TITLE
Effectiveness of a 10-week low back pain rehabilitation programme with and without bilateral blood flow restriction exercise; monitoring perceptions of pain and hypoalgesia effects.

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Effectiveness of a 10-week low back pain rehabilitation programme with and without bilateral blood flow restriction exercise; monitoring perceptions of pain and hypoalgesia effects.

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"When diamonds share their value with determined chunks of coal, it makes the world a more valuable place"

Abstract

Background We compared the effectiveness of a 10-week, low back pain (LBP) rehabilitation programme, with and without bilateral blood flow restriction exercise (BFR-RE). Monitoring perceptions of pain (POP), LBP pressure pain thresholds (PPT), hemodynamic variables (HV) and distal hypoalgesia effects within the lumbar region.

Methods 28 participants with LBP were block randomised (BFR-RE, n=14; Non BFR-RE, n=14) for this parallel-group, repeated measures study. Periodisation comprised 3 proprioceptive, endurance and strength phases of hip hinge and gluteal programming over 10-weeks, conducted twice weekly. Rating of perceived exertion (RPE) systematically regulated training load and resistance exercise (RE) protocols incorporated conventional hypertrophy and LBP rehabilitation methods, using BFR repetition guidelines. POP, PPT and HV were assessed pre-intervention - post session - post intervention, using the short form McGill pain questionnaire (SF-MPQ), pressure algometer (PA) and blood pressure monitor (BPM).

Results 1 withdrawal left 27 completing participants (BFR n=14, Non-BFR n=13), with no adverse baseline characteristics. Significant interactions occurred between BFRE-RE treatment and time ($F_1 = 6.31$, $p = 0.03$), reducing SF-MPQ values by 80%, 38% greater than Non-BFR ($t_{12} = 02.51$, $p < 0.03$). PPT's increased over time ($F_1 = 10.35$, $p = 0.007$), with no group differences (19 ± 0.10%) and main effects of treatment were insignificant for all HV (Systolic (SYS), $F_1 = 0.08$, $p = 0.08$; Diastolic (DIA), $F_1 = 0.37$, $p = 0.55$; Heart Rate (HR), $F_1 = 3.13$, $p = 0.10$; Mean Arterial Pressure (MAP), $F_1 = 0.17$, $p = 0.69$.

Conclusion BFR-RE affords LBP demographics who cannot tolerate load or are troubled by fear avoidance model (FAM) movement modifications, a rehabilitation method that reduces POP and enables corrective LBP exercise to be conducted with practitioners.

Key Points
Blood flow restriction resistance exercise (BFR-RE) reduces POP to a greater extent than non BFR-RE, using hip hinge and gluteal development low back pain (LBP) rehabilitation programme.
Resistance exercise (RE) and BFR-RE both increase LBP pressure pain threshold (PPT), with comparable between group differences.
BFR-RE increases mean arterial pressure (MAP) similarly, compared to Non BFR-RE across 20 rehabilitation sessions.

Keywords: Blood flow restriction; low back pain rehabilitation; perceptions of pain

Chapter 1.

Introduction

Low back pain (LBP) affects approximately 80% of adults at some stage during their lives, with a 20-45% chance of repeated reoccurrence 1 year after the first onset and a lifetime prevalence rate of 60-70% within some industrialised countries (1). Epidemiology studies identify static working postures, high intensity physical activity, excessive flexion/extension patterns of the trunk, poor muscular support and stabilisation strategies as risk factors that can produce LBP onset (2). Economic costs accumulate predominantly by virtue of LBP acting as a precipitating catalytic trigger for comorbidities such as obesity, depression and related injuries resulting from injurious biomechanical compensations (3,4).

Altered movement mechanics derive from modified locomotion patterns and irregular muscle recruitment during physical tasks, caused by fear of re-injury or exacerbation of symptoms (5,6). These behaviour modifications occur as a result of the fear avoidance model (FAM) is a primary reason for reported diminished levels of physical activity and subsequent deconditioned musculature in LBP sufferers (7–10), with kinesiophobia occurring due to heightened pain sensitivity, negative evaluations of associated movements and a perceived expectation of oncoming pain (11). A noteworthy obstacle for professionals looking to rehabilitate LBP demographics, get sufferers moving more and counteract FAM interruptions, is that a conclusive definition for LBP is not agreed amongst researchers. Consequently, the term non-specific low back pain (NSLBP) was established to categorise LBP with no designated pathoanatomical trigger or aetiology (12), which contrastingly, some specialists firmly denounce (13). This absence of cause and effect leaves many sufferers reluctant to rehabilitate (14) and controlled by their FAM, a primary reason for chronic LBP development (9). Nonetheless, a definition for LBP can be determined from the heterogeneous similarities amongst the overarching definitions in research. Therefore, pain located at the posterior of the

body from the seventh cervical vertebra to the lower gluteal fold (Figure 1.), with or without radicular neurological pain into one or both lower limbs, at durations of < six weeks (defined as sub-acute), < twelve weeks (identified as acute) and > twelve weeks (classified as chronic), accurately identifies individuals suffering from LBP (2,7,12,15).

Figure 1. LBP Categorisation zone

The vast majority of LBP treatment interventions seek to provide pain relief, with diagnosed LBP using precise surgical operations to directly resolve issues (16) and NSLBP undergoing a triage of eliminatory procedures, often using analgesics, intradiscal injections or pharmacological interventions (17). However, these interventions overlook the associated underlying mechanical issues and postural triggers possessed by the sufferer, which in a high proportion of chronic cases are related to mechanical, postural or muscular characteristics (18). Consequently, it should come as no surprise that LBP sufferers can display sub-optimal levels of physical conditioning and inferior preferential movement strategies (8,19), which can

effectively be addressed using exercise and physical activity (20–22). More specifically, refining commonly encountered movement strategies such as the hip hinge, that expands everyday pain free mechanics (23) and prescriptive corrective exercises, which encourage the development and re-integration of inhibited musculature suchlike the gluteal muscles (13). These two methods conducted concurrently would be particularly effective, attributable to the notion that autonomously skilled bending and physically conditioned posterior musculature, significantly reduces shear spinal compressional forces and ligamental strain, encouraging more support for intervertebral disks in a neutral posture (22). Whereby, musculoskeletal conditioning and movement modulation remove perturbed motor patterns, in accordance with the individuals pain triggers, subsequently sparring the spine (13). Due to FAM's influence on LBP demographics (10), the hypoalgesia experienced under blood flow restriction (BFR) should provide LBP demographics a superior rehabilitative environment. Blood flow resistance exercise (BFR-RE) is proven as a more tolerable and effective therapy for patients who cannot withstand exercise due to pain or weakness (24). BFR's peripheral analgesia documented in non-occluded and occluded limbs (25,26) should afford LBP suffers opportunities to refine movement patterns, without disruption from FAM. Furthermore, the ischemic conditions provide a superior environment for muscle hypertrophy to occur during low-load resistance training (27), expediting musculoskeletal conditioning with minimal associated risks (28). Therefore, based on positive outcomes in alternative rehabilitation cases (25,29,30), concurrent LBP rehabilitation exercises with applied BFR should provide acute pain reduction in perceptions of pain (POP), allowing FAM influences to diminish and required strength and conditioning to occur.

BFR constrains blood flow to a muscle, contemporarily using a tourniquet system and applying a pressurised cuff over the proximal portion of the upper or lower extremities. For consistent

occlusion pressures, individual limb occlusion pressures (LOP) are determined at rest using a personalised tourniquet (PT) device and any concurrent resistance exercise (RE) is conducted based upon a mode specified percentage of LOP (31). The PT partially restricts arterial inflow during muscle contraction, whilst completely occluding venous outflow of blood distal to the occlusion site, creating a hypoxic environment for the exercising muscle (24). This enables hypertrophic adaptions using low load resistance exercise (LL-RE) <50% 1-repetition maximum (RM), similarly to heavy load resistance exercise (HL-RE) at >65% 1RM (25,32), particularly advantageous to demographics not able to tolerate high loads or populations anxious when loading during injury rehabilitation. This ability to induce morphological adaptions during LL-RE (24) clinically reduces associated risks and perceptions of it for the patient, enabling greater patient security and expedited rehabilitation. BFR-RE research demonstrates safe hemodynamic responses (24), even indicating lower hemodynamic variables (HV) from BFR-RE than HL-RE and LL-RE (33). However, bilateral BFR-RE HV literature is limited in comparison to unilateral BFR-RE or bilateral blood flow restriction aerobic exercise (BFR-AE), with traditional unilateral BFR-RE using 80% LOP and BFR-AE utilising LOP (<60% LOP) (24). Therefore, bilateral BFR-RE should theoretically provide similar safe HV responses, as cardiovascular intensive bilateral BFR-AE <60% LOP and 80% LOP unilateral BFR-RE, providing maximal occlusion times and loads < 30% 1RM and used. Therefore, documenting HV such as systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR) and mean arterial pressure (MAP) HV during bilateral BFR-RE, would be valuable for BFR research progression, contributing to the expanding library of BFR-RE hypoalgesia and HV research (34–36). Exercise itself is an endogenous form of pain modulation, referred to as exercise induced hypoalgesia (EIH) (37,38). Common hypothesis for EIH include the elevation of opioids such as beta-endorphin at peripheral, spinal and central sites (39), increased circulatory concentrations of endocannabinoids, that contribute to the

