Comparative Effectiveness of Blood Flow Restriction Therapy versus Exercise Alone after Arthroscopic Rotator Cuff Repair: S-TRONGER Randomised Controlled Trial Protocol

Felipe Ponce-Fuentes *PT, MSc*
Escuela de Kinesiología, Facultad de Medicina y Ciencias de la Salud, Universidad Mayor, Temuco, Chile; Faculty of Physiotherapy, University of Valencia, Valencia, Spain

Iván Cuyul-Vásquez *PT, MSc*
Departamento de Procesos Terapéuticos, Facultad de Ciencias de la Salud, Universidad Católica de Temuco, Temuco, Chile

Joaquín Salazar-Méndez *PT, MSc*
Escuela de Kinesiología, Facultad de Salud, Universidad Santo Tomás, Chile

Enrique Lluch *PT, PhD*
Physiotherapy in Motion, Multi-Specialty Research Group (PTinMOTION), Department of Physiotherapy, University of Valencia, Valencia, Spain; Pain in Motion International Research Group, Vrije Universiteit Brussel, Brussels, Belgium

Joaquín Calatayud *PhD*
Exercise Intervention for Health Research Group (EXINH-RG), Department of Physiotherapy, University of Valencia, Valencia, Spain

José Casaña Granell *PT, PhD*
Exercise Intervention for Health Research Group (EXINH-RG), Department of Physiotherapy, University of Valencia, Valencia, Spain

Chad Cook *PT, PhD*
Department of Orthopaedics, Duke University School of Medicine, Duke University, Durham NC, USA

Filip Struyf *PT, PhD*
Department of Rehabilitation Sciences and Physiotherapy, Faculty of Medicine and Health Sciences, University of Antwerp, Belgium

ABSTRACT

The purpose of this trial is to evaluate the effect of postoperative exercises with blood flow restriction therapy (BFRT) for 12 weeks in patients undergoing arthroscopic rotator cuff repair, compared to postoperative exercises alone. Fifty-eight adults aged from 40 to 65 years with a confirmed diagnosis of symptomatic degenerative rotator cuff tear, and treated with an arthroscopic rotator cuff repair, will be recruited to participate in a randomised controlled trial with 1:1 randomisation. Participants will be stratified by sex (female and male) and site (three hospitals) to twice weekly, supervised postoperative exercises with BFRT or postoperative exercises alone for 12 weeks. The primary outcomes will be the changes in shoulder muscle strength and muscle mass through abduction and external rotation maximal voluntary isometric contraction and supraspinatus cross-sectional area, respectively. Secondary outcomes include active range of motion, pain intensity, upper limb disability, and quality of life. Between-group differences will be tested with a linear mixed-effects model. Outcomes will be measured at baseline, 4 weeks, and 12 weeks. This is the first randomised controlled trial investigating the clinical effects of BFRT in patients with a rotator cuff repair. The novel application of BFRT may be a suitable strategy to attenuate shoulder muscle atrophy and strength deficits in the early stages of postoperative rehabilitation after rotator cuff repair. The results of this trial will support researchers and clinicians in optimising the BFRT postoperative exercises in patients with rotator cuff repair.

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Key Words: Blood Flow Restriction Training, Clinical Trial, Exercise, Rotator Cuff Repair, Shoulder Pain

INTRODUCTION

Rotator cuff tears (RCTs) are one of the main causes of shoulder pain and disability, accounting for about 20% of all shoulder injuries (Lo & Burkhart, 2003), with an increasing prevalence among ageing populations (Wani et al., 2016). Traumatic RCTs typically occur in relatively younger persons (average age 54.7 years), predominantly males, often due to a fall on an outstretched arm (Mall et al., 2013). These tears are generally large, involve multiple tendons,

and the supraspinatus is affected in 84% of cases (Mall et al., 2013). Non-traumatic degenerative RCTs are more commonly associated with lifestyle and metabolic factors. For instance, in females, non-traumatic RCTs have been linked to thyroid disease (Oliva et al., 2014), whereas smoking and hypercholesterolemia are considered risk factors in men (Oliva et al., 2014).

Both conservative and surgical interventions are used to treat participants with RCTs (Dickinson & Kuhn, 2023). Regarding surgery, arthroscopic rotator cuff repair is one of the most common interventions (Shibata, 2016). The main goal of rehabilitation after rotator cuff repair is to recover upper limb function. Current guidelines recommend dividing the rehabilitation process into three stages based on time-specific criteria: Stage I (passive range of motion), Stage II (assisted active range of motion), and Stage III (active exercise in closed and open chain) (Kjær et al., 2018). There is currently controversy about the optimal postoperative rehabilitation protocol following arthroscopic rotator cuff repair, particularly for the early postoperative phase (Chen et al., 2024; Houck et al., 2017). While early range of motion may provide superior benefits in terms of recovery of shoulder mobility after arthroscopic rotator cuff repair, aggressive rehabilitation could compromise repair integrity (Houck et al., 2017) and adversely affect shoulder function in the long term (Li et al., 2018). Postoperative protocols that include early range of motion are usually limited to passive mobilisations and pendulum exercises, with no consideration for the use of shoulder strengthening interventions (Chang et al., 2015). Indeed, open-chain active range of motion exercises for the shoulder are not recommended until advanced tendon healing, which is typically no earlier than six weeks after surgery (Kjær et al., 2018). Since atrophy of the rotator cuff does not improve after rotator cuff repair and correlates with poor functional outcome (Gladstone et al., 2007), new therapeutic modalities that can attenuate muscle atrophy and increase rotator cuff strength without compromising tendon healing need to be considered.

