and post-exercise from two separate participants (1.07%). 3.7% of pulse oximeter readings were not recorded (82/2240). 278/280 sessions were successfully completed (adherence=99.3%). Mean push-ups to volitional failure increased by 40% (mean change=8.0, 95% CI 5.7, 10.3, $d=1.40$). Mean arm girth and mean number of prescribed repetitions completed were unchanged.

Conclusions

Garment integrated BFR is a safe and feasible option in the upper limb of healthy adults, with a secondary increase in push-ups to volitional failure also observed. Further studies are required to determine the efficacy of garment integrated BFR compared to other training methods, and the use of garment integrated BFR in other populations.

Key Messages Regarding Feasibility

1. It was uncertain if garment-integrated blood flow restriction training (BFR) could be safely applied and if participants would be adherent to its use.
2. Garment-integrated BFR was found to be safe and feasible, with participants adherent to its use.

3. Garment-integrated BFR can now be safely applied in a randomised controlled trial design to determine its efficacy when compared to either a wait and see control, or another form of BFR.

Background

Blood flow restriction (BFR) training originated in Japan and is known as “kaatsu” training, which translates as “added pressure” (1). BFR involves partial occlusion of limb vasculature using a tourniquet or cuff, positioned at the most proximal part of the limb being trained (2). Low-intensity exercise (~30% one-repetition maximum) in isolation facilitates muscle endurance rather than strength (3), but when combined with BFR, promotes greater strength adaptations and hypertrophy (4). Low-intensity exercise combined with BFR can facilitate comparable levels of hypertrophy and human growth hormone plasma concentration to high-intensity exercise (~70% one-repetition maximum; 5–7). It is hypothesised that partial occlusion of the vasculature may cause an acute muscle swelling response via an extracellular fluid shift, resulting in the activation of the rapamycin (mTOR) signalling pathway and stimulation of an anabolic response in muscle tissue (8–10).

The safe application of BFR has been reported in many different populations, with a paucity of minor and serious side-effects (11). Many individuals are unable to perform high-intensity exercise for variable logistical and safety reasons. BFR has previously been reported to facilitate hypertrophy and improve functional capacity in both healthy (12) and injured (13) populations. Current application of BFR training involves either the use of a pneumatic cuff or a simple tourniquet (e.g., rubber tubing). Pneumatic cuffs allow for standardisation of occlusion pressure and limb placement but are expensive (£350-£10,000) and require supervision for successful use, limiting their wider application. Simple tourniquets can be unsafe as they do not allow for standardisation of limb placement or the reproducible determination of partial (rather than total) occlusion pressure (14).

BFR is generally used by trained professionals with specialist equipment to accurately regulate applied occlusion pressures. Most research to date uses a defined percentage of total arterial occlusion pressure, which is not reflective of the practical application of BFR training (15). Comparable muscular responses in strength and hypertrophy are reported at varying levels of occlusion pressure (16), which questions the need for defined measurement of percentage of total arterial occlusion pressure outside of assuring partial (rather than total) occlusion pressure. Garment-integrated BFR has been developed to provide an inexpensive and safe method of BFR application. This allows for consistent placement of an integrated strap of a standardised width and the subjective but reproducible determination of occlusion pressure (17). Garment-integrated BFR can also be used without the supervision of a qualified professional, increasing the potential application in a variety of settings.

The primary aim of the study was therefore to explore the safety and feasibility of garment-integrated BFR in the upper limb of healthy adults, to inform upon future larger scale studies. A secondary aim was to explore the efficacy of garment-integrated BFR. The null hypothesis was that garment-integrated BFR of the upper limb would be unsafe and infeasible in healthy adults.

Methods

An observational safety and feasibility cohort study was conducted.

Ethical approval

Ethical approval was granted by the Queen Mary Ethics of Research Committee (QMREC2018/48/054).