regulation of pain within the central nervous system (40) and conditioned pain modulation as a result of cuff pressure coupled with the high level of ischemia and exercise induced muscle pain (34). Furthermore, BFR-RE has been shown to enhance EIH circulating substances, causing up-regulation of systemic EIH agents that influence nociceptor pain sensitivity and thresholds (38). Peripheral analgesic changes have been documented in non-occluded limbs, with evidence indicating EIH being present in body sites closest to the exercised muscle (26), possibly due to the hypoalgesia substances circulated within the blood (34), with hypoalgesia documented in non-exercising, non-occluded limbs and remote areas of the body in smaller magnitudes during BFR LL-RE (26,29,34,37). Therefore, the concurrent application of BFR and LBP rehabilitation exercise should afford LBP sufferers a less painful and expedited rehabilitation environment, resulting from theoretically reduced levels of pain or anxiety whilst performing the hinge motion and superior developmental environments for morphological gluteal adaption. Based on the preceding rationale, a 10-week comparative experimental, randomised control group study, should assess the parallel efficiency of BFR-RE and RE application within a concurrent LBP rehabilitation programme.

Hypothesis/Aim

The primary aims of this research are to identify whether LBP rehabilitation exercise is more effective and faster at reducing POP with BFR. Additionally, whether bilateral lower limb occlusion generates lumbar hypoalgesia, indicated by greater BFR-RE PPT. Secondary aims will monitor group differences in HV across 20 sessions using bilateral occlusion during BFR-RE, in an attempt to match the safe HV proven in BFR-AE and traditional unilateral BFR (24). Therefore, due to previous BFR research establishing peripheral distal limb hypoalgesia; furthermore, that hip hinge derivatives and gluteal development are proven rehabilitative strategies, the following hypothesis (*H*) is predicted: (1) This study will demonstrate greater reductions in POP for the BFR group; (2) Increased PPT within the BFR group; (3) Insignificant MAP increases between groups. Therefore, the null hypothesis (H_0); (1) would display no between group differences POP reductions; (2) identify no differences in post study PPT; (3) identify significant MAP increases amongst the BFR group.

Chapter 2.

Methodology

Participants

Twenty-eight participants were recruited (mean ± standard deviation: age = 41 ± 8.7 years; height = 1.75 ± 0.1cm; body mass = 74.9 ± 15.45 Kg; body mass index = 24.35 ± 3.46 m_2; blood pressure = 126.7 ± 16.85/80.6 ± 9.75/74.1 ± 13.85 mmHg; MAP 95.95 ± 11.2), referred from an affiliate orthopaedic surgeon and my data base of LBP patients within my professional network. Participants self-categorised their RE training history (8% no training history; 33% novice; 15% intermediate; 44% advanced) and were free from contraindications. Participants were instructed to avoid caffeine 6 hours prior to each session and declare any ingested substances that could promote hypertensive conditions or effect HV. All participants provided signed informed consent, in compliance with the Declaration of Helsinki (41) and ethical approval was granted by St Mary's University. Recruitment criteria permitted participants with chronic or acute LBP pain symptoms, located posteriorly between the seventh cervical vertebra and the lowest gluteal fold. Demographical and gender prevalence for LBP is vague; therefore, male or female participants between the ages of 18 and 65 were permitted (42). Exclusion criteria included contraindications from the BFR screening questionnaire, revised physical readiness questionnaire (PAR-Q) and participants who did not provide informed consent (24,41,43,44).

Sample Size Calculation

The primary outcome measure of pain modulation was used for sample size calculation using G*Power version 3.1 (45), based on a similar between group BFR comparison study (30). Therefore, to achieve a power of 80% at an alpha level of 0.05, a total of 26 participants were required to detect meaningful between group modulations in pain and too account for withdrawals (10%), 28-participants were recruited.

Experimental Design

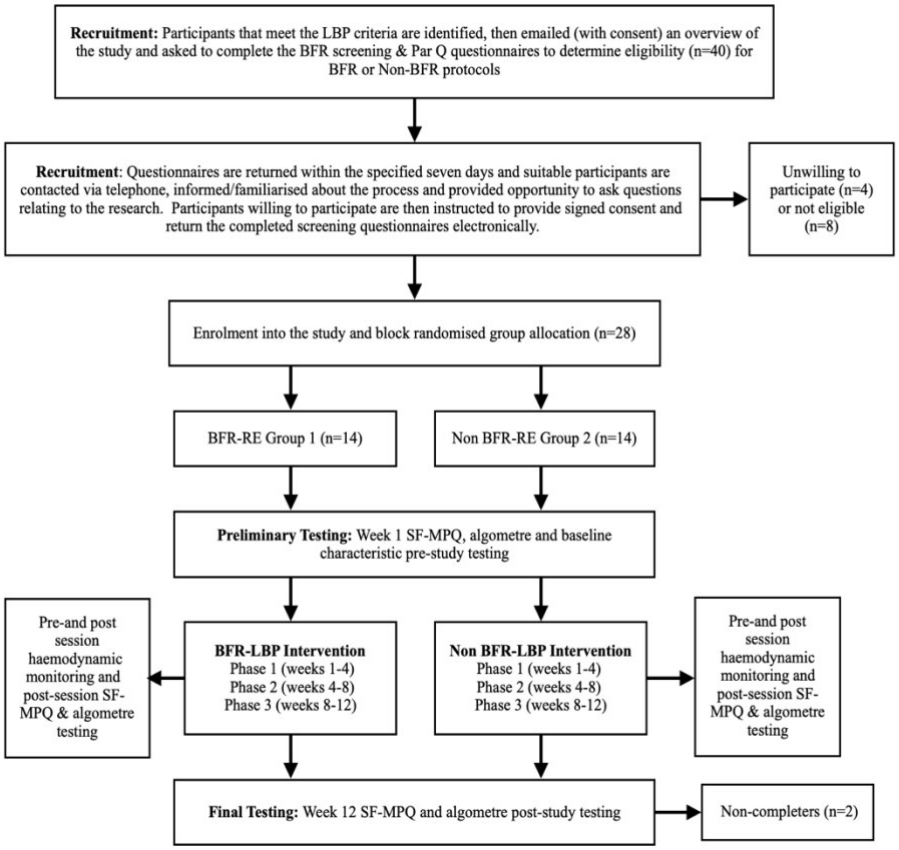
This study was a 10-week parallel group, two-arm, single assessor blinded, randomised between participants repeated measures design. Participants were block randomised (46) into groups of 4 by an independent affiliate to either the BFR-RE protocol (n= 14) or Non BFR-RE protocol (n= 14) groups, with 4 folded slips evenly distributed inside 7 opaque envelopes, and the BFR-RE group coded as group 1 and the Non BFR-RE group coded as group 2. The dependent variable LBP was assessed on a quantitative basis across a period of 20-sessions and assessed using the revised Short Form McGill Pain Questionnaire (SF-MPQ) and pressurised algometer (PA). The independent variables BFR-RE and Non BFR-RE groups both performed hip hinge optimisation and gluteal development programmes, with rating of perceived exertion (RPE) used as a regulatory procedure to control periodisation.