To increase skeletal muscle mass and strength, the American College of Sports Medicine (ACSM) recommends performing resistance exercise training at high intensity (> 80% of one-repetition maximum) (American College of Sports Medicine, 2009). However, these recommendations may be counterproductive for the early postoperative rehabilitation of an arthroscopic rotator cuff repair, as the tendon is in an early healing phase and shoulder movements are barely tolerated (Sgroi & Cilenti, 2018). In this context, alternative forms of traditional resistance exercise training such as blood flow restriction therapy (BFRT) are emerging to attenuate atrophy and allow muscle strength gains in the early postoperative rehabilitation (Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024).

BFRT is an intervention that combines an external pressure system or cuff applied to a limb, which partially restricts arterial blood flow and fully restricts venous blood flow, with low load resistance training (Patterson et al., 2019). The main advantage of BFRT is its ability to induce adaptations in skeletal muscle mass and strength with low-intensity resistance exercises through various metabolic, hormonal, and neuromuscular pathways (Wang et al., 2023). To date, there is limited formal study on the efficacy of BFRT both in healthy people and in patients with rotator cuff disorders. Lambert et al. (2023) demonstrated that the combination of low-load resistance exercises targeting the rotator cuff muscles with BFRT produced a significant increase in upper limb lean mass, shoulder strength, and muscular endurance in comparison to low-load resistance exercises alone in healthy adults (Lambert et al., 2021; Lambert et al., 2023). Furthermore, an 8% increase in biceps muscle thickness and a 12% increase in shoulder internal rotation strength have been reported after shoulder-targeted exercises plus BFRT, compared to shoulder-targeted exercises alone in patients with rotator cuff tendinopathy (Kara et al., 2023). Although these data suggest a potential role for BFRT in healthy people and patients with rotator cuff disorders, it is not yet known whether these results are generalisable to patients undergoing arthroscopic surgery for RCT. Specifically, it remains unknown whether patients with an arthroscopic rotator cuff repair would benefit from the combination of active shoulder rehabilitation exercises with BFRT in the early postoperative stages.

We will conduct an assessor-blinded multicentre randomised controlled trial comparing the effects of postoperative exercises with BFRT versus postoperative exercises alone on shoulder muscle strength and mass in patients undergoing arthroscopic rotator cuff repair. Physical function, shoulder pain, upper limb disability, and quality of life self-reported outcomes will also be compared between both intervention groups. It is hypothesised that exercises with BFRT will result in significantly greater improvements in shoulder strength and muscle mass compared to exercises alone after 12 weeks of postoperative rehabilitation programme for patients receiving an arthroscopic rotator cuff repair.

METHODS

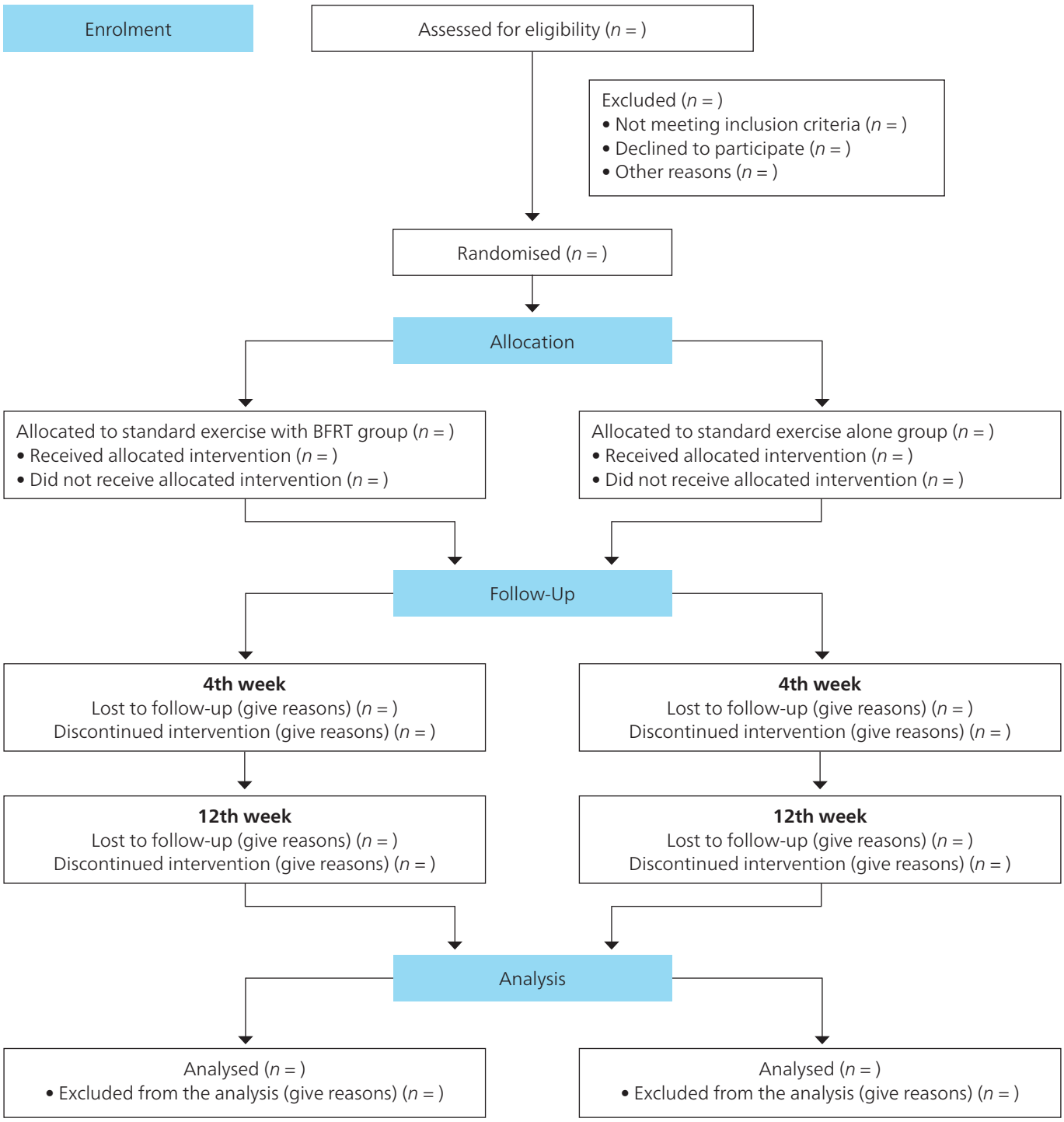
This trial protocol has been reviewed and approved by the ethics committee of the Araucanía Sur Health Service, Ministry of Health, Chile (protocol 396). Our study protocol follows the Standard Protocol for Randomised Interventional Trials (SPIRIT) (Chan et al., 2013), the Consolidated Standards of Reporting Trials (CONSORT) (Eldridge et al., 2016), the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014), and the Consensus on Exercise Reporting Template (CERT) (Slade et al., 2016) guidelines. This Shoulder Therapy and Rehabilitation OccludiNG ExeRcise protocol trial (S-TRONGER trial) was prospectively registered on ClinicalTrials.gov (NCT06788327) in January 2025 and recruitment started in March 2025. It is expected that recruitment will be finalised in March 2027. Figure 1 presents the CONSORT diagram for this protocol.