Participants

Participants were recruited as a sample of convenience and provided written informed consent prior to study commencement using Google Forms (Google LLC, California, USA). Sample size was based on previous guidelines for safety and feasibility studies (18), with a minimum of 12 male and 12 female participants sought. Participants were eligible for inclusion if they were over the age of 18 and currently in good health, injury-free in their upper limbs and willing to perform two BFR sessions per week and cease other forms of upper limb exercise for the study duration. Participants were excluded if they had any history of deep vein thrombosis (DVT) or pulmonary embolism (PE), a previous diagnosis of rhabdomyolysis, haemorrhagic or thrombotic stroke, previous surgery in the past six weeks, were currently or recently pregnant, or had a family history of any blood clotting disorder. Participants were also excluded if they had any prior experience with BFR.

Demographics

Eligible participants self-reported their age (in years), height (to the nearest cm), mass (to the nearest kg) and activity level using the Tegner scale. Combining both work and sports activities, the Tegner scale is a reliable and valid measure to reflect the average activity levels of recruited participants (19).

Experimental protocol

The study was conducted online using Microsoft Teams (1.400.11161, Microsoft, Washington, USA) due to the SARS-CoV-2 pandemic. All included participants followed a five-week upper limb BFR programme consisting of two sessions per week and a total of ten sessions and were advised to avoid other forms of upper limb exercise for the duration of the study. Participants were provided with a garment with integrated BFR (Hytro Limited, London, UK). This uses a standardised elastane strap (width 4cm) located at the most proximal part of the upper limb and secured with a Velcro mechanism (YKK Fastening Corp, Tokyo, Japan; see figure 1) to allow for standardisation of compression stimulus. Participants were also provided with a standardised resistance band (male=red [tension 7-16kgs] and female=yellow [tension 2-9kgs]), a flexible tape measure, and a pulse oximeter (NHS Pulse Oximeter, London, UK). Participants had an initial familiarisation meeting with a researcher (BD or EM), where they were introduced to the BFR programme and protocol. Participants were then instructed to pull the BFR strap on their dominant arm to its maximal position (reflecting 100% compression stimulus), before releasing to a perceived 50% compression stimulus, noting the corresponding number on the Velcro mechanism. Participants then underwent a three-minute passive BFR session at 50% compression stimulus to familiarise them to the

sensation of BFR, before releasing. Participants finally completed four sets of a single exercise (banded bicep curls) at 50% compression stimulus, resting for 30 seconds in between sets and taking a pulse oximeter reading before and after the exercise was completed with compression applied for familiarisation.

BFR programme

Each BFR session involved four exercises (push-ups, banded bent over rows, banded triceps extensions, and banded bicep curls). Male participants were instructed to complete full push-ups, whilst female participants were instructed to complete kneeling push-ups. Participants were required to complete four sets of each exercise (30/15/15/15 repetitions), taking a 30 second rest interval between sets and a two minute rest interval between exercises (1). If participants reached volitional failure prior to the prescribed number of repetitions in a set, they were asked to record their number of successful repetitions. Participants were instructed to tighten the BFR strap to a perceived compression stimulus of 50% for their first session and increase to 60% for their second session as a familiarisation week. Participants were then instructed to increase to a perceived compression stimulus of 70% for the remaining eight sessions (weeks two-five). The BFR strap was to be applied prior to commencing an exercise and remain secured for all four sets (i.e., 75 repetitions), releasing at the start of the two-minute rest interval between exercises.

Safety outcomes

Safety was determined by recording the occurrence of adverse events during and after BFR and by monitoring for potential arterial occlusive limb pressure using pulse oximetry.

Questionnaire

Potential adverse events that could reflect thrombosis or ischaemia (20) were monitored (see table 1). Participants were instructed to report the occurrence of these events by completing a safety questionnaire after each BFR session and attend a weekly virtual meeting with a researcher (BD/EM) to discuss any adverse events that may have occurred during the preceding week.