Experimental Protocol

Forty-volunteers who meet the recruitment criteria were contacted by email with an overview of the research procedures, then asked to complete the attached BFR screening questionnaire and Par Q. Eligible and willing participants were immediately contacted by telephone or email. Following receipt of signed consent forms and successful completion of screening questionnaires, participants were randomly allocated to either the BFR or Non-BFR groups, with the principal assessor of data-analysis and outcomes blinded to this group allocation. Preliminarily and baseline characteristic data collection occurred immediately prior to the commencement of session 1, also serving as pre-session 1 measurements. Primary pre - post-study assessments included participant completion of the SF-MPQ using email and applied PA testing, centrally placed between their L4 and L5 intervertebral disk. Pre-session measurements included a verbal confirmation that LBP conditions had not exacerbated to

unsafe participation levels, measurement of HV and for the BFR group only, LOP calculations. Both groups then carried out 20 LBP rehabilitation sessions over 10 weeks, separated into 3 phases of proprioceptive, endurance and strength protocols. Each session began with a preparatory warm-up and concluded with structured cool down activities. Following each session, immediate PA and HV measurement occurred and similarly to previous BFR studies, subjects were asked to identify their perception of pain 24 hours post session electronically using the SF-MPQ (25). Post-study SF-MPQ forms were completed 48 hours after the participants final session. An overview of the research procedure is provided within image 2 (Figure 2.).

Figure 2. Overview of study



Perception of Pain Testing

Participants were asked to identify their POP using the SF-MPQ (47–49), consisting of 15 affective (n=11) and sensory (n=4) pain descriptors that uses a scale of severity to establish the physical and emotional extent of their LBP, validated as a reliable method of detecting change in pain therapies with various populations (*r* 0.926) (50,51). Total POP value was calculated, by adding the numerical values of the subscale scores (0 = none, 1 = mild, 2 = moderate, 3 = severe).

Pressure Pain Testing

Additionally, pre-study and immediately after each training intervention, a PA (Wagner Instruments, FPX 25, 0.3% accuracy) was placed directly between the paraspinal region of participants L4 and L5 intervertebral disks, to monitor acute peripheral analgesic effects. LBP PPT reliability has been demonstrated (*r* = 0.990), requiring the mean score of 3 measurements and concurrent use of a self-reported pain questionnaire for comprehensive disability evaluation (52–54). The PPT location was selected, based on identification as the most prevalent point for LBP sufferers (55). Participants were standing for the PA reading, in order to discourage pelvic tilt during sitting, known to interact with LBP (56). PPT location was attained by placing both hands posteriorly on the iliac crest, with thumbs pointing towards each other and palpating for the larger L5 reference point and moving up one level to the L4 spinous processes. The 1cm^2 diameter PA head was perpendicularly applied centrally between the designated L4-L5 region and the participant was instructed to notify the experimenter once the immediate spot or surrounding areas became painful. The tester then applied force at a frequency of 1 kg per second until instructed to terminate force application; whereby, compressional force values were digitally recorded on the PA screen and converted to kg/cm^2.

Haemodynamic Measurements

HV SBP, DBP, HR and MAP were monitored immediately prior and upon completion of each training session, using a validated (57) digital blood pressure monitor (OMRON™ Evolve Model HEM-7600T-E Kyoto, Japan). HV readings were taken in the seated position, with the patients back vertically supported and arm rested at heart level, ensuring the cuff position resided parallel with the right atrium (58).

Blood Flow Restriction Application

BFR was conducted bilaterally using two automatic PT systems (Delfi Medical, Vancouver, BC, Canada) placed on the most proximal portion of both lower limbs. The PT has 3 variable sized cuffs designed to accommodate a range of limb circumferences (27.9 to 76.2cm), made of contour nylon (11.5cm x 86cm, 5mm thick) connected by airtight hose tubing to a PT device, that automatically calculates minimum LOP for full arterial occlusion (59) and is clinically validated as accurate and reliable (25). Participants limb circumference was measured to the point where the centre of the of the cuff will be and the corresponding Delfi Easi-Fit Tourniquet cuff was used continuously throughout the study. LOP was calculated in the supine position at the start of each session (25) and set at 80% LOP for the entirety of the programme in order to maximise fast twitch fibre recruitment (24). Continuous BFR application was implemented instead of removing the cuff during rest intervals, to produce no potential variations in HV (60) and when training muscles proximal to the cuff, higher occlusion pressures are required if distal hypoalgesia is to be achieved from BFR (61).

Programme Periodisation

Twenty sessions were allocated across 10-weeks, with 2 sessions per week proven effective in BFR and RT protocols for developments in muscle cross sectional area (CSA) or strength

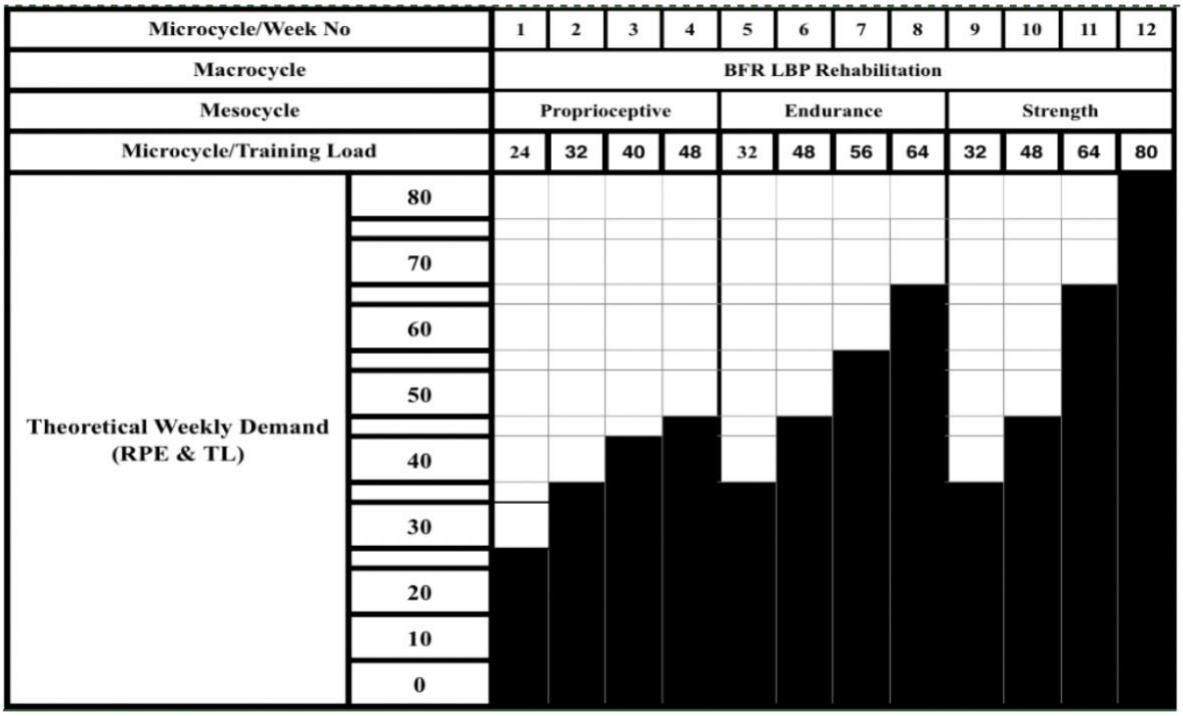
(24,62). Traditional linear periodisation was applied, with training load (TL) periodically altered in accordance with Selye's general adaption syndrome (63). TL was calculated using Foster and colleague's Session-RPE method (64), validated as a reliable stand-alone method of monitoring (65). Familiarisation occurred prior to data collection and participants were instructed to include all pain experienced within the cumulative TL total and to stay within the boundaries of the sessions assigned RPE (64). The RPE given is then multiplied by the length of the session (mins), providing a reflective arbitrary unit gauging the magnitude of TL for that session [TL (A.U.) = RPE x session duration (min)] (65).

Session Design

The 10-weeks were separated into 3 phases, comprising of systematic proprioceptive, endurance and strength phases (66) (Figure 3.). Exercise order systemically worked larger muscles and multi-joint exercises, followed by less mechanically demanding exercises thereafter, in the hope of reducing technique interference due to cumulative fatigue (67,68). Exercise techniques minimised spine compressional forces by ensuring no posterior pelvic tilt or lumbar flexion occurred during exercises (66). The repetition scheme followed BFR-RE guidelines, using 75 repetitions across 4 sets of exercises, in conventional order (30, 15, 15, 15) (69,70) whilst ensuring a maximum occlusion time of eight mins (24). Repetition duration was standardised using the 3-digit arrangement of tempo that dictates the eccentric, isometric and concentric phases of each repetition (71,72). Dynamic isotonic repetition speed is validated as suitable tempo in BFR procedures (73,74), with concurring agreement in RE protocols (75). Therefore, gluteal exercises were 6-seconds (3/1/2) with a lengthier eccentric phase, favourable for morphological CSA adaptations (76) and hip hinges exercises were 5-seconds per repetition, coupled with a more volitional concentric phase deemed appropriate for neurological modifications (77). Rest period recommendations for BFR and hypertrophy

concur at 30-60-seconds (78,79), ensuring continued cuff pressure application throughout for maximum skeletal muscle adaption (70).

