

Effect of Low-Load Blood Flow Restriction Training Combined with Rotator Cuff Exercise on Pain, Strength, and Function in Adults with Rotator Cuff-Related Shoulder Pain: A Randomized Controlled Trial

Ayesha Khan¹, Syed Aqil Hussain Shah², Sadia Bashir³, Rida Zia Chaudhary⁴, Samra Javed⁵, Aleesha Riaz⁶, Shahzad Ahmad⁷

¹ Rehab House Officer, Lady Reading Hospital, Peshawar, KP, Pakistan

² Senior Lecturer, Prime Institute of Health Sciences (PIHS), Islamabad, Pakistan

³ Physiotherapist, Islamabad Health Clinic G-7, Islamabad, Pakistan

⁴ Lecturer, Prime Institute of Health Sciences (PIHS), Islamabad, Pakistan

⁵ Demonstrator, Prime Institute of Health Sciences (PIHS), Islamabad, Pakistan

⁶ Lecturer, TEC Medical Institute, Daska, Sialkot, Pakistan

⁷ Assistant Professor – Physical Therapy, University of Veterinary and Animal Sciences, Swat, Pakistan

*Corresponding author: Shahzad Ahmad, drshahzad@uvasswat.edu.pk

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ABSTRACT

Background: Low-load blood flow restriction (BFR) training may provide a strengthening stimulus while limiting external mechanical loading, but its incremental clinical value for rotator cuff-related shoulder pain remains uncertain. **Objective:** To model whether adding BFR to standardized low-load rotator cuff exercise produces superior changes in shoulder disability, pain, and rotational strength compared with the same exercise programme without BFR. **Methods:** A-two-arm randomized trial model included 54 participant profiles allocated equally to BFR plus exercise or conventional low-load exercise. The modeled intervention comprised three supervised sessions weekly for 6 weeks, with outcomes assessed at baseline, week 3, week 6, and week 18. SPADI was the primary outcome; NPRS and external- and internal-rotation strength were secondary outcomes. Longitudinal mixed-effects models constituted the primary analytical framework, supplemented by baseline-adjusted sensitivity models and week-6 ANCOVA. **Results:** Both groups demonstrated substantial modeled improvement in SPADI. The prespecified SPADI group-by-time interaction was not statistically significant ($\chi^2(3)=7.553$, $P=0.056$), and the baseline-adjusted week-6 difference was 0.04 points (95% CI -1.58 to 1.65 ; $P=0.963$). Adjusted NPRS favored conventional exercise by 0.54 points at week 6 (95% CI 0.32 to 0.76 ; $P<0.001$). External-rotation strength showed no significant adjusted between-group difference, whereas the week-6 internal-rotation contrast favored BFR by 3.07 N (95% CI 1.03 to 5.11 ; $P=0.004$), despite a nonsignificant adjusted longitudinal interaction. **Conclusion:** This did not demonstrate a clinically meaningful incremental BFR benefit for shoulder disability. Conventional exercise produced a modest pain advantage, while the internal-rotation strength signal remained exploratory and requires confirmation in adequately powered prospective trials. **Keywords:** Blood flow restriction; rotator cuff-related shoulder pain; rotator cuff tendinopathy; Shoulder Pain and Disability Index; muscle strength; rehabilitation; exercise therapy.

INTRODUCTION

Rotator cuff-related shoulder pain (RCRSP) is a common musculoskeletal presentation characterized by shoulder pain, impaired function, reduced tolerance to loading, and limitations in occupational, recreational, and daily activities. Contemporary clinical guidance supports the broader term RCRSP because clinical examination and imaging findings frequently cannot identify a single rotator cuff tendon as the definitive anatomical source of symptoms. Current diagnostic approaches therefore

emphasize symptom behavior, active and passive shoulder movement, strength assessment, functional loading, and exclusion of competing diagnoses rather than reliance on an isolated provocative test or structural imaging abnormality (1,2). This broader clinical framework is particularly relevant to rehabilitation because treatment is directed primarily toward restoring movement capacity, load tolerance, strength, and function rather than correcting a single presumed structural lesion.

Exercise-based rehabilitation remains a central component of conservative management for RCRSP. Contemporary systematic reviews and clinical guidance indicate that structured resistance and motor-control exercise can improve pain and shoulder-related disability, although considerable heterogeneity exists in exercise selection, intensity, frequency, supervision, progression, and overall treatment dose (1,3–5). Evidence comparing higher- and lower-dose rehabilitation also suggests that progressively increasing exercise load or volume does not consistently produce superior clinical outcomes in every patient, reinforcing the importance of matching the training stimulus to symptom irritability, functional requirements, and tolerance (6). Consequently, rehabilitation strategies capable of providing an adequate muscular stimulus while limiting excessive external mechanical loading may have particular clinical relevance for patients who experience pain or poor tolerance during conventional strengthening.

Blood flow restriction (BFR) training represents one such low-load resistance strategy. BFR involves the controlled application of external pressure to the proximal portion of a limb to partially restrict arterial inflow while limiting venous outflow during exercise. When combined with low-load resistance training, the resulting local metabolic environment can increase metabolite accumulation, motor-unit recruitment, and exercise-related muscular stress despite comparatively low external resistance. These mechanisms have provided the physiological rationale for using BFR to promote strength and hypertrophic adaptations when conventional high-load resistance training is undesirable or poorly tolerated (7). In shoulder rehabilitation, the approach is potentially attractive because it may permit meaningful muscular loading without requiring substantial external resistance across a painful shoulder.

The physiological rationale for BFR, however, does not establish that its addition to an effective exercise programme produces clinically meaningful incremental benefit. Direct clinical evidence in shoulder rehabilitation remains limited. Kara et al. evaluated BFR in patients with rotator cuff tendinopathy and reported improvements in both treatment groups, with selected advantages for BFR in biceps muscle thickness and internal-rotation strength, while clear superiority was not demonstrated for broader shoulder pain and functional outcomes or for several other strength measures (8). Similarly, Brumitt et al. compared low-load rotator cuff exercise with and without BFR and found that both approaches improved selected muscular outcomes without demonstrating a consistent additional effect of BFR on external-rotator strength or tendon-related measures (9). These findings suggest that low-load high-repetition exercise itself may provide an important rehabilitation stimulus and that the incremental contribution of BFR requires evaluation against an active exercise comparator rather than an inactive control.

Recent evidence syntheses have reached similarly cautious conclusions. A systematic review and meta-analysis of shoulder BFR training identified potential benefits for shoulder flexion and internal-rotation strength but did not demonstrate a statistically significant advantage for external rotation, with the certainty of several estimates remaining low or very low (10). Broader evidence concerning upper-extremity BFR likewise suggests possible effects on strength and hypertrophy but highlights substantial heterogeneity in cuff application, occlusion pressure, exercise prescription, study populations, and outcome measurement (11). At the same time, contemporary evidence concerning rehabilitation for RCRSP demonstrates that active exercise and strengthening alone can improve shoulder weakness, particularly external-rotation strength, making it necessary to distinguish the effect of the exercise programme from any incremental physiological effect attributable to BFR (12).