Study design

This study will be a two-arm, assessor-blinded randomised controlled trial. Fifty-eight participants will be randomised into two intervention groups using a 1:1 allocation ratio. The experimental group will receive postoperative exercises with BFRT, and the control group will receive postoperative

Figure 1

Proposed CONSORT Diagram of Enrolment, Allocation, Follow-up, and Analysis for Each Arm of the Study



exercises alone. Randomisation will occur after baseline assessment (T_0) using computer-generated random blocks, stratified by sex and hospital. A member of the research team, who is not involved in the assessments or treatments, will oversee the allocation process. Both groups will undergo 12 weeks of intervention, with assessments performed at baseline (T_0), week 4 (T_1), and the end of the intervention week 12 (T_2). The study schedule is presented in Table 1.

Participants

Participants aged 40 to 65 years with a confirmed diagnosis

Table 1

Study Schedule

Schedule details	Study period			
	Enrolment	Allocation	Post-allocation	
Time point	T_{-1}	T_0	T_1 (week 4)	T_2 (week 12)
Enrolment	X			
Eligibility screen	X			
Informed consent	X			
Allocation		X		
Interventions				
Exercises with BFRT (intervention)		—	—	—
Exercises alone (control)		—	—	—
Assessments				
Demographic data		X		
Physical function variables				
Muscle strength		X	X	X
Muscle mass		X	X	X
Active range of motion		X	X	X
Self-reported variables				
Pain intensity (VAS)		X	X	X
Disability (SPADI)		X	X	X
Quality of life (WORC)		X	X	X
Adverse events			X	X
Statistical analysis				X

Note. BFRT = blood flow restriction therapy; VAS = visual analogue scale; SPADI = shoulder pain disability index; T_{-1} = 3 days prior to baseline assessment; T_0 = baseline assessment; WORC = Western Ontario Rotator Cuff Index.

of symptomatic degenerative full-thickness RCT involving at least the supraspinatus tendon (full thickness and width), verified by magnetic resonance imaging and treated with an arthroscopic rotator cuff repair will be included. They should be able to read and understand Spanish. Participants will be excluded if they present one of the following: A massive irreparable RCT, concomitant fracture, labral or nerve injury, suspicion of developing/diagnosis of a frozen shoulder, revision surgery after rotator cuff repair, previous corticosteroid injection (< 1 year), recent surgery (< 1 year) in the contralateral shoulder, a history of deep venous thrombosis/pulmonary embolism, peripheral vascular disease, thrombophilia or clotting disorders, severe or uncontrolled hypertension, or any comorbid condition that impedes participants from completing the intervention. Participants will be asked not to start any other intervention, including an exercise programme, while participating in the study.

Recruitment

This multicentre study will take place at Padre las Casas Hospital, Nueva Imperial Intercultural Hospital, and Villarrica Hospital, all located in the Araucanía region, Chile. Participants will be recruited primarily from the physiotherapy units of each hospital and will be assessed for eligibility between March 2025 and March 2027. A researcher will invite patients to participate in the study and will determine during the first assessment session which patients meet the eligibility criteria and inform them about the objectives and the study details. A six-step model will be used to ensure accurate recruitment of eligible patients following previous recommendations (Realpe et al., 2016): (1) explanation of the condition, (2) reassurance about receiving treatment, (3) information about why the study is necessary, (4) explanation of the purpose of the study, (5) a balanced view of integrating BFRT into traditional physiotherapy after rotator cuff surgery, and (6) explanation of study interventions and follow-up measurements. This process will be supported by a recruitment script, written by the research team and used in the first assessment session by the researcher. Patients who meet the selection criteria will be invited to sign informed consent prior to their participation in the study.