Figure 3. Programme periodisation



Exercise Selection

Each session began with a non-occluded warm up, conforming to the raise, activate, mobilise and potentiate (RAMP) protocol (63). The warm-up routine consisted of a technically uninstructed 5-minute walk, raising physiological parameters (80). Followed by, birddog, curls up and side bridge exercises, activating the gluteal complex (80) and concluding with a 3 point contact hip hinge (head, back and gluteal), potentiating trunk stabilisation and diminishing postural risks for the forthcoming session (80,81). Phase 1 utilised a progressive framework in accordance with skill acquisition philosophy (SA) (82), which implemented the hinge motor pattern engram using muscle awareness and activation protocols. Primary exercise prescription in phase 1 emphasised spinal disassociation using the hip hinge, by holding a dowel anteriorly in front of the body, followed by preliminary gluteal complex training emphasising gluteus

medius activation with exercises such as the clamshell, side lying lateral leg raises with external rotation and maximum voluntary contraction standing wall press exercises (83,84). Phase 2 transitioned with hinge pattern variation/advancement using a dowel within the good morning exercise, followed by localised muscular endurance and hypertrophy protocols. Focus was placed upon CSA development of the gluteus maximus by incorporating unilateral and bilateral back bridges whilst ensuring a knee angle of 120 degrees for minimal hamstring contribution (66,85) concluding with butterfly hip thrusts (86). Minimal load is utilised during phases 1 and 2, due to potential hindering effects of external load on technical skill acquisition (82). Phase 3 developed upon previously established endurance foundations by developing strength within back extensor musculature and lumbar extension patterns, using the Romanian Deadlift (RDL) hinge derivative (87) and lifting straps, in order to ensure the weight being lifted is a not limited by grip capacity (88). Phase 3 gluteal strengthening exercises included an elevated, loaded or unloaded hip thrust, band resisted gluteal bridges and static lunges (86,89,90), with static lunges performed in-line for greater gluteus maximus activation (Marchetti et al, 2018). Each session concluded with static stretching of the hamstrings, hip flexors and pectorals based on Janda's observations (91) and associated posterior muscle stiffness or kyphotic posture in LBP demographics (92).

Data Storage and Analysis

Descriptive statistics (mean ± SD) were used to describe participant baseline characteristics and all statistical analysis was performed using IBM SPSS Statistics version 26.0 (IBM Corp, Chicago, IL, USA). Data are presented as mean ± SD with 95% CI unless stated otherwise. Differences between groups in baseline characteristics were assessed using independent-samples t-tests for continuous dependant variables and Fishers exact test for categorical data. Normal distribution of data was assessed using the Shapiro-Wilks test (p>0.05) and outliers

were assessed, by no studentized residuals greater than ± 3 standard deviations. If data was not normally distributed, a logarithm transformation was carried out. SF-MPQ scores, PPT readings and HV were assessed using a 4 x 2 (treatment x time) two-way repeated measures ANOVA, with group allocation (BFR vs. Non-BFR) as the between subject's factors and time (pre - post), as the within-subjects dependant factors. For statistically significant two-way interactions, paired sample *t* tests with Bonferroni correction were used for post-hoc analysis, to determine individual differences at an alpha of $p < 0.05$.

Chapter 3.

Results

Participants and Research Alterations

One participant withdrew before completing the study (n=1), for reasons unrelated to the research, leaving 27 completed participants (93%, BFR n=14, Non-BFR n=13). There were significant between group differences for age, height, SYS and HR baseline characteristics (Table 1.). Session attendance was 100% for both groups. However, due to significant global implications of the covid-19 pandemic, training interventions were terminated with immediate effect on March 19th, 2020, by order of the ethics committee at St Mary's University. Therefore, the study was revised from the proposed 24 sessions to 20 for both groups, with the post-study SF-MPQ being completed electronically 48-hours after participants last session. Consequently, no resting post-study algometer or haemodynamic variables were collected. Therefore, study analysis was revised to incorporate an average reading of participants last 3 sessions algometer results, due to validity in the spinal region relying upon an average of 3 readings (52,93,94) and pre-session 20 hemodynamic pressures, to comprehensively assess pre - post study changes for these criteria.

Table 1.) Group Characteristics (Mean ± Standard Deviation)

	BFR-RE (n=14)	Non-BFR-RE (n=13)	*p* value
Age (years)	38 ± 8	44 ± 9	0.70
Gender (male/female)	7/5	6/7	0.45
Body mass (kg)	74.6 ± 13.4	73.8 ± 18.9	0.48
Height (cm)	1.76 ± 0.8	1.73 ± 0.1	0.52
Body mass index (kg/m2)	23.9 ± 3.1	24.5 ± 4.1	0.16
Blood Pressure (mmhHg)			
Systolic	120.4 ± 11.7	133.4 ± 19.3	0.81
Diastolic	79.9 ± 8.3	81.4 ± 11.3	0.15
Mean arterial pressure	93.3 ± 8.5	98.7 ± 13.4	0.48
Heart rate (BPM)	78.5 ± 11.6	69.3 ± 14.9	0.68
Training history			
no history/ novice/ intermediate / advanced	1/5/2/6	1/4/2/6	0.99
Contraindications	None	None	
BFR Pressure (mmHg)			
LOP			
Left limb	205.1 ± 22.90		
Right limb	205.9 ± 23.00		
Difference	14.1 ± 5.3		
80% LOP			
Left limb	164 ± 18.4		
Right limb	164.1 ± 18.70		
Difference	11 ± 4.3		

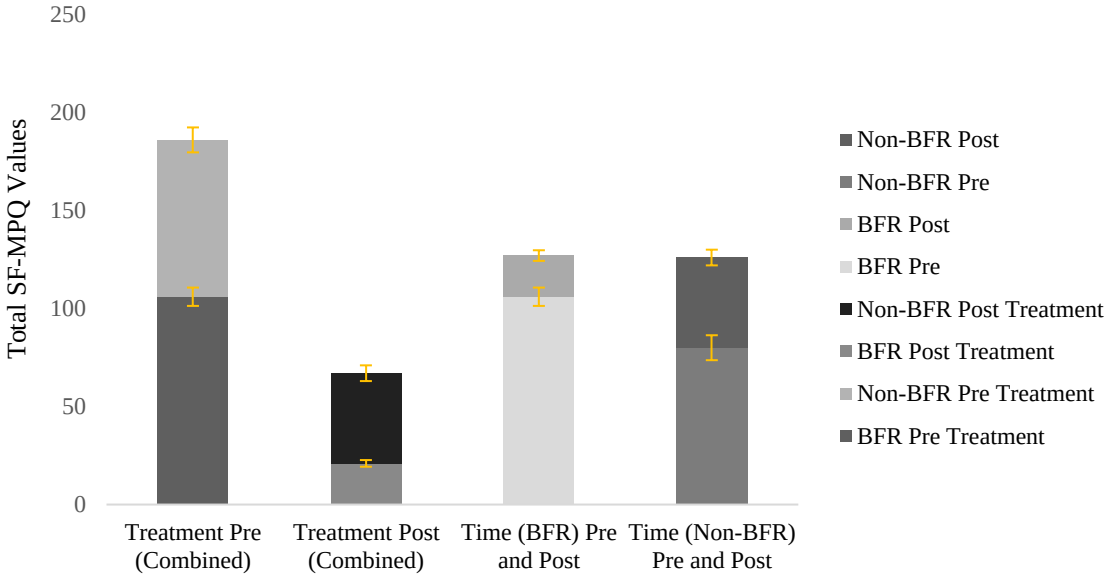
BFR-RE **blood flow restriction resistance exercise, Non-BFR-RE non blood flow restriction exercise,** ***LOP*** **limb occlusion pressure**

Perceptions of Pain Scores Statistical Analysis

There was a statistically significant two-way interaction between treatment and time (F_1 [2,22] = 6.31, p = 0.03), with mean differences 2.64 ± 0.26 (95% CI, 2.08 to 3.20). Post-hoc analysis indicated BFR elicited significant SF-MPQ decreases (t_{12} = -02.51, p < 0.03) and mean differences -01.00 ± 1.44 (95% CI, -1.87 to -0.13) SF-MPQ values. There was a main effect

of time (F_1 = 21.4, p = 0.001), with mean differences 1.61 ± 0.25 (95% CI, 0.62 to 1.70) and SF-MPQ scores significantly decreasing POP pre - post (36 ± 0.54%). There were no significant group differences for main effects of treatment (F_1 = 21.02, p = 0.92), with mean differences -0.02 ± 0.28 (95% CI, -0.66 to 0.59) (Figure 4.).