Table 1: adverse events monitored for the duration of the BFR programme

Adverse events during exercise	Adverse events post exercise
Excessive pain (subjective severity)	Excessive pain (subjective severity)
Chafing/abrasions	Shortness of breath
Bruising/pressure marks	Whole arm swelling
	Chafing/abrasions
	Bruising/pressure marks
	Persistent tingling/paraesthesia
	Numbness/loss of sensation

Pulse oximetry

Participants were required to confirm the presence of an upper limb pulse by taking a pulse oximeter reading before commencing each exercise (once their BFR strap had been applied at the required perceived compression) and once each exercise had been completed (prior to releasing their BFR strap and commencing their rest period). Pulse oximetry has been reported to be a valid method of ensuring sub-occlusive arterial pressure (i.e., the presence of a pulse) in the upper limb when compared to the gold standard of ultrasound doppler (21).

Feasibility outcomes

Successful recruitment was determined by the time within which a minimum of 24 participants could be recruited, with a maximum of three months defined a priori.

Successful adherence was determined by monitoring the number of sessions completed by each participant (x/10), with a minimum of 80% required a priori.

Successful data collection was determined by outcome measure capture, with a minimum of 80% required a priori.

Efficacy outcomes

Push-ups to volitional failure

All participants performed a push-ups to volitional failure test in their familiarisation meeting, but before their BFR familiarisation. Total push-ups were observed and recorded by the researcher during the video call and the test was ceased once participants failed to meet the minimum movement standard of 90° elbow flexion (i.e., volitional failure). This was then repeated in the final meeting after the five-week BFR programme. Push-ups to volitional failure was chosen as a proxy measure of strength as it has been reported to correlate well with a one repetition maximum bench press using an equivalent load (22). It

could also be performed virtually and without requiring participants to attend a human performance laboratory during the SARS-CoV-2 pandemic.

Arm girth

Arm girth was measured by the participant using a flexible tape measure according to the International Society for the Advancement of Kinanthropometry (ISAK) guidelines (23). Participants were instructed to measure from their acromion process to their cubital fossa on their right arm, marking the midpoint. Participants were then instructed to take a circumferential measurement of their arm at this point to the nearest 0.5cm, with their arm relaxed in the anatomical position (23).

Number of prescribed repetitions completed

The total number of repetitions completed were compared from week two to week five, excluding week one as a familiarisation week, as a measure of muscular endurance (24).

Statistical analysis

Data were collected and collated using a customised spreadsheet (Microsoft Excel 16.0.13426320270, Microsoft, Washington, USA). Safety and feasibility data were analysed using Microsoft Excel. Safety outcomes were calculated by dividing the incidence of reported adverse events by the total number of BFR sessions (x/280) and expressed as a percentage. Adherence outcomes were calculated by dividing the number of completed sessions by the total number of prescribed sessions (x/280) and expressed as a percentage.

Efficacy data were analysed using JAMOVI (v.1.6.23, the JAMOVI project, Sydney, Australia). Mean change and associated standard deviation (SD) were calculated for push-ups to volitional failure and arm girth (follow up – baseline), and total number of repetitions completed (week five – week two). A Shapiro-wilk normality test was conducted to determine if data were normally distributed. As a feasibility study not powered a priori to detect statistical significance, dependent sample t-tests were not performed, and p-values not reported, because of the potential for type II error and to avoid giving the impression of there being robust findings from a feasibility design. Instead, mean change with 95% confidence intervals (CI) and effect sizes (25) were calculated. If normally distributed, Cohen's *d* was interpreted as trivial (<0.2), small (0.2-0.49), medium, (0.5-0.79) and large (≥ 0.8 ; 26) and if non non-normally distributed, rank biserial correlation (RBC) was interpreted as strong positive correlation (1.0), no correlation (0), strong negative correlation (-1.0; 27).

Results

Participants

28 participants (15 male, 13 female) were recruited and 27 (14 male, 13 female) completed the study and are included in all analyses. One male participant failed to appropriately follow the protocol and did not

complete the study. Cohort demographic data are presented in table two.