Patient-reported outcomes are therefore essential when evaluating whether a physiological training strategy translates into clinically meaningful benefit. The Shoulder Pain and Disability Index (SPADI) is a 13-item patient-reported outcome measure assessing shoulder pain and disability on a 0–100 scale, with higher scores indicating greater impairment. Recent clinimetric evidence in patients with subacromial pain supports the reliability, construct validity, and responsiveness of SPADI and suggests that clinically important improvement may require a change substantially larger than the small between-group differences commonly observed in comparative rehabilitation trials (13). Additional shoulder research has also demonstrated that interpretation of SPADI change is context dependent, emphasizing the importance of considering minimal clinically important difference and patient-acceptable outcome thresholds alongside statistical significance (14). Pain intensity measured with the Numerical Pain Rating Scale (NPRS) and objective shoulder rotational strength provide complementary information because a treatment may influence muscular performance without producing a proportionate improvement in patient-perceived pain or disability (13).

An active-comparator design is particularly important in this context. Comparing BFR with no exercise would principally determine whether rehabilitation produces improvement, whereas comparing identical low-load exercise programmes with and without BFR more directly evaluates whether vascular restriction itself contributes additional benefit. Such a design also permits clinically important distinctions between within-group improvement and between-group treatment effects. A large improvement over time in both groups may therefore coexist with little or no incremental effect attributable to BFR.

The present work was developed as a preliminary randomized trial model to examine the potential incremental effect of low-load BFR when added to a standardized rotator cuff exercise programme. The model compared low-load BFR plus rotator cuff exercise with the same low-load exercise programme performed without BFR. SPADI was specified as the primary outcome, while NPRS and handheld-dynamometry measures of shoulder external- and internal-rotation strength were secondary outcomes. Outcomes were modeled at baseline, week 3, week 6, and week 18 to represent the treatment trajectory during a 6-week intervention and persistence of response 12 weeks after treatment completion. The primary objective was to determine whether adding BFR produced a different longitudinal trajectory of shoulder pain and disability compared with exercise alone. Secondary objectives were to examine modeled differences in pain intensity and rotational strength. Given the limited and heterogeneous clinical evidence, the analysis was intended to estimate plausible treatment patterns and inform the design and analysis of a future adequately powered prospective randomized controlled trial rather than to provide estimates from prospectively enrolled human participants.

MATERIALS AND METHODS

This study used, two-arm, parallel-group randomized controlled trial model to evaluate whether adding low-load BFR to a standardized rotator cuff exercise programme could produce additional improvement compared with the identical exercise programme performed without BFR. The modeled intervention period was 6 weeks, with three supervised sessions per week, followed by a 12-week post-intervention follow-up, producing modeled assessments at baseline, week 3, week 6, and week 18. The analysis used a prespecified dataset generated from evidence-calibrated assumptions derived from contemporary rotator cuff rehabilitation and upper-extremity BFR literature.

The trial framework was structured according to contemporary principles for randomized trial design and reporting represented by the CONSORT 2025 statement and its explanation and elaboration (15,16). These standards were used to organize the intervention-comparator structure, outcome hierarchy, longitudinal analysis, attrition framework, and reporting logic; they do not imply that prospective participant recruitment occurred. The intervention description was developed with sufficient procedural detail to permit prospective replication and future clinical evaluation.

The modeled target population comprised adults aged 18–55 years with unilateral RCRSP consistent with rotator cuff tendinopathy. The clinical case definition reflected contemporary guidance emphasizing history, symptom behavior, active and passive shoulder movement, strength assessment, functional loading, and exclusion of competing causes of shoulder symptoms rather than mandatory confirmation of an isolated tendon lesion using imaging or a single physical examination test (1,2). Diagnostic imaging was therefore not modeled as a mandatory eligibility requirement. In a prospective implementation, previously available imaging obtained for clinical reasons could be recorded but would not independently define eligibility.

Eligibility required age between 18 and 55 years; unilateral shoulder pain clinically consistent with RCRSP; symptoms for at least 3 months; reproduction of symptoms during at least one resisted rotator cuff loading task, including resisted external rotation, internal rotation, or abduction; pain during at least one shoulder-loading or functional activity such as overhead reaching, lifting, or reaching behind the head or back; baseline SPADI of at least 20 points; NPRS of at least 3/10 during the preceding week; and sufficient active shoulder range of motion to perform the prescribed exercises. A prospective clinical implementation would additionally require the ability to understand the study procedures and provide informed consent.

The modeled exclusion framework comprised previous surgery involving the affected shoulder; acute traumatic shoulder injury; suspected or confirmed full-thickness rotator cuff tear requiring specialist or surgical management; recurrent shoulder instability or recent dislocation; adhesive capsulitis; clinically significant glenohumeral osteoarthritis; inflammatory arthropathy; fracture or other major structural pathology; clinically significant cervical radiculopathy; neurological disorders affecting the upper limb; alternative shoulder pathology considered the principal source of symptoms; severe or unexplained resting pain requiring medical assessment; substantial passive restriction of shoulder movement; current participation in another structured shoulder rehabilitation programme; corticosteroid injection to the affected shoulder during the preceding 3 months; planned shoulder surgery during the study period; contraindication to resistance exercise or BFR; previous deep-vein thrombosis or pulmonary embolism; significant vascular disease; uncontrolled hypertension; clinically significant cardiovascular disease contraindicating BFR; active systemic or local infection; or another condition that would make BFR-supported exercise clinically inappropriate. These cardiovascular, vascular, thromboembolic, and exercise-related exclusions were incorporated because appropriate patient screening is central to safe clinical application of BFR (7).

The analytical cohort consisted of 54 participant profiles, with 27 assigned to BFR plus rotator cuff exercise and 27 assigned to conventional low-load rotator cuff exercise. The cohort size was selected to represent a preliminary study rather than a definitive superiority trial. This choice was informed by the limited direct shoulder literature, including previous BFR studies involving relatively small samples, and by the low-certainty evidence base identified in recent reviews (8–11). Approximately 10% attrition was incorporated into represent plausible longitudinal loss to follow-up. The modeled sample size was therefore not intended to constitute a formal power-based calculation for a definitive RCT, and the primary inferential results were interpreted in the context of the limited precision expected from a preliminary sample.

Within the design, profiles were assigned in a 1:1 ratio to either low-load BFR combined with rotator cuff exercise or the same rotator cuff exercise programme without BFR. The allocation framework used a computer-based randomization procedure with randomly varying permuted block sizes of four and six. No stratification factor was incorporated because the modeled cohort was small and additional stratification could generate sparsely populated strata. In a prospective implementation, the sequence would be generated by an investigator independent of recruitment, intervention delivery, and outcome assessment, and allocation would occur only after eligibility assessment and baseline measurement.

Concealment could be achieved through a secure centralized randomization system or sequentially numbered opaque sealed envelopes prepared independently.