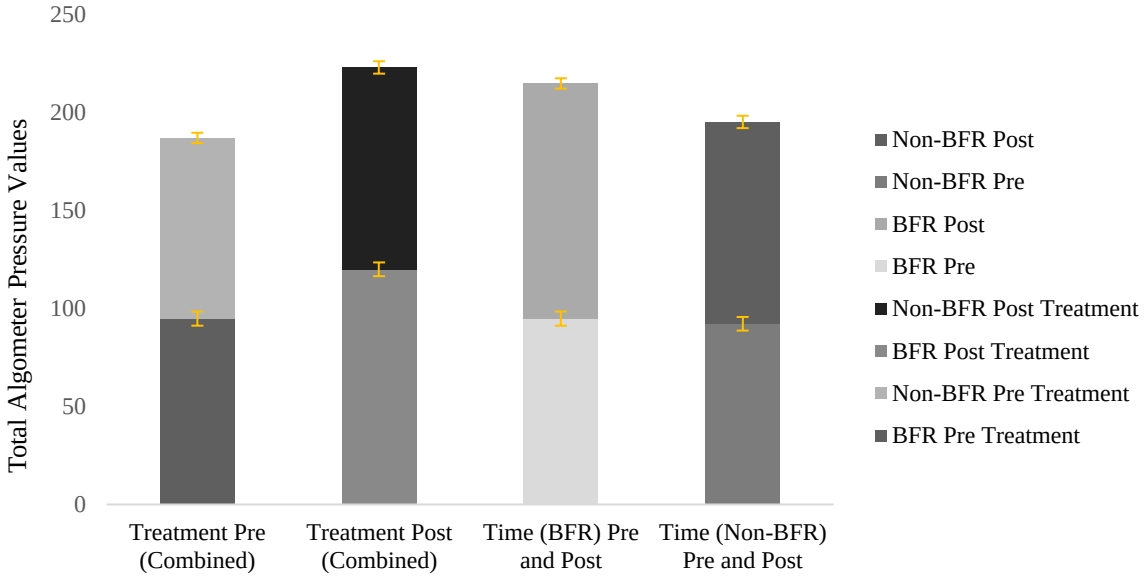
Figure 4. SF-MPQ main effects



Pressure Pain Threshold Value Statistical Analysis

There was no statistically significant two-way interaction between treatment and time (F_1 [2,22] = 1.12, p = 0.31), with mean differences 6.86 ± 1.03 (95% CI, 4.61 to 9.12). There was a main effect of time (F_1 = 10.35, p = 0.007), with mean differences -1.37 ± 0.42 (95% CI, -2.31 to 0.44 and increasing PPT pre - post (19 ± 0.10%). However, main effects of treatment showed PPT values were not significantly different (F_1 = 0.06, p = 0.82), with mean differences 0.31 ± 1.34 (95% CI, -2.60 to 3.24) (Figure 5.).

Figure 5. Algometer main effects



Hemodynamic Variable Pressure Statistical Analysis

Supporting hemodynamic results data presented in table 2 (Table 2.). Statistically significant two-way interactions between treatment and time occurred with SYS (F_1 [2,22] = 12.18, p = 0.004). Post-hoc analysis indicated BFR elicited significant SYS increases (t_{12} = 03.49, p < 0.004). However, DIA (F_1 = 0.96, p = 0.81); HR (F_1 = 0.12, p = 0.73); and MAP (F_1 = 1.77, p = 0.21) were not significant. Main effects of time were insignificant for SYS (F_1 = 1.43, p = 0.26); DIA (F_1 = 0.15, p = 0.71); HR (F_1 = 0.03, p = 0.86); and MAP (F_1 = 0.14, p = 0.72) HV. Main effects of treatment were statistically insignificant in SYS (F_1 = 0.08, p = 0.08),; DIA (F_1 = 0.37, p = 0.55); HR (F_1 = 3.13, p = 0.10); and MAP (F_1 = 0.17, p = 0.69) data (Figure 6).

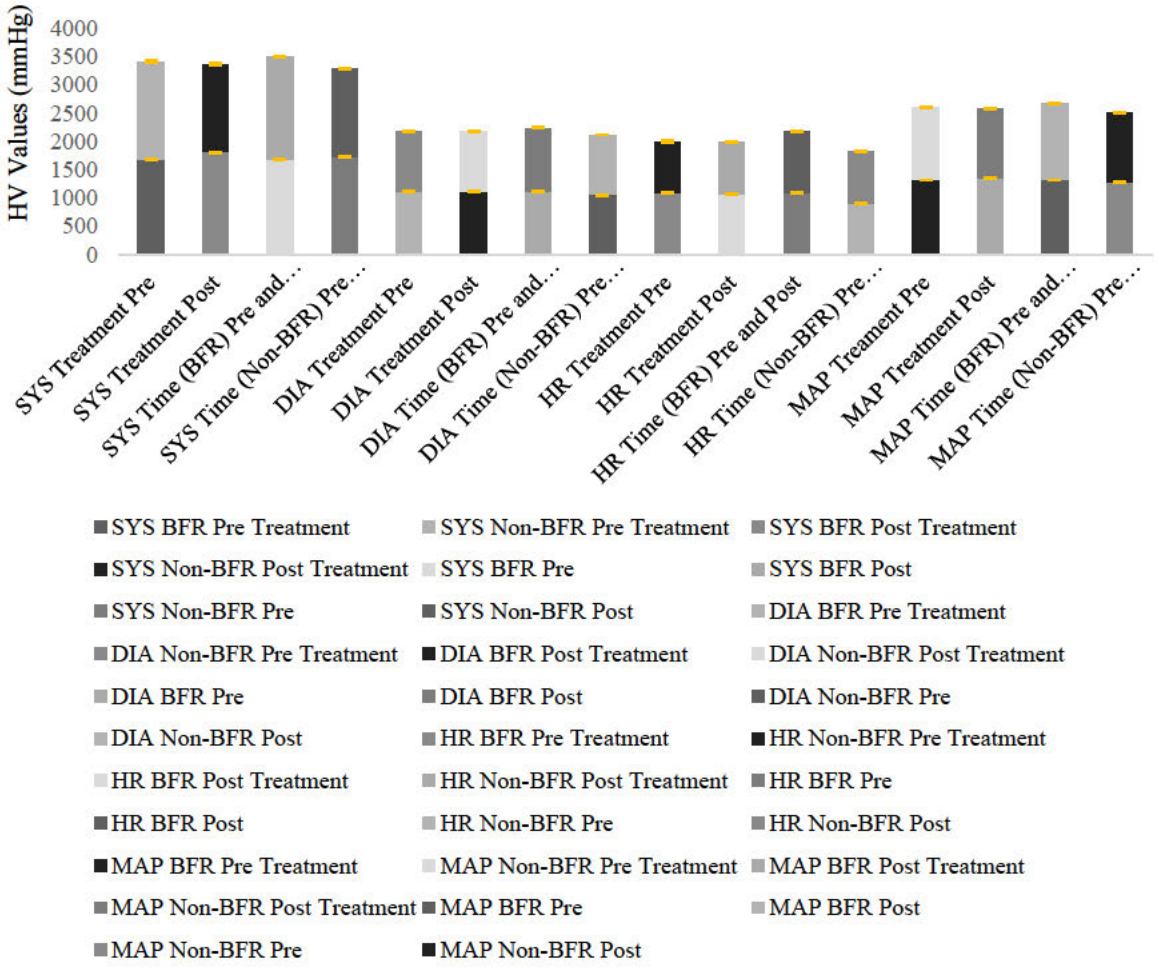
Table 2.) Hemodynamic Results (mmHg) Supporting Data

Measure	Mean Difference	Standard Deviation	(95% CI)
Group x time interaction			
SYS*	121.23	3.24	114.16 to 128.31
SYS Post Hoc*	21.10	21.80	07.91 to 34.23
DIA	78.76	2.02	74.37 to 83.17
HR	78.07	3.32	70.82 to 85.33
MAP	93.43	2.43	88.12 to 98.74
Main effects of time			
SYS	2.85	2.38	2.34 to 8.04
DIA	-0.77	2.00	-5.14 to 3.60
HR	-0.54	2.91	-6.87 to 5.79
MAP	0.69	1.87	-3.38 to 4.77
Main effects of treatment			
SYS	-1.62	5.67	-12.97 to 10.74
DIA	-1.92	3.15	-8.79 to 4.95
HR	7.62	4.31	-1.77 to 17.00
MAP	-1.57	3.79	-9.83 to 6.69

BFR-RE blood flow restriction resistance exercise group, Non-BFR-RE non blood flow restriction exercise group, SYS systolic blood pressure, DIA diastolic blood pressure, HR heart rate, MAP mean arterial pressure

* Significant change ($p < 0.05$)

Figure 6. Hemodynamic variables main effects



Chapter 4.