Table 2: baseline demographic data

	<i>Age</i> (years)	<i>Height</i> (cm)	<i>Mass</i> (kg)	<i>Tegner</i> scale
Mean (\pm SD)	31.6 (\pm 9.1)	173.8 (\pm 9.1)	71.9 (\pm 11.6)	6.5 (\pm 0.7)

Safety outcomes

Adverse events

One participant reported one incidence of excessive pain during exercise (0.36%). Two participants reported one incidence of excessive pain post-exercise (0.72%). One participant reported one incidence of bruising in the locality of the BFR strap post-exercise (0.36%). No other adverse events were reported.

Pulse oximetry

An absent pulse oximeter reading was reported by four participants either before or after an exercise a total of 82 (out of 2240) times (3.7%), with one participant reporting an absent pulse oximeter reading 56 times and another participant reporting an absent pulse oximeter reading on 24 occasions. The remaining two incidences of absent pulse oximeter readings came from two separate participants.

Feasibility outcomes

Recruitment commenced on 08/03/2021 and ceased on 25/03/2021, with 28 participants successfully recruited and enrolled within three months.

278/280 sessions were successfully completed (adherence=99.3%). One male participant did not complete the final week of the protocol.

Full data were collected from 27/28 participants (96%).

Efficacy outcomes

Push-ups to volitional failure

Mean number of push-ups increased from baseline (20.6 \pm 10.3) to follow up (28.6 \pm 11.4), reflecting a mean increase of 40%. Shapiro-Wilk test for normality indicated normally distributed data ($p=0.7$) and a mean change of 8.0 (95% CI 5.7, 10.3, Cohen's d 1.40; see figure 2a and table 3).

Arm girth

No change in arm girth was observed from baseline (30.8 ±3.6) to follow up (30.9 ±3.28). Shapiro-Wilk test for normality indicated non-normally distributed data (p=0.01) and so a mean change <0.001 (95% CI -0.5, 1.0, RBC 0.08; see figure 2b and table 3).

Number of prescribed repetitions completed

The total number of repetitions completed each week increased from week two (576.7 ±30.5) to week five (581.9 ±34.0). Shapiro-Wilk normality test indicated non-normally distributed data (p≤0.001) and so a mean change of 11.5 (95% CI 0.50, 28.00, RBC 0.50; see figure 2c and table 3).

Table 3: mean change, 95% CIs and effect sizes for efficacy data

	Mean change	Lower 95% CI	Upper 95% CI	Effect size	
Push-ups to volitional failure	8.00	5.74	10.26	Cohen's <i>d</i>	1.40
Arm girth	<0.001	-0.50	1.00	Rank biserial correlation	0.08
Total repetitions	11.50	0.50	28.00	Rank biserial correlation	0.50

Discussion

This study aimed to explore the safety, feasibility, and efficacy of garment-integrated BFR in the upper limb of healthy adults. Consistent with our hypotheses, garment-integrated BFR was identified to be safe and feasible, with increases observed in push-ups to volitional failure and total repetitions completed, but not participant-measured arm girth.

Safety

Garment-integrated BFR was identified to be safe for use in the upper limb of healthy adults, reflected by the minimal presence of adverse events and confirmation of sub-occlusive pressure using perceived compression stimulus. Muscle soreness is a common side effect of low load resistance exercise combined with BFR (1), which may persist for up to 72 hours (20). Two participants (8%) in this study reported excessive muscle pain post-exercise. Upon further exploration, one of these participants failed to cease the protocol at the point of volitional failure, instead completing the maximum possible repetitions with small rest intervals. The other participant went against the advised study protocol and combined his BFR protocol with regular golf (36 holes in a five-day period). After a week of prescribed rest and reinforcement of instructions these participants returned to the protocol without any further excessive muscle soreness, indicating that their initial episodes are unlikely to be the direct result of garment-integrated BFR.