Randomisation, allocation concealment, and blinding

Participants will be randomised using a centralised computer-generated random number generator (www.random.org) into one of the two intervention groups (1:1). To ensure

participants have equal chances of receiving exercises with BFRT or exercises alone, randomisation will be stratified by sex and hospital using a variable block size. Group allocation will be concealed by a research member using sequentially numbered opaque envelopes. These envelopes will be opened by the participant, in the presence of the recruitment team, but not in the presence of the outcome assessor. The statistician and the outcome assessor will be blinded to the group allocation, data collection, and analysis of the participants. Unblinding will only be permitted in response to regulatory requirements or at the end of the study. Participants will not be blinded to the allocated treatment due to the impossibility of concealing the interventions, as they are dissimilar in nature. The physiotherapists performing the interventions will not be blinded to the allocated treatment, as they need to know which intervention will be applied in each case.

Interventions

Both groups (postoperative exercises with BFRT and exercises alone) will receive an individualised 12-week physiotherapy programme that includes 24 one-on-one supervised physiotherapy sessions (2 sessions per week). In addition, each participant will perform two non-supervised exercise sessions per week, at home, on alternate days, from the physiotherapy sessions. After surgery, the affected shoulders of all participants will be immobilised in a sling with a bolster for 2 weeks, followed by 3 weeks of immobilisation in a sling without a bolster.

Two weeks post-surgery, both intervention groups will start an evidence-based physiotherapy programme developed for patients who receive an arthroscopic rotator cuff repair (Kjær et al., 2018; Kjær et al., 2021). This programme will be structured into three postoperative stages: Stage I (weeks 2 to 4), Stage II (weeks 5 to 8) and Stage III (weeks 8 to 12). Stage I will be primarily focused on shoulder-assisted passive range of motion and active-assisted range of motion exercises. Stages II and III will include shoulder and periscapular strengthening exercises in both closed and open chains with gradual loading of the rotator cuff tendons. Each supervised physiotherapy session will last approximately 45 min and include eight, six and six shoulder exercises in Stages I, II and III, respectively, for both intervention groups. All week-by-week predetermined exercise progressions in each stage will be selected and implemented following the recommendations of Kjær et al. (2018, 2021). In both treatment groups, during each supervised session, participants will be asked to perform all exercises with pain levels below five on the verbal Numeric Pain Rating Scale (NPRS). Physiotherapists responsible for implementing the exercise intervention will receive instructions on how to implement the postoperative physiotherapy programme, including the allowed pain intensity, and frequency of the shoulder exercises. In addition, each participant will perform two non-supervised exercise sessions at home per week, on alternate days from the physiotherapy sessions. All details of the home exercise programme are presented in Appendix A.

Exercises alone

Participants in the control group will start with flexion, abduction, and external rotation passive mobilisations, active supine bench press and active-assisted shoulder flexion for a total of eight exercises in Stage I. Then, the participants will perform six active and active-assisted exercises per session focused on flexion, abduction, external, and internal rotation of the shoulder in Stage II. Finally, six active and active-resisted shoulder exercises per session will be performed in Stage III. The description of the supervised physiotherapy protocol is described in Appendix B.