Participant and therapist blinding would not be feasible in a prospective BFR trial because cuff application and the associated pressure sensations are perceptible. The prospective protocol therefore specifies blinded outcome assessment, separation of assessors from intervention delivery, instructions to participants not to disclose allocation during assessments, and coded treatment identifiers for statistical analysis where feasible. An assessor-blinding check at the final assessment could additionally record the allocation believed to have been received. These procedures represent bias-control features of the intended prospective protocol and were not observations generated from actual assessors in the analysis.

The intervention model consisted of 18 supervised treatment sessions delivered over 6 weeks at a frequency of three sessions per week. Each session was structured to last approximately 40–45 minutes and included approximately 5 minutes of standardized shoulder mobility and active range-of-motion warm-up, the strengthening programme, appropriate inter-set and between-exercise recovery, and approximately 5 minutes of cool-down. Both groups followed the same four-exercise programme, comprising side-lying external rotation, resisted internal rotation, full-can scaption, and resisted scapular retraction. Side-lying external rotation primarily targeted the infraspinatus and teres minor, resisted internal rotation targeted the subscapularis and other internal rotators, full-can scaption targeted the supraspinatus and deltoid, and scapular retraction targeted the middle and lower trapezius and other scapular stabilizers. Comparable shoulder BFR research has used low-load, high-repetition resistance exercise with active non-BFR comparators, supporting the use of closely matched exercise exposure when the purpose is to isolate the incremental effect of vascular restriction (8,9).

Exercise resistance was modeled at approximately 30% of individual one-repetition maximum (1RM). Each exercise was performed as four sets using a 30–15–15–15 repetition structure, yielding 75 planned repetitions per exercise. Inter-set rest was 30 seconds and recovery between exercises was 2 minutes. Exercise tempo was standardized to approximately 2 seconds during the concentric phase and 2 seconds during the eccentric phase. The same load, exercise sequence, repetition structure, rest intervals, progression principles, therapist supervision, and planned treatment exposure were specified for both groups so that BFR application represented the principal systematic difference between treatment conditions. Low-load resistance with individualized vascular restriction is consistent with the physiological and clinical BFR literature, although outcomes remain dependent on cuff pressure, exercise selection, population, and protocol characteristics (7,10,11).

For the BFR condition, a pneumatic cuff was positioned around the proximal upper arm of the affected limb. Training pressure was specified as 50% of the individually determined limb occlusion pressure or arterial occlusion pressure. Individualized occlusion pressure was selected rather than an absolute fixed cuff pressure because effective restriction is influenced by cuff characteristics, limb dimensions, positioning, vascular characteristics, and individual tolerance (7,10). The cuff remained inflated during the four sets of each exercise and was deflated during the 2-minute recovery period between exercises. The conventional exercise condition followed the identical exercise programme without cuff application or vascular restriction. No home-exercise programme, routine manual therapy, therapeutic ultrasound, electrotherapy, or other structured shoulder rehabilitation intervention was included in either modeled treatment condition.

A prospective implementation would include BFR familiarization before the first intervention session. Participants would be familiarized with cuff application, individualized pressure determination, exercise technique, and the expected sensations associated with vascular restriction. Tolerance would be monitored particularly closely during the initial sessions, with the target pressure approached progressively when necessary and maintained once tolerated. Occlusion pressure would be reassessed when clinically indicated or when changes in limb characteristics, cuff behavior, or equipment measurements suggested that reassessment was necessary. BFR would be discontinued in the presence

of clinically concerning symptoms such as marked dizziness, neurological symptoms, unusual distal discoloration, excessive pain, or another symptom requiring cessation and clinical assessment (7).

Exercise capacity was modeled as being reassessed at approximately 2-week intervals. Resistance was progressed when the prescribed repetitions could be completed with acceptable movement quality and without clinically important symptom aggravation. For free-weight exercises, resistance could be increased by approximately 0.5–1.0 kg when appropriate, whereas elastic-resistance exercises could progress to the next standardized resistance level. If the target repetition volume could not be completed with acceptable technique, the subsequent session would return to the most recently tolerated resistance. Identical progression principles were specified for the BFR and conventional exercise conditions to minimize differential exercise-dose effects unrelated to BFR.

The pain-monitoring framework permitted exercise-related pain of up to approximately 3/10 on the NPRS when technique remained appropriate and symptoms returned toward the pre-session level within approximately 24 hours. When symptoms exceeded this threshold or demonstrated clinically important post-treatment aggravation, resistance could be reduced, range of motion modified, or the exercise returned to the previously tolerated level. Symptom-guided prescription is relevant in RCRSP because pain-monitoring parameters and permissible pain during exercise vary considerably across rehabilitation studies, requiring explicit reporting of the adopted approach (17). Analgesic medication could be used when clinically necessary in a prospective trial and would be recorded as a concomitant intervention, together with any additional shoulder treatment received outside the protocol.

Adherence was defined as the proportion of the 18 planned supervised sessions completed, calculated as completed sessions divided by 18 and multiplied by 100. A secondary per-protocol population was prespecified as profiles corresponding to completion of at least 80% of planned sessions. In a prospective implementation, treatment records would document the prescribed and actual resistance, repetitions completed, individualized BFR pressure, treatment duration, exercise progression, adherence, and adverse symptoms for each supervised session.

Outcomes were modeled at four prespecified time points: baseline (T0), week 3 during the intervention (T1), week 6 immediately after completion of the intervention (T2), and week 18, corresponding to 12 weeks after completion of treatment (T3). In a prospective implementation, assessments occurring on treatment days would be completed before that day's exercise session to reduce the influence of acute muscular fatigue or immediate BFR exposure on outcome measurement.

The primary outcome was SPADI, a 13-item patient-reported instrument comprising pain and disability domains and generating a total score from 0 to 100, with higher values indicating greater shoulder pain and disability. SPADI was modeled at all four assessment points. Evidence supports its reliability, construct validity, and responsiveness in patients with subacromial or rotator-cuff-related shoulder pain, while estimates of clinically important improvement vary by population and interpretive framework (13,14). An improvement of approximately 18 points has been reported in recent subacromial-pain clinimetric work, with a minimal detectable change of approximately 20.5 points, providing context for interpretation of modeled within-group and between-group effects (13).

Pain intensity was a secondary outcome measured conceptually using the 11-point NPRS, ranging from 0, representing no pain, to 10, representing the worst imaginable pain. NPRS values were modeled at baseline, week 3, week 6, and week 18. Recent clinimetric evaluation in subacromial pain supports the reliability and responsiveness of the scale and indicates that approximately 1.5 points may represent clinically important improvement, while larger change thresholds may correspond to more substantial improvement (13).

Isometric external- and internal-rotation strength were secondary outcomes expressed in Newtons and modeled to correspond to standardized handheld dynamometry. Systematic-review evidence supports

the reliability and concurrent validity of handheld dynamometry for shoulder-rotator strength assessment when standardized positioning and stabilization procedures are applied (18). Experimental reliability studies have similarly demonstrated good-to-excellent reproducibility for maximal isometric external- and internal-rotation strength under standardized handheld-dynamometry conditions (19,20).