A maximum of 80% arterial occlusive pressure is advocated when combining BFR with resistance exercise (1). Use of BFR with total occlusive pressure is not advised to minimise the potential for more serious adverse events (1). In the absence of a gold standard of ultrasound doppler, pulse oximetry was used to ensure sub-occlusive arterial pressure (21). A successful pulse oximeter reading was achieved 2158/2240 times, with a pulse oximeter reading absent 82 times (3.7%). Upon further exploration, one participant accounted for 56/82 absent readings, which was rectified by the provision of a new pulse-oximeter, suggesting equipment failure. A further participant accounted for a further 24 absent pulse oximeter readings, likely to be explained by the use of acrylic false nails (28). Participant determined compression stimulus is therefore a safe method to use in future trials to ensure sub-occlusive pressure when using garment-integrated BFR, with the secure Velcro mechanism allowing for consistent replication of the required compression stimulus.

Feasibility

All three of the apriori defined feasibility outcomes were satisfied. The required number of participants were comfortably recruited within three months, and complete data were obtained from 96% of participants. Adherence to the garment-integrated BFR protocol used was high (99.3%), which is comparable to adherence rates reported by other BFR feasibility studies in clinical populations (29). The one male participant who failed to complete the final two BFR sessions wished to return to his typical upper limb training routine, which led to his withdrawal. Overall, this gives a high degree of confidence that garment-integrated BFR could be scaled up and investigated using a randomised controlled trial design.

Efficacy

Whilst not designed for hypothesis testing, a mean increase of eight push up repetitions to volitional failure was observed. This may reflect an improvement in muscle strength, as push-ups are a valid predictor of upper body strength (22). An increase in strength would also be expected after combining low load resistance training with BFR (4). The absence of a control group in this study means that it is impossible to separate a dependent training effect from an independent effect of BFR. With feasibility established, future research should look to investigate the efficacy of garment-integrated BFR in an adequately powered trial with an appropriate control.

No change in participant-measured arm girth was observed amongst the participants in this study. Because of the limitations placed on clinical research during the SARS-CoV-2 pandemic, participants were required to measure their own arm girth using a flexible tape measure, whilst observed by a researcher, leading to questionable reliability. Limb girth is also affected by several variables beyond muscle hypertrophy, including water retention and adipose tissue. Future studies are advised to apply valid and reliable methods of body composition testing, such as muscle cross-sectional area magnetic resonance imaging (30,31) once the pandemic-related restrictions on clinical research are lifted.

A modest mean increase of 11.5 repetitions was observed between weeks two to five. Total number of repetitions completed is a valid predictor of muscular endurance (24) and an improvement in muscular endurance would be expected when combining low load resistance training with BFR (4). The ceiling of the prescribed repetitions was 600 repetitions per week and eight participants were completing this maximum volume from week two, indicating that the prescribed training protocol was not an appropriate challenge for almost one third of the cohort. Participants were unable to access gym facilities and perform a more specific protocol reflective of their baseline condition due the SARS-CoV-2 pandemic. Future studies should look to explore low load resistance training that is specific to the individual, combined with BFR, and include a muscular endurance test using a fixed percentage of one repetition maximum to volitional failure (32), to appropriately evaluate the effect of garment-integrated BFR on muscular endurance.

Interpretation

Garment-integrated BFR can be used safely in the upper limb of healthy adults when a subjective measure of compression stimulus is used. It is plausible that this safety outcome is generalisable to wider populations beyond healthy adults, but future trials should look to confirm this ahead of commencement if investigating a population beyond healthy adults. Recruitment, adherence, and data collection were all successful, meaning that a future larger scale trial is feasible. The feasibility of randomisation was not investigated in this study, and a future trial should therefore have appropriate stop/go criteria should initial randomisation prove infeasible.