Exercises with BFRT

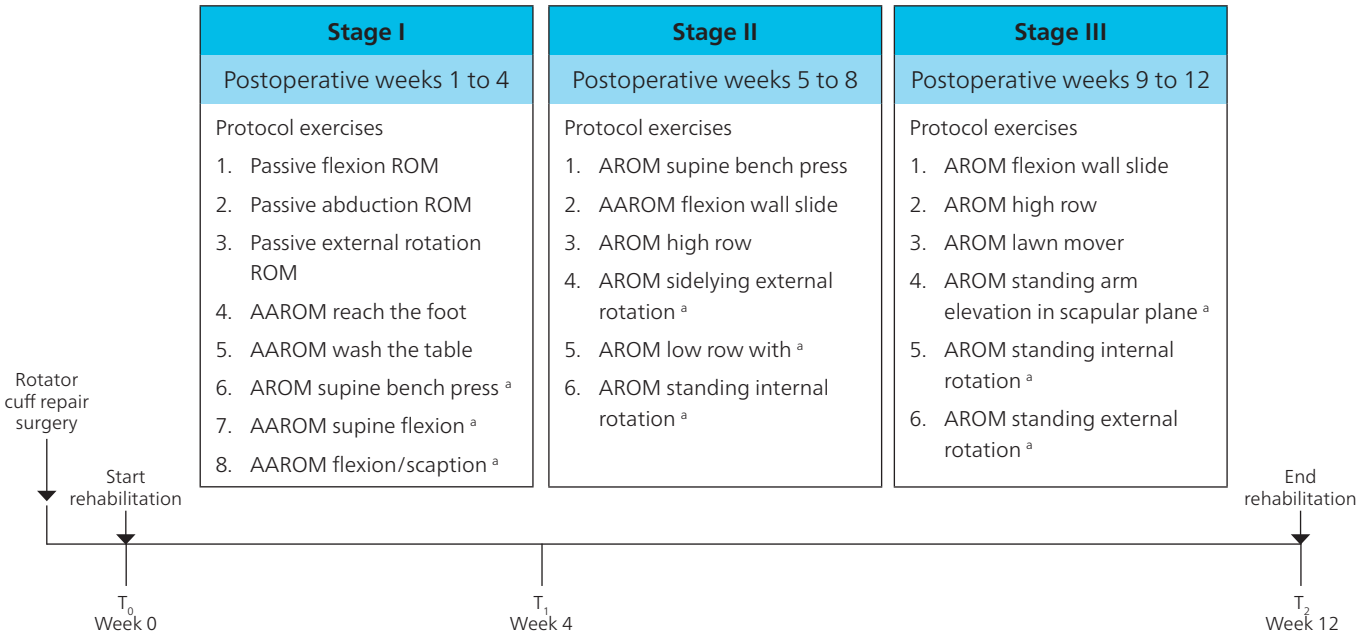
Participants in the experimental group will perform the same exercises as the control group, with the addition of BFRT in three exercises per stage. BFRT will be implemented according to current evidence-based guidelines (Patterson et al., 2019) and following the recommendations of previous studies using BFRT in patients with arthroscopic rotator cuff repair (Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024). In each supervised session, BFRT will be added to three exercises focused on shoulder-assisted passive range of motion and active-assisted range of motion in Stage I, and to three shoulder and periscapular progressive strengthening exercises in closed and open chain with gradual loading of the rotator cuff tendons in Stages II and III (Appendix B). An auto-regulated portable BFRT SmartCuffs® 3.0 Pro system with a 17-inch long and 5-inch-wide cuff (Smart Tools Plus, Strongsville, Ohio, United States), placed on the most proximal part of the arm, will be used. Each BFRT session will begin with a maximal occlusion test to personalise the occlusion pressure to the participant. The limb occlusion pressure will be set at 50% of the maximum occlusion pressure in Stage I and 60% in stages II and III (Bowman et al., 2020; Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024). The participant will perform 75 repetitions of each BFRT exercise, divided into four sets (30, 15, 15, and 15 repetitions). During each session, the intensity of exercise will be individually tailored using both the pain monitoring model approach (pain should be kept below five on the NPRS) and Borg's CR10 perceived exertion scale (1 = "very weak" to 10 = "extremely strong"). The load intensity during the BFRT exercises will be set near to 3 out of 10 on Borg's CR10 scale ("weak"), which corresponds to 30% of 1RM effort (Buckley & Borg, 2011). The physiotherapist performing the intervention will adjust the loads during each exercise to achieve the target range of perceived exertion (3/10). After each exercise, the cuff will be deflated, and the patient will rest for 2 min. An overview of the study rehabilitation interventions is shown in Figure 2.

Outcome measures

The descriptive characteristics of the participant and their medical history will be assessed, followed by muscle morphology, muscle strength, and mobility. Standardised 2 min rest periods will be used between strength assessments of each muscle group and between mobility assessments. The self-report questionnaires will be presented on paper at the end of the assessment sessions.

Figure 2

Representation of Treatment Schedule and Timepoint Assessments



Note. ROM = range of motion; AAROM = active-assisted range of motion; AROM = active range of motion; T_0 = baseline assessment; T_1 = 4-week assessment; T_2 = 12-week assessment.

[a] Exercises with BRFT in experimental group.

Primary and secondary outcomes will be evaluated in a single session at baseline (T_0), week 4 (T_1), and week 12 (T_2). The time allocated for each assessment will be 60 min for T_0 and 45 min for T_1 and T_2. A progress tracking chart will be used as an individualised motivational strategy for each participant.

Primary outcomes

The primary outcomes used in this study will be the between-group changes in shoulder muscle strength and muscle mass.

1. Shoulder strength

Shoulder muscle strength will be measured through maximal voluntary isometric contraction (MVIC) in shoulder abduction and external rotation at 20° of abduction using an ActivForce 2 digital handheld dynamometer (Activbody, San Diego CA, USA) (Karagiannopoulos et al., 2022). Three trials will be performed for each direction at maximal effort. Each isometric contraction will last 3 s. Measurements will be taken bilaterally, and the average of the three maximal trials will be used for data analysis. The MVIC tests demonstrate excellent reliability, with intraclass correlation coefficients (ICCs) ≥ 0.93 for shoulder muscle strength (Meldrum et al., 2003). The minimal detectable change ($MDC_{\%}$) for shoulder abduction strength is 14.8% (Karabay et al., 2020) and 15.8% for external rotation (Holt et al., 2016).

2. Shoulder muscle mass

The cross-sectional area (CSA) of supraspinatus will be measured bilaterally using ultrasound imaging with a high-resolution, multifrequency (8-13 MHz) linear transducer (LOGIQ F8, GE Healthcare, Wauwatosa, WI, USA) based on the recommendations of a previous study (Safford et al., 2024). The participant will be seated with the trunk in a neutral position, the elbow flexed to 90°, and the shoulder in neutral position. The transducer will be placed on the superior aspect of the shoulder, and the CSA of the supraspinatus muscle will be identified from the posterior edge of the acromion to the medial edge of the spine of the scapula (Safford et al., 2024). The average of the three ultrasound measurements will be used for data analysis.