Discussion

This study is the first to investigate bilateral BFR-RE effects on POP and PPT in LBP demographics. The main findings of this clinical study were: BFR-RE reduces LBP POP to a greater extent than Non BFR-RE (Figure 7.); LBP PPT increases within the lumbar region using BFR-RE and Non-BFR-RE, with no significant differences between groups (Insert Figure 8.); BFR-RE increases MAP insignificantly compared to Non-BFR-RE (Insert Figure 9.). Therefore, evidence supports acceptance of the *H* for BFR-RE inducing superior POP reductions and BFR-RE producing insignificant MAP elevations and the *Ho* is accepted for PPT displaying no between group differences. These findings significantly influence LBP and BFR literature, providing foundational rationale for future research to explore concurrent BFR-RE LBP rehabilitation programming and distal BFR hypoalgesia research concepts.

Figure 7. Mean SF-MPQ variability across 20 sessions

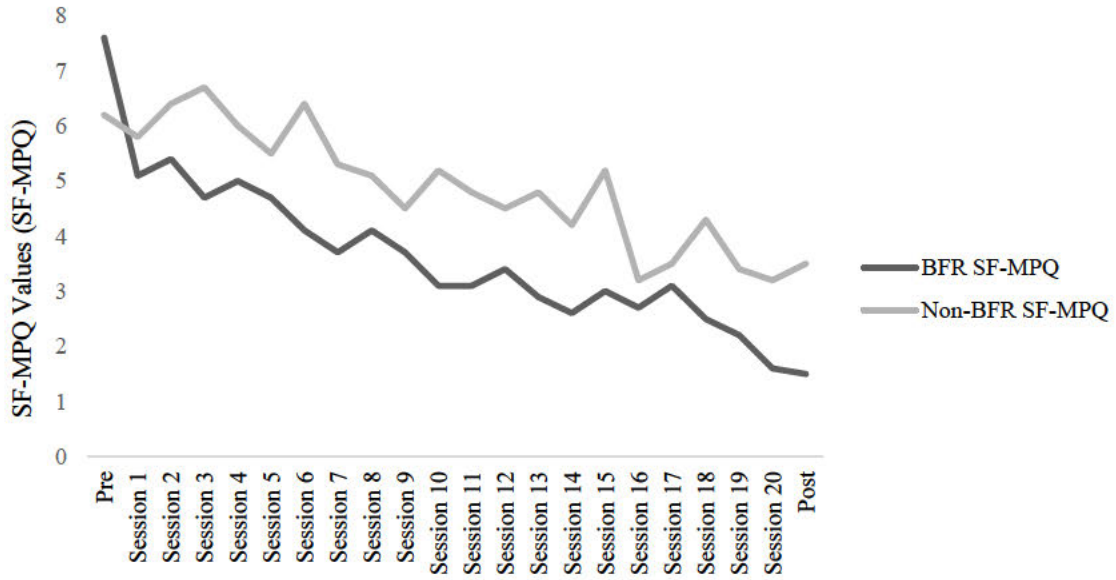


Figure 8. Mean algometer variability across 20 sessions

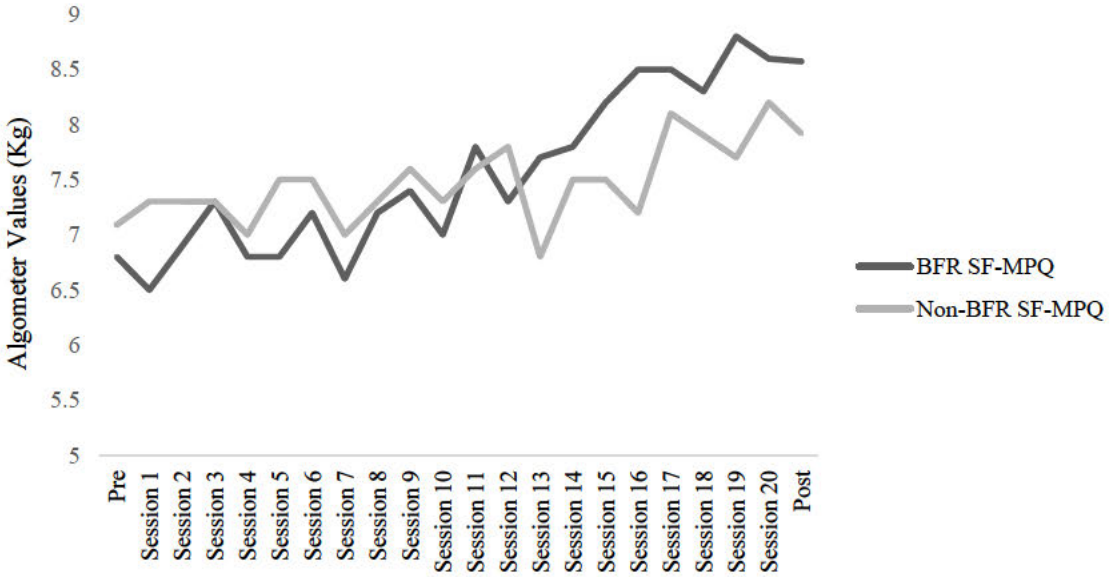
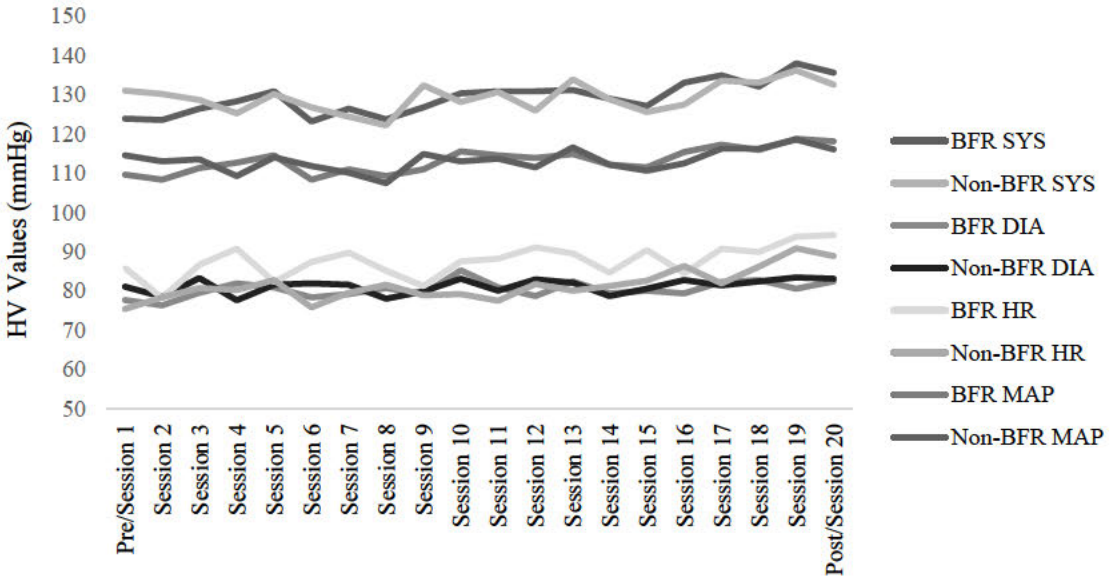


Figure 9. Mean hemodynamic variabilty across 20 sessions



Perceptions of Pain

These results support previous literature, reporting BFR-RE as superior in reducing POP 24-hours post-training in comparison to Non BFR-RE (25,30,95). The extent of improvement across 20 sessions for the BFR-RE group was 80%, 38% greater compared to the Non BFR-