Conclusion

Garment-integrated BFR is safe and feasible in the upper limb of healthy adults and can be applied in a resistance training setting using existing BFR protocols. Further work is required to investigate the efficacy of garment-integrated BFR and determine its comparability or superiority to existing BFR methods with respect to facilitating muscle hypertrophy, strength and endurance.

Declarations

Ethics approval and consent to participate

Ethical approval was granted by the Queen Mary Ethics of Research Committee (QMREC2018/48/054).

Consent for publication

We consent for this manuscript to be published upon completion of peer-review.

Availability of data and material

Raw data can be provided upon request.

Competing interests

Dr Warren Bradley is the founder and chief technical officer of Hytro Limited. Dr Bradley was involved in the conception of the study and the preparation of the manuscript but was not involved in the collection or analysis of data.

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The garments and consumables for this study were provided by Hytro Limited. Authors' contributions

BD: study conception, data collection and analysis, manuscript preparation

EM: study conception, data collection and analysis, manuscript preparation

WB: study conception, manuscript preparation

BN: study conception, data collection and analysis, manuscript preparation

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BD and EM completed this study as part of their intercalated degree (iBSc) in Sports and Exercise Medicine at Queen Mary University of London.

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Figures



Figure 1

garment integrated BFR with Velcro mechanism

Figure 2a

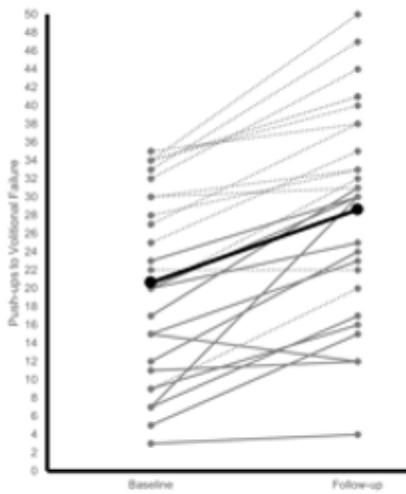


Figure 2b

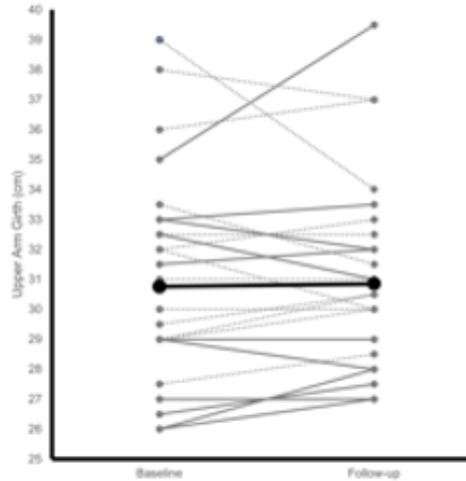


Figure 2c

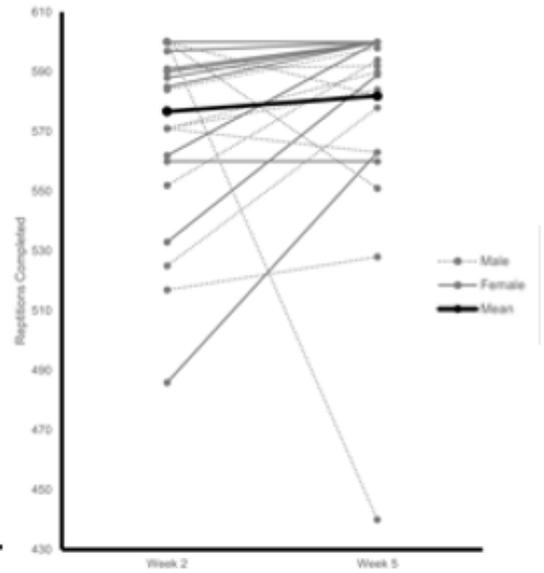


Figure 2

a-c: individual participant data at baseline and follow up for push-ups to volitional failure and arm girth, and from weeks two to five for total repetitions completed

Supplementary Files

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