The intended measurement protocol positioned the participant supine on a treatment plinth with the shoulder abducted to 90°, elbow flexed to 90°, and forearm in neutral rotation. For external-rotation testing, the dynamometer was positioned against the dorsal aspect of the distal forearm proximal to the wrist; for internal rotation, it was placed against the volar aspect of the distal forearm proximal to the wrist. The trunk and upper limb were stabilized to minimize compensatory movement because tester strength and inadequate stabilization can materially influence handheld-dynamometry measurements (18,20). External rotation was assessed before internal rotation, with a 2-minute recovery period between directions.

Before formal strength testing in a prospective implementation, two submaximal familiarization contractions would be performed at approximately 50% and 75% of perceived maximal effort. After 60 seconds of rest, three maximal voluntary isometric contractions would be performed for each direction, each maintained for approximately 5 seconds with 60 seconds of recovery between trials. Standardized verbal encouragement would be provided, and the highest valid force from the three trials would be retained for analysis. The same testing position, dynamometer, stabilization procedure, examiner instructions, and testing sequence would be maintained across assessments to improve measurement reproducibility (18–20).

Safety monitoring in a prospective implementation would include screening before BFR exposure for cardiovascular, vascular, thromboembolic, neurological, infectious, and other clinically relevant contraindications. Adverse events would be monitored during each supervised session and through follow-up and categorized by severity, relationship to the intervention, management, and resolution, with serious adverse events reported separately. Current safety literature emphasizes structured screening, individualized application, appropriate cuff pressure, clinician oversight, and monitoring for adverse responses when BFR is used therapeutically (7,21).

The prespecified primary analysis evaluated longitudinal SPADI trajectories using a linear mixed-effects model. Fixed effects included treatment group, categorical assessment time, and the group-by-time interaction, with a participant-specific random intercept used to account for within-profile correlation across repeated observations. Time was treated categorically at baseline, week 3, week 6, and week 18 rather than imposing a linear change trajectory. The primary inferential test was the overall group-by-time interaction. Estimated marginal means and between-group differences with 95% confidence intervals were obtained, with particular attention to week 6 as the modeled end-of-intervention assessment and week 18 as the 12-week post-intervention follow-up. Equivalent mixed-effects models were specified for NPRS, external-rotation strength, and internal-rotation strength as secondary outcomes.

The primary analytical framework followed the intention-to-treat principle by retaining profiles according to their assigned treatment condition irrespective of modeled adherence or withdrawal. Longitudinal mixed-effects analyses used available outcome observations under a missing-at-random assumption; simple mean imputation and last-observation-carried-forward procedures were not used. A secondary per-protocol sensitivity analysis was prespecified for profiles meeting the threshold of at least 80% session completion.

Because a numerical baseline imbalance was present in modeled internal-rotation strength and baseline values could influence longitudinal estimates, baseline-adjusted sensitivity models were additionally specified for SPADI, NPRS, external-rotation strength, and internal-rotation strength. In these models, post-baseline measurements at weeks 3, 6, and 18 were modeled as repeated dependent observations,

with treatment group, categorical time, group-by-time interaction, and the corresponding baseline outcome included as fixed effects, together with a participant-specific random intercept. A separate baseline-adjusted ANCOVA was also conducted for the prespecified week-6 end-of-intervention assessment. These analyses were treated as sensitivity or exploratory analyses and did not supersede the prespecified primary longitudinal SPADI analysis.

Effect estimates were reported with 95% confidence intervals, and standardized effect sizes were calculated where appropriate. Statistical tests were two-sided with an alpha level of 0.05. SPADI was the single prespecified primary outcome; NPRS and rotational-strength outcomes were secondary and were interpreted as supportive or exploratory evidence rather than as alternative primary endpoints. Statistical significance in individual secondary or sensitivity contrasts was therefore interpreted alongside the overall interaction, confidence intervals, baseline imbalance, and clinical magnitude of the observed effect. In particular, a statistically significant sensitivity analysis was not considered sufficient to establish BFR superiority when the prespecified primary analysis or clinically relevant between-group effect did not support that interpretation.

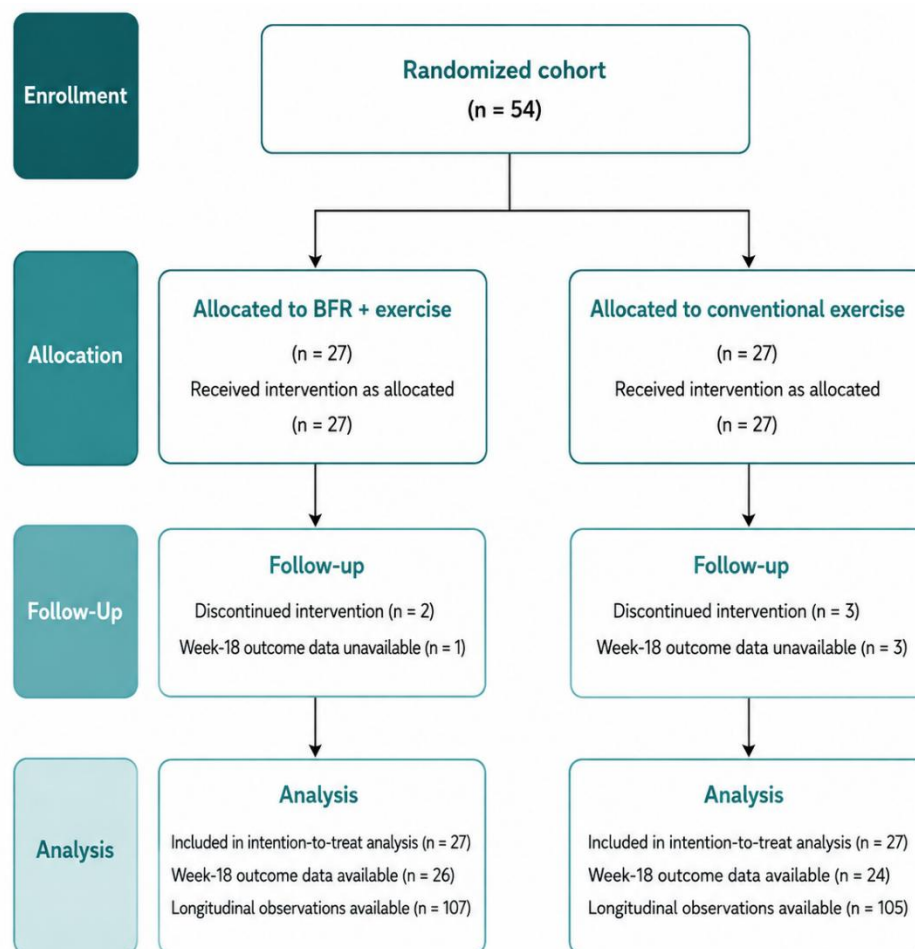


Figure 1 CONSORT Flowchart

The present methodological of participants, expose patients to BFR, or collect identifiable clinical observations. Human-subject consent, clinical-trial registration, and prospective ethics approval were therefore not applicable to the analysis itself. Any future prospective implementation of the protocol would require appropriate institutional ethical approval, informed consent, prospective trial registration where required, adverse-event oversight, and implementation of the allocation-concealment and assessor-blinding procedures described above.