RE group, exceeding EIH values reported in previous and recent BFR-RE literature (34,37). The rationale behind this supreme increased effect could be attributable to the nature of prescribed exercises generally carried out during BFR-RE. As a consequence of patient limitations during rehabilitation, exercise prescription is often open kinetic chain (OKC), isolated and subsequently carried out under minimal load (96). Exercise selection within this study utilised both OKC and closed kinetic chain (CKC) movements, requiring compound muscle recruitment, know to upregulate circulatory blood flow across extremities (97). As previous literature hypothesised, BFR pain inhibition results from interactions between cardiovascular and metabolic musculoskeletal mechanisms (34); therefore, greater muscle contribution may provide enhanced distal EIH effects. Furthermore, the pioneering bilateral occlusion employed presumably contributed to the effectiveness of POP reductions, as double limb occlusion potentially provided twofold efficient metabolic reactions potent enough to travel to the LBP region. Bilateral occlusion is typically exclusive to BFR aerobic exercise, with cuff pressures of >40% LOP utilised (24). Therefore, the higher 80% LOP, bilateral occlusion and continuous cuff application seemingly enhance distal systemic responses (70), with the preceding rationale likely explaining the immediate 32% drop in BFR-RE POP values after just one session, compared to the 6% of the Non-BFR group. The extent of the interventions effectiveness at reducing POP is qualitatively supported with verbal analysis of participants chosen descriptors across the pre - intra - post SF-MPQ's. BFR completely removed LBP described as tender, throbbing, shooting, aching, sharp, stabbing and heavy in 57, 50, 43 and 29% of BFR-RE participants respectively, with 28% of participants reporting partial effectiveness at reducing sharp and aching symptoms by 50%. However, 35% of BFR participants reported no pre - post changes of aching symptoms. Comparatively, 23% of the Non-BFR-RE group had total elimination of the following descriptors pre - post only: tiring-exhausting; tender; and sharp, with 50% reductions to hot-burning; aching; tiring-exhausting;

sickening; heavy; gnawing; and throbbing symptoms for 62% of participants respectively. However, 38% of Non-BFR participants had no changes to aching symptoms also. The following descriptor removals were exclusive to the BFR group: stabbing; gnawing; splitting; and hot-burning, whilst fearful was the only descriptor solely eradicated in the Non-BFR group. When analogous descriptors were used in both groups SF-MPQ's, BFR was 34%, 35%, 28%, 28%, 20%,14% more effective at entirely removing tender; throbbing; shooting; aching; sharp; and heavy descriptors respectively. Interestingly, whilst BFR was more effective at eliminating physical descriptions, when the emotional descriptors tiring-exhausting; sickening; and punishing-cruel were used, Non-BFR was equally as effective pre - post. The is likely a result of RE alone being considered an effective rehabilitative mechanism for a number of psychological conditions, inducing circulatory opioid substances for EIH effects (38,98). Emotional distress is a proven trigger/exacerbator of LBP (99), indicating causal and symptomatic connections to acute or chronic emotional experiences (100). This would help explain the reduced effectiveness in removing vaguer descriptors such as aching, heavy and gnawing, open to interpretation by the sufferer and associated specialist. In an attempt to identify specific correlations between the psychological influence on LBP, future research would benefit from clarifying LBP onset events prior to data collection and implement additional monitoring methods. Furthermore, the stubborn removal of aching symptoms could be attributable to periodisation and programming variables, with extended rehabilitation periods preferable for LBP. Any tissues affected are not guaranteed to completely recover or be restored to standard function within any conventional 6-12-week rehabilitation period, and the associated mechanical and neurological disorders surrounding LBP (15) make direct exercise prescription implausible. Only 5-15% of reported LBP cases are allocated to diagnosable pathological causalities such as discogenic herniations, osteoporotic fractures, vertebral spasms and facet or referred radicular pain (101); therefore, the majority of cases are

unallocated with definitive cause and effect (102,103). This increasing prevalence of NSLBP, corresponds with the rising economic burden LBP places on our healthcare systems (104). Therefore, a logical solution would be the early introduction of back-care awareness amongst children, previously met with encouraging outcomes (105). This seems a sensible route for future research to pursue, as LBP diagnosis is occurring increasingly sooner in younger populations now, compared to 10 years prior (15). Early LBP diagnosis encourages FAM modifications and can induce development of chronic LBP onset (6,9), with POP inhibiting sufferers physical activity levels (5). However, BFR's now confirmed superior effects at reducing POP provide current LBP FAM sufferers and practitioners alike, additional rehabilitation solutions for reducing neuropathic LBP symptoms, nociceptive pain and emotional distress.

Lumbar Pressure Pain Threshold

This research supports previous literature in establishing LBP PPT increases as a result of RE overall (106,107), as no significant BFR-RE effects were demonstrated. However, the assessment of LBP intervention effectiveness using lumbar PPT is one of divided opinion (107), as the use of pain questionnaires appear hierarchical (149). The rationale for no substantial BFR-RE effects, connect with to the POP improvements detected 24 hours post-training using the SF-MPQ. With definitive peripheral hypoalgesia mechanisms still undergoing investigation (34), theorised circulatory EIH effects powerful enough to positively interact with lumbar PPT might be subject to a period of delay. Current theories suspect, circulatory concentrations of endocannabinoids modulate pain receptors at central nervous system sites such as the spine, and elevate circulating quantities using BFR-RE and EIH (39,40). However, RE does not stimulate HV similarly to aerobic exercise (69). Therefore, future BFR-RE research should introduce more strenuous cardiovascular components to LBP

programming, if greater distal hypoalgesia is to be achieved with PPT. Based on LBP guidelines, increasing warm up durations from 5-10 minutes should provide sufficient vascular stimulation, preferably using a seated, less impactful mode of exercise for reduced LBP interference (81). Furthermore, demographics with a history of chronic LBP exhibit characteristic signs of weak gluteal and tight hamstring muscles, subsequently causing posterior inhibition and flexion/facilitation of the hip flexors (108), which causes the erector spinae muscles to create excessive forces within the lumbar spine (13). This posterior hypertonia can affect spinal fascia and increase PPT sensitivity at surrounding areas (109). Therefore, early stages of LBP rehabilitation and exercise induced adjustments in resting muscle tone may induce temporary increases of PPT, which is reflected in the data. Despite no significant differences, PPT continued to rise in both groups overall as the programme progressed and had reductions in PPT at both stages of phase transition (week 7-9 and 15-17). This is consistent with PPT research data (110,111) and provides insight into predictability of PPT fluctuations and rationale for alternative PPT site testing at various rehabilitation stages. However, a consideration for researchers when proposing different PPT testing sites, is extended LBP durations correlate to reductions in PPT sensitivity (110). Different anatomical, ligaments and subcutaneous regions can become desensitized through increased neural transmission stimulating nociceptive pathways (110). Therefore, bilateral and multi-site testing is advocated across diverse spine segments. Furthermore, due to participants arriving in deconditioned states, initial PPT scores may be misleading as to the effectiveness of BFR-RE. This is also reflected in the data, showing immediate increases in PPT sensitivity within the BFR group. Due to BFR's superior effects at inducing hypertrophy using LL-RE (24) and that early participants efforts were modulated using TL at the start of programming, the BFR group would still have created considerable changes to muscle cross sectional area (30). Future research should consider this aspect, when using concurrent BFR-RE and modulated TL.

Hemodynamic Variables

Pre - post analysis was not possible due to Covid-19 interference; therefore, analysis was conducted using pre-session 1-20 readings Findings were consistent with previous overviews of BFR HV literature, demonstrating non-hazardous significant HV increases across 20 sessions (112,113). Bilateral LOP readings were correspondingly similar for both limbs, with average 80% LOP pressures calculated at 164.00 and 164.15 mmHg respectively, with mean differences of 0.8 ± 10 mmHg, indicating precision with the PT and that bilateral BFR limb pressures are comparable. BFR SYS readings elevated greatest (21.1 ± 21.8); however, the effect across time was not significant and can be attributed to the comparable 20mmHg increases associated with whitecoat hypertension (114). Periodisation RPE adherence was deemed successful from HV analysis, with MAP systematically increasing across phases (112.7; 113.6; 117.4 mmHg) and higher HR variability indicating more strenuous exertion values (115). This insignificant HV increase supports future research exploring more intensive bilateral programming methods during BFR-RE, with ischemic preconditioning and reperfusion rationale for LBP demographics. Due to proven effectiveness in surgical settings at promoting analgesia in patients without the use of concurrent exercise, concurrent short duration isometric, resistance or any exercise that targets muscles proximal to the subjects reported origin of pain (24,116) could serve as alternative or progression from this programme.