All the ultrasound measurements will be performed by the outcome assessor, who will be trained by an experienced certified sonographer, with 10 years of experience in musculoskeletal ultrasound assessment. ImageJ version 1.45s (NIH, Bethesda, MD), a computerised image analysis programme, will be used for supraspinatus CSA measurement. Intra- and inter-rater reliability of ultrasound measurements will be calculated before initiating the study, and additional training will be provided if the values of the ICC are below 0.90, which is consistent with results in the literature (Harris-Love et al., 2016). Ultrasound assessment of supraspinatus CSA is a reliable method for evaluating the shoulder muscle mass (ICC = 0.97) (Shah et al., 2017). The MDC for supraspinatus CSA is 0.8 cm^2 (Shah et al., 2017).

Secondary outcomes

The secondary outcome measures will be (i) shoulder flexion, abduction, and external rotation active range of motion measured with a 2° sensitivity goniometer (Enraf-Nonius, Netherlands) (Norkin & White, 2016), (ii) pain intensity at rest and worse movement, evaluated with the Visual Analogue Scale (VAS) (Michener et al., 2011), (iii) upper limb disability

evaluated with the Shoulder Pain Disability Index (SPADI) (Roach et al., 1991), and (iv) quality of life measured with the Western Ontario Rotator Cuff Index (WORC) (Kirkley et al., 2003).

Descriptive characteristics and other outcomes

The baseline characteristics of the sample including age, sex, height, weight, educational level, ethnicity, marital status, job type, frequency of physical activity, comorbidities, smoking, use of medication, rotator cuff tendons affected, tear size, time since diagnosis, and time since surgery will be recorded.

Other outcomes measured during each physiotherapy session will also be recorded including pain intensity (NPRS; at the beginning and end of the session), perceived exertion (Borg's CR10; at the end of the session) and global rating of change (GROC; at end of the session). Each participant will complete an exercise diary to record home exercise sessions and assess adherence to the home rehabilitation programme.

Adverse events or side effects

Participants will be informed about the potential side effects resulting from each intervention, including instructions on how they should proceed if they occur. In particular, participants in the exercises with the BFRT group will be informed that they may experience mild side effects, such as numbness, a cold sensation, or minor bruising at the application area that often resolve in less than 24 hr (Hughes & Patterson, 2020). Furthermore, participants in the exercises with BFRT group will be informed that this intervention may cause serious adverse events, although the probability is very low (deep vein thrombosis: 0.06%, pulmonary embolism: 0.008%, and rhabdomyolysis: 0.008%) (Nakajima et al., 2006). In each supervised session, the participant will be asked to report any side effects or adverse events.

Data management

The protocols for informed consent, screening scripts, intervention handbook, and data forms will be available in a paper folder for study staff. Study data will be collected and managed by blinded study personnel using electronic data collection methods or double data entry via the SSASur website, a secure web-based data capture application with real-time data entry validation, audit trails, and transaction logs.

Data analysis

Sample size

The required sample size will be calculated using G*Power software (version 3.1). A repeated measures analysis of variance (ANOVA) model will be used, including the interaction between groups. The sample size calculation will be based on a previous study that reported a partial eta squared effect size of $\eta p^2 = 0.17$ for between-group differences in muscle strength after rehabilitation with BFRT (Karanasios et al., 2022). To achieve 80% power at an alpha level of 0.05, a total of 50 participants (25 per group) will be recruited.

Data analysis

An intention-to-treat analysis will be performed, which includes all randomly assigned participants. Descriptive statistics will be used to identify the demographic and clinical characteristics of the participants. The normality and sphericity of the data will be verified with the Kolmogórov-Smirnov and Mauchly tests, respectively. To verify randomisation, baseline characteristics will be compared between groups using t tests, Chi square tests, Wilcoxon rank-sum tests, or Fisher exact tests, as appropriate. Characteristics that are different between groups ($p < 0.10$) and considered potential confounders will be included in the models described below. The differences analysis will be tested with linear mixed-effects models. Treatment (BFRT and control), time (baseline, week 4, and week 12), treatment by time interaction, and baseline covariate will be fixed effects, and participant will be the random effect in the linear mixed-effects models for shoulder muscle strength, supraspinatus CSA, active range of motion, pain intensity, disability, and quality of life variables. Furthermore, the effect sizes within and between groups will be calculated using the partial eta squared. Effect sizes of 0.01 will be considered small, 0.06 medium, and 0.14 large (Cohen, 2013). The level of significance will be established at $p \leq .05$. All statistical analyses will be performed using SPSS version 25.0 software (SPSS Inc, Chicago, IL).

Training, fidelity, and monitoring

The physiotherapists responsible for implementing the interventions will be trained by a physiotherapist with more than 15 years of clinical experience in musculoskeletal rehabilitation, certified in BFRT and with prior published BFRT studies in upper limb pathology (Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024; Ponce-Fuentes, Cuyul-Vásquez, & Ó Conaire, 2024). This training period will begin one month before the start of the study and include instruction on the theory and application of BFRT, as well as practice trials of the BFRT protocol with healthy persons to ensure consistency among physiotherapists. The training sessions will consist of two days of training (6 hr per day) in a workshop format, which will include theoretical foundations, question-and-answer sessions and role-playing exercises to demonstrate how to support participants. The training sessions will be complemented by a comprehensive manual providing clear instructions to clinicians on all aspects of the interventions. In addition, a standardised treatment diary checklist will be available for each participant session to promote adherence to the treatment protocol and assess treatment fidelity. Finally, a practical test will be conducted to verify adherence to treatment protocols. The fidelity of the intervention will be assessed at one of the first five visits for each participant in both intervention groups by a team member not responsible for delivering the interventions. If intervention fidelity is less than 90% at any check, a recheck will be performed within the next five visits. If the procedural reliability remains below 90%, additional individual training sessions will be completed.