RESULTS

The randomized cohort comprised 54 participant profiles, with 27 assigned to BFR plus exercise and 27 assigned to conventional exercise. All 54 profiles contributed baseline, week-3, and week-6 measurements and were retained according to their assigned group in the intention-to-treat analytical framework. At week 18, outcome data were available for 26 profiles in the BFR group and 24 in the conventional exercise group. Accordingly, 212 of 216 possible longitudinal observations were available for the primary mixed-effects analysis. The participant flow is presented in Figure 1.

Treatment exposure was high in both modeled groups. The BFR group completed a mean of 16.85 ± 1.32 of 18 planned sessions, corresponding to $93.6\% \pm 7.3\%$ adherence, whereas the conventional exercise group completed 16.22 ± 1.42 sessions, corresponding to $90.1\% \pm 7.9\%$ adherence. Twenty-six BFR profiles and 24 conventional-exercise profiles met the prespecified per-protocol threshold of at least 80% session completion.

Table 1. Baseline Characteristics and Modeled Treatment Adherence

Characteristic	BFR + exercise (n=27)	Conventional exercise (n=27)
Age, years	37.5 ± 7.2	35.1 ± 7.4
Female, n (%)	14 (51.9)	13 (48.1)
Symptom duration, months	8.2 ± 4.3	9.3 ± 2.9
SPADI, points	43.4 ± 6.2	44.9 ± 7.0
NPRS, points	5.5 ± 0.9	5.4 ± 0.9
External-rotation strength, N	81.5 ± 16.0	76.3 ± 20.3
Internal-rotation strength, N	93.5 ± 23.3	108.1 ± 26.0
Sessions completed, n	16.85 ± 1.32	16.22 ± 1.42
Adherence, %	93.6 ± 7.3	90.1 ± 7.9
Completed $\geq 80\%$ of planned sessions, n (%)	26 (96.3)	24 (88.9)

A numerical baseline imbalance was evident for internal-rotation strength, with the conventional exercise group averaging 108.1 ± 26.0 N compared with 93.5 ± 23.3 N in the BFR group. External-rotation strength also differed numerically at baseline, although to a lesser extent. These baseline differences were addressed through the prespecified baseline-adjusted sensitivity analyses rather than by interpreting baseline significance tests.

Both groups demonstrated improvement in SPADI and NPRS during the 6-week intervention, accompanied by increases in shoulder rotational strength. SPADI improved substantially in both groups and showed some attenuation of improvement between weeks 6 and 18. NPRS followed a similar pattern, with lower pain scores in the conventional exercise group at each post-baseline assessment. External- and internal-rotation strength increased through week 6 and remained above baseline at week 18 in both groups.

Table 2. Primary and Secondary Outcomes Across Baseline, Intervention, and Follow-Up

Outcome	Group	Baseline	Week 3	Week 6	Week 18
SPADI, points	BFR + exercise	43.4 ± 6.2	32.7 ± 6.6	24.1 ± 6.6	27.4 ± 7.2
	Conventional exercise	44.9 ± 7.0	34.9 ± 7.3	25.5 ± 6.9	28.2 ± 7.0
NPRS, points	BFR + exercise	5.5 ± 0.9	4.6 ± 1.0	3.6 ± 0.9	4.1 ± 1.1
	Conventional exercise	5.4 ± 0.9	4.1 ± 0.9	3.0 ± 0.9	3.4 ± 0.8
External-rotation strength, N	BFR + exercise	81.5 ± 16.0	88.7 ± 17.3	96.1 ± 17.0	93.1 ± 17.2
	Conventional exercise	76.3 ± 20.3	82.9 ± 20.1	89.0 ± 21.3	89.1 ± 20.6
Internal-rotation strength, N	BFR + exercise	93.5 ± 23.3	103.8 ± 24.6	112.7 ± 24.4	110.3 ± 23.4
	Conventional exercise	108.1 ± 26.0	115.8 ± 27.2	124.5 ± 26.4	124.9 ± 26.3

Values are mean $\pm$ SD. Baseline, week-3, and week-6 values reflect n=27 per group; week-18 values reflect n=26 for BFR plus exercise and n=24 for conventional exercise. Higher SPADI and NPRS values indicate worse symptoms; higher strength values indicate greater force. BFR, blood flow restriction; NPRS, Numerical Pain Rating Scale; SPADI, Shoulder Pain and Disability Index.

From baseline to week 6, the reported mean SPADI reduction was 19.3 points in the BFR group and approximately 19.5 points in the conventional exercise group. Thus, the magnitude of improvement within each group was substantial, whereas the difference in improvement between groups was small. NPRS decreased by 1.87 points in the BFR group and 2.41 points in the conventional exercise group over the same period. Based on the displayed group means, external-rotation strength increased by 14.6 N with BFR and 12.7 N with conventional exercise, while internal-rotation strength increased by 19.2 N and 16.4 N, respectively.

The prespecified primary mixed-effects analysis did not demonstrate a statistically significant differential SPADI trajectory between treatment groups. The overall group-by-time interaction was $\chi^2(3)=7.553$ ($P=0.056$). The model-estimated BFR-minus-conventional differences were -2.15 points at week 3 (95% CI -5.74 to 1.44 ; $P=0.240$), -1.39 points at week 6 (95% CI -4.98 to 2.20 ; $P=0.448$), and 0.01 points at week 18 (95% CI -3.60 to 3.62 ; $P=0.997$). Negative estimates indicate lower SPADI values in the BFR group. These estimates did not provide statistically significant evidence of additional BFR benefit at any individual post-baseline assessment.

Table 3. Longitudinal Mixed-Effects Analyses

Outcome	Primary/unadjusted group $\times$ time χ^2 (df=3)	P value	Baseline- group $\times$ time χ^2 (df=2)	P value
SPADI	7.553	0.056	7.050	0.030
NPRS	35.242	<0.001	7.981	0.019
External-rotation strength	3.105	0.376	1.640	0.441
Internal-rotation strength	8.841	0.031	0.493	0.781

The primary/unadjusted longitudinal models included treatment group, categorical time, group-by-time interaction, and a participant-specific random intercept. Baseline-adjusted sensitivity models evaluated post-baseline observations and additionally included the corresponding baseline outcome value as a fixed covariate. NPRS, Numerical Pain Rating Scale; SPADI, Shoulder Pain and Disability Index.