Considerations

These results must be interpreted with caution and a number of considerations for future research should be borne in mind. BFR-RE research often utilises strength or endurance testing methods to quantify intervention effectiveness (28). However, the undefined clarity surrounding LBP and the predominantly de-conditioned or chronically sedentary

demographics effected (2), indicated analysis and non-strenuous testing procedures were better suited to satisfy LBP health and safety considerations. As such, participant training history and physical capacities were inconsistent, producing variable motor pattern engram abilities, lactate thresholds, dietary, psychological and physical characteristics, all of which are known to interact with LBP in some capacity (4). Something future studies should consider. Furthermore, tremendous vigilance must be present with degenerative or more severe LBP patients, as the hypoalgesia generated from BFR could afford some patients opportunity to exceed their usually painful and symptomatic ranges of motion (ROM). However, by monitoring patient's pain triggers prior to BFR application within the warmup, hazardous ROM can be established and avoided if required at precise stages of rehabilitation.

Conclusion

The study was pioneering for bilateral BFR-RE LBP research and as such, provides foundational evidence and innovative methods that progresses LBP rehabilitation and BFR methodology. These results demonstrate that bilateral LBP BFR-RE is superior at decreasing physical LBP POP, with insignificant HV variability compared to RE and similar effectiveness at reducing emotional LBP POP as RE. Despite RE historically and regularly proven as beneficial for acutely treating and preventing chronic LBP, clinical treatment pathways do not customarily integrate RE as a priority rehabilitation pathway. Therefore, as BFR-RE accelerates perceptual improvements to LBP sensations, with equivalent distal lumbar hypoalgesia effects as RE, this particularly benefits demographics who cannot tolerate load, are troubled by FAM modifications or practitioners looking to integrate RE using an expedited procedure. Therefore, clinical practitioners seeking rehabilitation methods to use with LBP patients should consider implementing BFR concurrently with hip hinge and gluteal development programming, as the minimal risk, removal of FAM manifestations and expedited

results should encourage patients to utilise the benefits of RE using BFR-RE. The findings and recommendations for future research herein, provide reactive and preventative strategies to address LBP and potentially alleviate the economic burden LBP places on our healthcare system and economy.

Author contributions JF contributed to conceptualisation, writing, data analysis and data collection. SP and LH contributed by reviewing research proposals.

Data availability statement The datasets generated and analysed during the study are not publicly available due to the nature of patient confidentiality but are available from the corresponding authors on reasonable request with permission.

Compliance with ethical standards

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Conflicts of interest Jamie Farrell, Dr Stephen Patterson and Dr Luke Hughes have no conflicts of interest that are directly relevant to the content of this article.

Ethical approval and consent to participate Ethical approval for the research was granted by St Mary's University's Ethics Committee. Written informed consent was obtained from each of the participants in compliance with the Declaration of Helsinki (2013).

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Appendices

Signed Ethics Application

St Mary's University Twickenham London

Approval Sheet

Name of proposer(s)	Jamie Farrell
Name of supervisor	Stephen Patterson, Sarah Coakley, Luke Hughes
Programme of study	MSc Strength and Conditioning
Title of project	Effectiveness of a 12-week low back pain rehabilitation protocol with and without blood flow restriction, monitoring proximal hypoalgesia affects from distal bilateral lower limb training with blood flow restriction.

Supervisors, please complete section 1. If approved at level 1, please forward a copy of this Approval Sheet to the Faculty Ethics Representative for their records.

SECTION 1: To be completed by supervisor.			
☐ Approved at Level 1. ☑ Refer to Faculty Ethics Representative for consideration at Level 2 or Level 3.			
Signature of Supervisor (for student research projects):		Date:	

SECTION 2: To be completed by Faculty Ethics Representative.			
☒ Approved at Level 2. ☐ Level 3 consideration is required by Ethics Sub-Committee.			
Signature of Faculty Ethics Representative:		Date:	06/12/19

Infiormation Sheet

The Research Project:

You are being invited to take part in a research project; however, before you decide to participate, it is important you understand the why the study is being conducted and the requirements for participation. Therefore, this document will provide an overview on the essential elements of the study and is intended to guide you in making a decision.

The study will monitor a 12-week low back pain rehabilitation protocol, with and without blood flow restriction, monitoring proximal hypoalgesic effects, haemodynamic variables and perceptions of pain from distal bilateral lower limb training with applied blood flow restriction. The primary purpose of the research is to potentially identify an expedited method of training for low back pain rehabilitation and to theoretically provide further evidence supporting blood flow restrictions peripheral hypoalgesic affects. This could provide valuable data and treatment strategies for practitioners, hopefully diminishing the financial global burdens associated with low back pain and provide sufferers less pain during recovery training.

The study is being organised by myself (Jamie Farrell) with supervision from Stephen Patterson (stephen.patterson@stmarys.ac.uk). The results of the research will be processed with the intention of publication; therefore, signed consent will be required and data will be kept for a period of 10 years. All results will be made available to subjects electronically via email and should the research be accepted into a publication; you will not be identified unless you have given consent. I can be contacted at info@jfpersonalfitness.com or 07710022221 for further information.

Participation Details Of The Research Project:

You have been invited based on your particular highlighted/diagnosed area of low back pain, which for this study includes anybody with any pain located at the posterior of the body from the seventh cervical vertebra to the lowest gluteal fold, with or without radicular neurological pain into one or both lower limbs. Participants are under no obligation to take part and may withdraw at any point by notifying one of the organisers and completing a withdrawal form, subsequently returning it to me via email.

The participant pathway commences with an initial invite to the study, followed by carefully reading and understanding this participation information document. Following this, should the person choose to take part, they will be required to sign the attached consent form and complete the blood flow restriction and physical readiness questionnaires included within the email. From this, exclusion criteria will be determined based on the answers provided and opportunities for any pre-research questions will be available before the study starts on January 6th, 2020 and throughout its duration. The research will last for 12 weeks,

concluding on 27th March 2010. Each session will take 25-30 minutes and attendance will be required twice weekly for the studies duration. During the session participants will be carrying out a low back pain rehabilitation protocol. Each session will systematically consist of a warm-up, followed by a primary high rep hinge movement and three subsequent gluteal development exercises with or without blood flow restriction applied bilaterally via a personalised tourniquet system. At the first session and on the concluding session in week 12, participants will be asked to complete a McGill Pain Questionnaire, providing an articulated interpretation of their current pain levels. Additionally, immediately post each session a pressurised algometer will be place centrally on the subjects lumbar paraspinal region to provide supporting data for perceived pain levels. Subjects will be required to avoid caffeinated products prior to sessions, as haemodynamic variables will be monitored immediately pre and post training sessions using a digital blood pressure monitor. It is essential that participants familiarise themselves with the numerical rating of perceived exertion scale, in order for training sessions to be conducted with the appropriate intensity. Programming will require subjects to stay within the boundaries of session assigned exertion level, taking into account any exercise induced effort and low back pain discomfort.

The risks associated with the research are comparable to those of any exercise regime, including but not limiting to cardiac events and musculoskeletal injuries. Additionally, blood flow restriction stimulates varying degrees of vascular and fibrinolytic changes, with numerous studies identifying safe and effective guidance. Guidelines such as appropriate warm up routines, minimal occlusion times and the completion of the physical activity and blood flow restriction questionnaires significantly reduce the associated risk levels.

All the information collected will be kept strictly confidential and you will not be able to be identified or be identifiable in any reports or publications without your consent. Any data collected about you in the questionnaires will be stored online in a form protected by passwords and other relevant security technology. Additionally, all data will be stored and kept on St Mary's University servers.

You will be given a copy of this form to be kept together with a copy of your consent form. I look forward to hearing from you and am available should you have any questions now or at any point during the study.

-Kind regards-

Jamie Farrell, ASCC, ASCA L CSCS

[redacted]

stephen.patterson@stmarys.ac.uk

Consent Form

St Mary's University Twickenham London

Name of Participant: _____

Title of the project: Effectiveness of a 12-week low back pain rehabilitation protocol with and without blood flow restriction, monitoring proximal hypoalgesia affects from distal bilateral lower limb training with blood flow restriction.

Main investigator and contact details: Jamie Farrell [redacted]

Members of the research team: Jamie Farrell/ Stephen Patterson/ Luke Hughes/ Sarah Coakley

1. I agree to take part in the above research. I have read the Participant Information Sheet which is attached to this form. I understand what my role will be in this research, and all my questions have been answered to my satisfaction.
2. I understand that I am free to withdraw from the research at any time, for any reason and without prejudice.
3. I have been informed that the confidentiality of the information I provide will be safeguarded.
4. I am free to ask any questions at any time before and during the study.
5. I have been provided with a copy of this form and the Participant Information Sheet.

Data Protection: I agree to the University processing personal data which I have supplied. I agree to the processing of such data for any purposes connected with the Research Project as outlined to me.

Name of participant (print)……..

Signed……..…… Date……..