The outcome assessors responsible for evaluating all outcome variables will be trained on how to implement the participants' eligibility criteria, appropriate assessment of outcome measures, and how to correctly record data. Outcome assessors will undergo fidelity testing every 6

months. Data files will be reviewed on an ongoing basis to confirm that results are completed per protocol. If procedural reliability is below 90%, additional training sessions will be conducted.

A data monitoring committee composed of two researchers will review continuously the progress of the study, access interim results, and make the final decision to terminate the trial. Also, the data monitoring committee will review the presence of any adverse events every four months. If the number of participants reporting an intervention-related adverse event reaches five (unfavourable and unintended sign, symptom, or disease, generally manageable and reversible, e.g., nausea, headache, mild rash) or if one serious intervention-related event occurs (severe event related to life-threatening situation, death, situation that requires hospitalisation, or causes persistent/significant disability), the study will be suspended until the committee monitor evaluates the study-relatedness for each incident and determines whether continuing is appropriate. In addition, the informed consent and de-identified data of all participants will be stored in a secure database with daily backup. Hard copies of the data will be kept in an approved, secure storage facility. Any protocol amendment will be communicated to the Scientific Ethics Committee of the Chilean Ministry of Health, which will annually audit the correct functioning of the research.

Dissemination plan

The study findings will be reported to participants, stakeholder groups, at conferences, and in peer-reviewed publications.

DISCUSSION

Despite the growing use of BFRT for treating different musculoskeletal disorders, few studies have assessed its use in the rehabilitation of people with shoulder pain (Ceballos et al., 2022; Kara et al., 2023; McGinniss et al., 2022; Miller et al., 2022; Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024). To our knowledge, only one case report has evaluated the effects of BFRT in a patient with an arthroscopic rotator cuff repair (Ponce-Fuentes, Cuyul-Vásquez, Carranza, et al., 2024). In this study, a 54-year-old man with an arthroscopically treated full-thickness rotator cuff tear completed a 12-week postoperative rehabilitation programme that included low-load resistance exercises with BFRT. The patient demonstrated clinically significant improvements in long head biceps brachii muscle thickness, shoulder abduction and external rotation strength, shoulder range of motion, movement-evoked pain, and physical function. However, due to design limitations, the authors recommended conducting a randomised clinical trial comparing the effectiveness of adding BFRT to postoperative physiotherapy exercises versus postoperative physiotherapy alone following an arthroscopic rotator cuff repair.

Other studies have assessed the effect of BFRT for people with rotator cuff disorders, but not specifically in a population undergoing rotator cuff surgery. For instance, a significant increase in biceps muscle thickness and shoulder internal rotation strength has been reported in patients with rotator cuff-related shoulder pain receiving BFRT (Kara et al., 2023). However, the study included participants treated conservatively for shoulder pain secondary to rotator cuff tendinopathy (without a rotator cuff tear), in which considerations related to tendon healing and irritability levels are not comparable to those patients undergoing a post-operative rehabilitation programme after rotator cuff repair. A case series study found a clinically significant improvement in shoulder strength and physical function after six to 12 weeks of BFRT in patients who underwent shoulder stabilisation surgery (McGinniss et al., 2022). However, this study presents critical differences with our trial protocol due to (i) exclusion of patients with rotator cuff repair, with BFRT performed only in patients with glenoid labrum or glenohumeral ligament injuries that had been surgically repaired, and (ii) inclusion of a young population (military cadets), which differs from our study, which will include adults up to 65 years old. Lastly, two case reports showed clinically significant improvements in shoulder isometric strength, range of motion, and patient-reported function in patients with shoulder subacromial impingement after BFRT in patients with subacromial pain (Ceballos et al., 2022; Miller et al., 2022).

The results of this trial could have a significant impact due to the lack of current evidence on the effectiveness of low-load postoperative resistance exercises with the addition of BFRT for patients with surgically repaired rotator cuffs, who need tailored exercise approaches to ensure both safety and feasibility. In fact, in the initial stage of postoperative rehabilitation for rotator cuff repair, early tendon healing, and low tolerance to shoulder movement could cause more pain and irritability of the local tissue should high-intensity resistance training or low load to volitional failure be used. This would lead to difficulties in improving muscle mass and strength in the early stages of postoperative rehabilitation (Sgroi & Cilenti, 2018). In this context, the novel application of BFRT may be a suitable strategy to attenuate shoulder muscle atrophy and strength deficits in the early stages of postoperative rehabilitation for patients undergoing an arthroscopic rotator cuff repair.

We recognise that there are several limitations to this study. For example, physiotherapists will not be blinded to treatment groups due to evident differences in the interventions applied. We have attempted to minimise potential bias by using standardised scripts to explain the BFRT intervention, and all assessments will be performed by researchers who will be blinded to the participant's allocated intervention. Finally, another limitation is the absence of a sham-BFRT control group, which allows for the assessment of the influence of non-specific factors, including natural history or contextual factors associated with the effect of BFRT.

DISCLOSURES

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PERMISSIONS

This study was approved by the ethics committee of the Araucanía Sur Health Service, Ministry of Health, Chile (protocol 396).