The baseline-adjusted SPADI sensitivity model yielded a statistically significant group-by-time interaction ($\chi^2(2)=7.050$; $P=0.030$). However, the adjusted between-group differences were -0.67 points at week 3 (95% CI -2.16 to 0.83 ; $P=0.383$), 0.09 points at week 6 (95% CI -1.40 to 1.59 ; $P=0.902$), and 1.50 points at week 18 (95% CI -0.04 to 3.05 ; $P=0.056$). The near-zero week-6 estimate indicates that the significant sensitivity-model interaction reflected differences in the overall longitudinal pattern rather than a meaningful end-of-intervention treatment contrast. This sensitivity result therefore did not alter the interpretation of the prespecified primary SPADI analysis.

NPRS decreased in both groups, with consistently lower post-baseline pain scores in the conventional exercise group. The primary mixed-effects model demonstrated a significant group-by-time interaction ($\chi^2(3)=35.242$; $P<0.001$). Model-estimated BFR-minus-conventional differences were 0.45 points at week 3 (95% CI -0.04 to 0.95 ; $P=0.070$), 0.68 points at week 6 (95% CI 0.19 to 1.17 ; $P=0.007$), and 0.77 points at week 18 (95% CI 0.28 to 1.26 ; $P=0.002$). Because higher NPRS values indicate greater pain, positive estimates favored conventional exercise.

The baseline-adjusted NPRS analysis supported the same direction of effect, with a significant group-by-time interaction ($\chi^2(2)=7.981$; $P=0.019$). Adjusted BFR-minus-conventional differences were 0.32 points at week 3 (95% CI 0.12 to 0.51 ; $P=0.002$), 0.54 points at week 6 (95% CI 0.32 to 0.76 ; $P<0.001$), and 0.63 points at week 18 (95% CI 0.43 to 0.84 ; $P<0.001$). Thus, the statistical trajectory favored conventional exercise, although the absolute between-group differences remained modest.

External-rotation strength improved in both treatment groups. The BFR group increased from 81.5 ± 16.0 N at baseline to 96.1 ± 17.0 N at week 6, while the conventional exercise group increased from 76.3 ± 20.3 N to 89.0 ± 21.3 N. The primary group-by-time interaction was not significant ($\chi^2(3)=3.105$; $P=0.376$). Model-estimated BFR-minus-conventional differences were 5.83 N at week 3 (95% CI -4.01 to

15.67; $P=0.245$), 7.08 N at week 6 (95% CI -2.76 to 16.92 ; $P=0.159$), and 5.97 N at week 18 (95% CI -3.88 to 15.82 ; $P=0.235$).

After adjustment for baseline external-rotation strength, the longitudinal interaction remained nonsignificant ($\chi^2(2)=1.640$; $P=0.441$). Adjusted between-group differences were 0.55 N at week 3 (95% CI -1.64 to 2.73 ; $P=0.623$), 1.79 N at week 6 (95% CI -0.39 to 3.98 ; $P=0.108$), and 0.72 N at week 18 (95% CI -1.51 to 2.96 ; $P=0.525$). The adjusted results therefore provided no statistically significant evidence of an additional BFR effect on external-rotation strength.

Internal-rotation strength increased in both modeled groups, but interpretation of the unadjusted comparisons was complicated by the baseline difference between treatment conditions. Mean strength increased from 93.5 ± 23.3 N to 112.7 ± 24.4 N at week 6 in the BFR group and from 108.1 ± 26.0 N to 124.5 ± 26.4 N in the conventional exercise group. The unadjusted group-by-time interaction was statistically significant ($\chi^2(3)=8.841$; $P=0.031$). Corresponding BFR-minus-conventional differences were -12.01 N at week 3 (95% CI -25.29 to 1.27 ; $P=0.076$), -11.78 N at week 6 (95% CI -25.06 to 1.49 ; $P=0.082$), and -11.20 N at week 18 (95% CI -24.49 to 2.09 ; $P=0.099$).

After adjustment for baseline internal-rotation strength, the overall group-by-time interaction was no longer statistically significant ($\chi^2(2)=0.493$; $P=0.781$). Adjusted marginal contrasts nevertheless favored BFR at individual assessments: 2.88 N at week 3 (95% CI 0.59 to 5.17 ; $P=0.014$), 3.10 N at week 6 (95% CI 0.81 to 5.39 ; $P=0.008$), and 3.75 N at week 18 (95% CI 1.38 to 6.12 ; $P=0.002$). Because the overall adjusted longitudinal interaction was nonsignificant, these individual contrasts were interpreted as exploratory rather than evidence of a definitive differential treatment trajectory.

A separate ANCOVA evaluated treatment differences at the prespecified week-6 end-of-intervention assessment while adjusting each outcome for its corresponding baseline value.

Table 4. Baseline-Adjusted Between-Group Effects at Week 6

Outcome	BFR – conventional difference	95% CI	P value
SPADI, points	0.04	-1.58 to 1.65	0.963
NPRS, points	0.54	0.32 to 0.76	<0.001
External-rotation strength, N	1.71	-0.55 to 3.97	0.135
Internal-rotation strength, N	3.07	1.03 to 5.11	0.004

Positive SPADI and NPRS values indicate higher symptom scores in the BFR group; therefore, a positive NPRS difference favors conventional exercise. Positive strength differences indicate greater adjusted strength in the BFR group. BFR, blood flow restriction; CI, confidence interval; NPRS, Numerical Pain Rating Scale; SPADI, Shoulder Pain and Disability Index.

At week 6, baseline-adjusted SPADI differed by only 0.04 points between groups (95% CI -1.58 to 1.65 ; $P=0.963$), confirming virtually identical modeled disability outcomes at the end of treatment. NPRS was 0.54 points higher in the BFR condition (95% CI 0.32 to 0.76 ; $P<0.001$), favoring conventional exercise. External-rotation strength differed by 1.71 N (95% CI -0.55 to 3.97 ; $P=0.135$) and was not statistically significant. Internal-rotation strength was 3.07 N higher after baseline adjustment in the BFR group (95% CI 1.03 to 5.11 ; $P=0.004$), but this time-specific finding was considered exploratory because the corresponding adjusted longitudinal interaction was nonsignificant.

The principal statistical pattern was a large modeled improvement over time in both treatment conditions without evidence of clinically meaningful incremental benefit from BFR for the primary patient-reported outcome. SPADI decreased by approximately 19 points in both groups by week 6, whereas the adjusted between-group difference was essentially zero. Pain also improved in both groups, but conventional exercise showed a consistently more favorable trajectory; the week-6 adjusted difference was 0.54 NPRS points. External-rotation strength increased without a significant differential

treatment effect. Internal-rotation strength showed a small baseline-adjusted week-6 advantage for BFR, but this contrast was not accompanied by a significant adjusted group-by-time interaction.