CONTRIBUTIONS OF AUTHORS

Design conceptualisation and methodology, FP-F, JC, JCG, and FS; validation, JC, JCG, CC, and FS; formal analysis, FP-F; data curation, not applicable; writing—original draft preparation, FP-F, IC-V, and JS-M; writing—review and editing, JC, JCG, CC, and FS; funding acquisition, no funding.

ADDRESS FOR CORRESPONDENCE

Felipe Ponce-Fuentes, Escuela de Kinesiología, Facultad de Medicina y Ciencias de la Salud, Universidad Mayor, Chile.

Email: felipe.poncef@umayor.cl

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Appendix A

HOME EXERCISE PROTOCOL AFTER ROTATOR CUFF REPAIR

Exercise number	Exercise name	Dose	Materials
		Stage I (postoperative weeks 2 to 4)	
1	AAROM reach the foot (flexion)	60 reps (30, 30), VAS < 5, twice per week on the days without physiotherapy session	Chair
2	AAROM wash the table (flexion on table)	60 reps (30, 30), VAS < 5, twice per week on the days without physiotherapy session	Table
3	AAROM supine flexion	60 reps (30, 30), VAS < 5, twice per week on the days without physiotherapy session	Not necessary
4	AROM supine bench press	60 reps (30, 30), VAS < 5, twice per week on the days without physiotherapy session	Broomstick
		Stage II (postoperative weeks 5 to 8)	
1	AROM sidelying external rotation	60 reps (30, 30), VAS < 5, twice per week on the days without physiotherapy session	Not necessary
2	Isometric hold for shoulder flexion	60 reps (30, 30), 5 s hold each rep, VAS < 5, twice per week on the days without physiotherapy session	Not necessary
3	AAROM abduction	60 reps (20, 20, 20), VAS < 5, twice per week on the days without physiotherapy session	Broomstick
4	AAROM flexion wall slide	60 reps (20, 20, 20), VAS < 5, twice per week on the days without physiotherapy session	Not necessary
		Stage III (postoperative weeks 9 to 12)	
1	AROM supine external rotation (hand to neck)	60 reps (20, 20, 20), VAS < 5, twice per week on the days without physiotherapy session	Not necessary
2	AROM supine internal rotation (hand to lower back)	60 reps (20, 20, 20), VAS < 5, twice per week on the days without physiotherapy session	Not necessary

Note. AAROM = active-assisted range of motion; AROM = active range of motion; reps = repetitions; VAS = visual analogue scale.

Appendix B

SUPERVISED PROTOCOL OF THE EXERCISES WITH AND WITHOUT BFRT AFTER ROTATOR CUFF REPAIR

Exercise number	Exercise name	Dose	Materials
		Stage I (postoperative weeks 2 to 4)	
1	Passive ROM: Flexion	2 min, VAS < 5	Not necessary
2	Passive ROM: Abduction	2 min, VAS < 5	Not necessary
3	Passive ROM: External rotation	2 min, VAS < 5	Not necessary
4	AROM supine bench press with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 s rest, 2 min inter exercise rest with reperfusion, VAS < 5	Broomstick
5	AAROM supine flexion with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 s rest, 2 min inter exercise rest with reperfusion, VAS < 5	Not necessary
6	AAROM flexion/scaption with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 s rest, 2 min inter exercise rest with reperfusion, VAS < 5	Jump rope
7	AAROM reach the foot (flexion)	60 reps (15, 15, 15, 15), VAS < 5	Chair
8	AAROM wash the table	60 reps (15, 15, 15, 15), VAS < 5	Table
		Stage II (postoperative weeks 5 to 8)	
1	AROM sidelying external rotation with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 sec rest, 2 min inter exercise rest with reperfusion, VAS < 5	Not necessary
2	AROM low row (extension) with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 sec rest, 2 min inter exercise rest with reperfusion, VAS < 5	TheraBand
3	AROM standing internal rotation with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 sec rest, 2 min inter exercise rest with reperfusion, VAS < 5	TheraBand
4	AAROM abduction	60 reps (15, 15, 15, 15), VAS < 5	Broomstick
5	AAROM flexion wall slide	60 reps (15, 15, 15, 15), VAS < 5	Not necessary
6	AROM high row	60 reps (15, 15, 15, 15), VAS < 5	TheraBand
		Stage III (postoperative weeks 9 to 12)	
1	AAROM flexion wall slide	60 reps (15, 15, 15, 15), VAS < 5	Not necessary
2	AROM high row	60 reps (15, 15, 15, 15), VAS < 5	TheraBand
3	AROM lawn mover	60 reps (15, 15, 15, 15), VAS < 5	Dumbbell
4	AROM standing arm elevation in scapular plane with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 sec rest, 2 min inter exercise rest with reperfusion, VAS < 5	Dumbbell
5	AROM standing internal rotation with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 s rest, 2 min inter exercise rest with reperfusion, VAS < 5	TheraBand
6	AROM standing external rotation with BFR addition	75 reps (30,15, 15, 15), 2 s concentric: 2 s eccentric, LOP 50%, RPE 3/10, 30 s rest, 2 min inter exercise rest with reperfusion, VAS < 5	TheraBand

Note. AAROM = active-assisted range of motion; AROM = active range of motion; BFR = blood flow restriction; LOP = limb occlusion pressure; reps = repetitions; ROM = range of motion; RPE = rate of perceived exertion; VAS = visual analogue scale.