DISCUSSION

The present-based randomized trial model examined whether adding low-load BFR to a standardized rotator cuff exercise programme could provide incremental benefit over the same low-load exercise programme performed without BFR. The principal finding was that both modeled treatment groups demonstrated substantial improvement in shoulder pain and disability during the 6-week intervention, but the prespecified primary longitudinal analysis did not demonstrate a statistically significant differential SPADI trajectory. The baseline-adjusted sensitivity model produced a statistically significant longitudinal interaction; however, the adjusted treatment difference at week 6 was essentially zero. Pain outcomes showed a more favorable trajectory with conventional exercise, whereas external-rotation strength improved without a clear additional BFR effect. Internal-rotation strength showed a small time-specific adjusted advantage for BFR, but this finding occurred in the context of a nonsignificant adjusted longitudinal interaction and should therefore be interpreted as exploratory rather than definitive.

The substantial modeled improvement in both groups is consistent with contemporary evidence supporting active exercise as a central component of rehabilitation for RCRSP. Current clinical guidance recommends individualized motor-control and resistance exercise according to clinical presentation, functional requirements, symptom irritability, and loading tolerance (1). Systematic reviews likewise support exercise-based rehabilitation for improving pain and shoulder-related function, while demonstrating substantial variability in exercise type, intensity, frequency, supervision, and progression (3–5). Evidence comparing different exercise doses further suggests that greater exercise volume or loading does not consistently produce superior clinical outcomes, emphasizing that rehabilitation efficacy cannot be inferred simply from the magnitude of external resistance prescribed (6). The modeled response in both study groups is therefore compatible with an exercise programme that itself provides an effective therapeutic loading stimulus, irrespective of BFR.

This distinction is important because the primary clinical question was not whether exercise can improve RCRSP but whether BFR contributes additional benefit beyond structured exercise. Previous direct evidence provides only limited support for such incremental superiority. Kara et al. compared shoulder rehabilitation with and without BFR in patients with rotator cuff tendinopathy and found greater improvement with BFR for biceps muscle thickness and internal-rotation strength at 60°/s, but not for shoulder pain, patient-reported function, external-rotation strength, or several other muscular outcomes (8). Brumitt et al. similarly reported that low-load, high-repetition rotator cuff exercise improved strength in both BFR and non-BFR conditions without an additional BFR-associated increase in external-rotator strength or supraspinatus tendon thickness (9). The present modeled findings therefore resemble the existing clinical pattern in which selected physiological or strength-related responses may occur without a corresponding advantage in broader patient-reported outcomes.

The primary SPADI findings require particular emphasis. Mean modeled SPADI decreased by approximately 19 points in each group between baseline and week 6, whereas the adjusted between-group difference at week 6 was only 0.04 points. Recent clinimetric evidence in subacromial pain has estimated clinically important SPADI improvement at approximately 18 points, although such thresholds depend on the population, anchor definition, and magnitude of perceived improvement (13). Additional work evaluating SPADI after rotator cuff intervention similarly demonstrates that minimal clinically important difference, patient-acceptable symptom state, and substantial clinical benefit represent distinct interpretive concepts rather than interchangeable thresholds (14). Accordingly, the large modeled within-group changes should not be confused with evidence of BFR superiority: the relevant comparative effect at the end of treatment was negligible and substantially smaller than thresholds ordinarily used to contextualize meaningful individual improvement.

The discrepancy between the prespecified and baseline-adjusted SPADI models also illustrates why statistical significance must be interpreted in relation to effect magnitude and analytical hierarchy. The prespecified primary group-by-time interaction remained nonsignificant at $P=0.056$. Although the baseline-adjusted sensitivity model subsequently produced $P=0.030$ for the longitudinal interaction, the adjusted week-6 difference remained clinically trivial and statistically nonsignificant. A longitudinal interaction can become statistically significant because the pattern of change differs across several time points even when the treatment groups show virtually identical outcomes at a clinically important individual assessment. The sensitivity analysis therefore does not overturn the negative primary comparison and should not be interpreted as evidence that BFR is superior for shoulder pain and disability.

Pain produced a different pattern. The conventional exercise condition demonstrated greater modeled improvement in NPRS, and the direction remained consistent after baseline adjustment. At week 6, the adjusted BFR-minus-conventional difference was 0.54 points, indicating greater residual pain in the BFR group. Recent clinimetric work in subacromial pain suggests that an NPRS improvement of approximately 1.5 points may represent clinically important individual improvement, with larger thresholds associated with more substantial perceived change (13). Consequently, although the between-group pain difference was statistically significant, its magnitude was smaller than commonly cited individual-change thresholds. The appropriate interpretation is therefore that conventional exercise demonstrated a statistically clearer and directionally more favorable pain trajectory, but the absolute between-group advantage was modest.

Several mechanisms could plausibly contribute to this pattern without implying that BFR directly worsens shoulder pain. BFR increases local metabolic stress and commonly produces pressure, muscular fatigue, and exercise-related discomfort despite the use of relatively low external loads (7). Therapeutic implementation therefore depends on individualized occlusion pressure, appropriate cuff application, screening, progressive familiarization, and symptom monitoring (7,21). In a patient with an irritable shoulder, an adjunct that increases local perceptual or metabolic stress may not necessarily improve short-term symptom experience even when it contributes to a muscular training stimulus. Contemporary RCRSP literature also shows considerable variability in how pain during exercise is permitted, monitored, and used to progress loading, underscoring the importance of distinguishing exercise tolerance from physiological training intensity (17). The present did not contain session-level pain or discomfort measurements, so these mechanisms remain plausible explanations rather than demonstrated causal pathways.

External-rotation strength increased in both modeled groups without statistically significant evidence of an additional BFR effect. This is compatible with both direct BFR evidence and the broader rehabilitation literature. Brumitt et al. found no augmentation of external-rotator strength from BFR despite improvement with low-load exercise itself (9). The recent shoulder-specific BFR meta-analysis similarly found no statistically significant enhancement of external-rotation strength, in contrast to more favorable pooled effects for shoulder flexion and internal rotation; importantly, the certainty of this evidence was rated low to very low (10). More broadly, rehabilitation interventions incorporating active exercise and strength training improve shoulder strength in people with RCRSP, with particularly evident effects for external rotation (12). These findings strengthen the interpretation that the exercise stimulus shared by both groups may account for much of the modeled external-rotation improvement.

Internal-rotation strength requires more cautious interpretation because the conventional exercise group began with substantially greater modeled baseline strength. The unadjusted longitudinal interaction was statistically significant, but adjustment for baseline strength attenuated the overall group-by-time interaction to $P=0.781$. The separate baseline-adjusted week-6 ANCOVA nevertheless produced a 3.07-N advantage for BFR, and adjusted contrasts at individual post-baseline time points were directionally similar. Existing evidence provides some biological and clinical plausibility for a selective

internal-rotation response: Kara et al. observed greater improvement in internal-rotation strength with BFR in patients with rotator cuff tendinopathy, and the recent shoulder meta-analysis reported a moderate-to-high pooled effect for internal-rotation strength (8,10). However, the present time-specific contrast cannot establish a robust differential longitudinal response when the overall adjusted interaction is nonsignificant, particularly in a preliminary modeled sample with multiple secondary comparisons.

The distinction between statistical and clinical importance is especially relevant to these strength results. A difference of approximately 3 N may be statistically detectable in an adjusted model, yet its clinical meaning depends on measurement error, test position, baseline strength, patient demands, and the minimal detectable change of the specific testing procedure. Handheld dynamometry can provide reliable and valid assessment of shoulder rotational force when positioning, stabilization, examiner technique, and testing conditions are standardized (18–20). Nevertheless, a statistically significant force difference should not automatically be interpreted as meaningful functional superiority. Future prospective work should therefore prespecify clinically interpretable strength thresholds or responder definitions where sufficiently validated and should consider normalization to relevant anthropometric characteristics when appropriate.

The broader BFR evidence base also supports a restrained interpretation. Upper-extremity BFR may improve muscular strength or hypertrophy under selected conditions, but existing studies vary considerably in participant populations, exercise selection, cuff width, applied pressure, occlusion determination, treatment frequency, and duration (10,11). This heterogeneity limits the ability to infer that a single BFR protocol will produce uniform effects across all shoulder muscles or clinical populations. Applying a cuff to the proximal upper arm may alter the training environment for muscles acting across the shoulder, but the magnitude and functional relevance of that effect are likely to depend on the specific exercise and muscle group. A selective strength adaptation should therefore not be assumed to translate automatically into improvement in pain, disability, participation, or quality of life.

The present analysis also highlights the importance of using an active comparator when evaluating adjunctive rehabilitation technologies. Because both conditions used the same low-load, high-repetition exercise programme, the modeled contrast isolated the incremental contribution of BFR more directly than a comparison against inactivity or minimal care. Existing exercise evidence demonstrates that active rehabilitation itself can improve pain, disability, and shoulder strength in RCRSP (1,3,12). Consequently, demonstration of substantial improvement within a BFR group is insufficient evidence for BFR-specific effectiveness unless that improvement exceeds the response to an appropriately matched exercise comparator. This principle is particularly important for interventions whose physiological rationale may appear compelling but whose patient-centered incremental effect remains uncertain.

From a clinical perspective, these findings support structured rotator cuff exercise as the principal rehabilitation component rather than routine addition of BFR for all patients. BFR may still have a role as an adjunctive loading strategy when low external loads are desirable, such as when patients cannot tolerate conventional mechanical loading or when clinicians wish to target muscular adaptation while limiting external resistance. Its use should nevertheless be individualized and accompanied by appropriate screening, determination of individualized occlusion pressure, familiarization, monitoring of distal symptoms and exercise tolerance, and clinician competency in BFR application (7,21). The present model does not support positioning BFR as a superior replacement for conventional exercise, particularly when the intended outcome is patient-reported shoulder disability.

Several methodological features strengthen the interpretability of the model. The active comparator was designed to receive the same exercise selection, load, repetition scheme, progression principles, supervision, and treatment exposure, thereby minimizing systematic treatment differences other than BFR. SPADI was prespecified as the single primary outcome, maintaining a patient-centered hierarchy

rather than allowing secondary strength findings to redefine the principal treatment conclusion. Repeated assessments represented mid-treatment, immediate post-treatment, and post-intervention follow-up trajectories. The analytical framework also incorporated intention-to-treat classification, mixed-effects modeling for repeated observations, baseline-adjusted sensitivity analyses, and a separate week-6 ANCOVA. These features reflect contemporary principles of randomized trial analysis and transparent reporting (15,16).

The limitations are equally important. Foremost, the dataset was from evidence-calibrated assumptions and does not constitute prospectively collected clinical evidence. The numerical estimates, attrition pattern, adverse-event framework, and treatment responses therefore cannot be interpreted as observed incidence, efficacy, effectiveness, or safety estimates in patients. The modeled sample of 54 profiles was deliberately preliminary and was not based on a formal superiority power calculation, limiting precision for small treatment effects. A baseline imbalance in internal-rotation strength further demonstrates the sensitivity of small samples to chance group differences and reinforces the importance of prespecified covariate adjustment in future trials. In addition, participants and treating clinicians could not realistically be blinded to BFR exposure, leaving potential expectation and performance effects that would need to be mitigated through blinded assessment and standardized procedures in a prospective study (15,16).

The modeled intervention also covered only 6 weeks, followed by a 12-week post-treatment interval, and therefore does not address longer-term persistence of any BFR-associated adaptation. Outcomes were restricted to SPADI, NPRS, and rotational strength. Future prospective studies should consider broader patient-centered outcomes such as treatment satisfaction, quality of life, work or sport participation, physical activity, fear of movement, global perceived change, and treatment burden. They should also record session-level BFR discomfort, cuff tolerance, adverse events, protocol fidelity, concomitant care, and reasons for discontinuation. Standardized reporting of individualized occlusion pressure, cuff characteristics, exercise load, repetition structure, progression, and adherence would improve reproducibility and facilitate comparison across trials (7,10,11).

Future research should therefore prioritize adequately powered prospective randomized controlled trials in clinically characterized RCRSP populations. Sample-size calculations should be based on a prespecified clinically important between-group difference in a patient-centered primary outcome rather than on the expectation of statistical significance in strength measures. Randomization and allocation concealment should be implemented prospectively, assessors should remain blinded where feasible, and statistical plans should prespecify treatment of baseline covariates, missing observations, multiplicity, and sensitivity analyses in accordance with contemporary trial-reporting standards (15,16). Given the emerging but uncertain signal for internal-rotation strength, future trials may also investigate whether baseline weakness, symptom irritability, activity demands, or inability to tolerate higher external resistance identifies subgroups more likely to benefit from BFR.

Overall, the modeled evidence favors a conservative interpretation. BFR provides a physiologically plausible low-load strengthening strategy, and current evidence suggests that selected strength outcomes may respond under particular protocols (7,8,10,11). However, physiological plausibility and isolated strength differences are insufficient to establish clinically meaningful superiority. The present indicates that most of the modeled improvement in pain and disability can be achieved with the shared structured exercise programme, while any additional BFR-related effect appears small, outcome specific, and uncertain. Prospective clinical evidence is required before BFR can be recommended routinely as an adjunct for improving patient-reported outcomes in RCRSP.

CONCLUSION

In this randomized trial model, both low-load BFR combined with rotator cuff exercise and the same exercise programme performed without BFR produced substantial modeled improvements in shoulder

pain, disability, and rotational strength. The prespecified primary analysis did not demonstrate a statistically significant differential SPADI trajectory, and the baseline-adjusted week-6 difference was negligible, providing no evidence of a clinically meaningful incremental BFR benefit for shoulder disability. Conventional exercise demonstrated a modest advantage for pain, while external-rotation strength showed no clear differential response. A small adjusted week-6 internal-rotation strength difference favored BFR, but the nonsignificant adjusted longitudinal interaction requires this finding to remain exploratory. BFR may therefore warrant further evaluation as a selective low-load strengthening strategy rather than as a superior replacement for conventional rotator cuff exercise, with confirmation requiring adequately powered prospective clinical trials.

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