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Effects of exercise therapy with blood flow restriction on shoulder strength: protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Blood flow restriction therapy (BFRT) has gained attention for its capacity to induce substantial muscle hypertrophy and strength gains even when employing relatively minimal loads. Strength training is of significant importance in the rehabilitation of patients experiencing shoulder pain, which may arise from a multitude of sources, including rotator cuff injuries, tendinopathies or postsurgical recovery. However, traditional resistance training can be challenging for these individuals due to the presence of pain and functional limitations. In this regard, BFRT in conjunction with low-load strength training may prove an efficacious alternative. The integration of BFRT into rehabilitation protocols for shoulder pain could provide a viable pathway to improving muscle strength and facilitating recovery while minimising the risk of exacerbating pain or injury. The primary objective of this study is to conduct a systematic review of the effects of training with BFRT of the upper limb on shoulder strength.

Methods and analysis A comprehensive database search will be conducted across multiple platforms, including PubMed, Scopus, Ovid, Web of Science, EBSCO, Cochrane Central, PEDro and Google Scholar, using predefined key terms without any language restriction. The particular focus of the study will be clinical trials with a controlled group that assess the impact of BFRT on upper extremity, neck and trunk muscles in both healthy individuals and patients. The primary outcome measure will be shoulder strength and power in different directions. The Cochrane Collaboration's Risk of Bias 2 tool will be employed for the purpose of evaluating the risk of bias inherent to the studies in question. A meta-analysis will be conducted using Stata software. The Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach will be employed to evaluate the quality of evidence for the primary outcomes.

Ethics and dissemination The previously published papers will be used for all analyses in this study. Results will be disseminated through professional networks, presentations at conferences and publication in a peer-reviewed journal. No ethics approval is required.

PROSPERO registration number CRD42024605189.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of a well-established methodological framework will ensure the production of a high-quality review.
⇒ Comprehensive electronic and manual searches over a wide time period will strengthen our review by reducing publication bias.
⇒ No language restrictions on articles will ensure inclusion of relevant studies.
⇒ The heterogeneity of the studies may impose some limitations on the overall results.

INTRODUCTION

Hypertrophy and increased muscle strength are mainly achieved during a high-load resistance training programme.[1] Such a high load is often not achievable in the clinical setting due to the presence of pain, the repair process and functional limitations.[2] Shoulder problems are one of the most common musculoskeletal conditions that result in patient disability due to loss of joint range of motion, shoulder rotator muscle weakness and atrophy.[3 4] The benefits of strengthening the shoulder muscles in improving pain and disability in these patients are well known, but these patients are unable to perform vigorous physical activity.[5]

Recently, exercise with blood flow restriction therapy (BFRT), also known as Kaatsu training, has been raised as an appropriate choice for patients who cannot perform high-intensity exercise, but clinically require it to improve muscle strength and function.[5 6] Today, exercise with BFRT is increasingly being considered in rehabilitation and sports. BFRT is a technique that uses low-intensity exercise with blood flow obstruction to achieve results similar to high-intensity exercise.[6 7] This method is the application of a tourniquet to the proximal portion of the limb to restrict blood flow during exercise.[8] Although the technique's underlying mechanism of action is not known, it is believed that vascular occlusion contributes to muscle hypertrophy through the following mechanisms: (1) elevated hormone concentrations

with decreased venous return, (2) increased muscle protein synthesis through the mammalian target of rapamycin (mTOR) pathway, (3) an increase in chemical biomarkers indicating increased stellate cell activity and (4) increased fast twitch recruitment.[9]

BFRT helps rehabilitate musculoskeletal conditions such as knee osteoarthritis, reconstructions such as anterior cruciate ligament surgery, ruptures of Achilles tendon and after tendon repair. It strengthens muscles, improves function and endurance, and alleviates pain.[10 11] Several recent studies have investigated the effects of upper limb BFRT on shoulder muscle structure and function,[8 12] but the evidence in this area is sparse. The lack of evidence for using BFRT in the upper extremity may be due to the anatomical location of large muscle groups, which affects the BFRT cuff placement and presents a limitation in creating blood flow occlusion compared with the lower extremities. The large muscles of the lower extremity are mostly located distal to the BFRT cuff, and measuring muscle strength and thickness in these muscles is more accessible.[8] On the other hand, most of the vascular obstruction and the suspected mechanisms occur distal to the pressure cuff. Despite the methodological dispersion of the literature, the treatment with BFRT with low training load has been shown to have the same effectiveness as resistance training with high load in improving the muscle strength of the upper trunk, according to a meta-analysis carried out in this area. Of course, the results were accompanied by serious uncertainties due to the limited number of studies in the meta-analysis.[13]

Understanding the effectiveness of BFRT combined with exercise in improving shoulder strength can greatly assist therapists and athletic trainers in choosing a less risky but more effective treatment, thereby reducing the time needed to recover. Therefore, the aim of this study is to conduct a systematic review of the effects of training with BFRT of the upper limb on the strength of shoulder movements.

METHODS AND ANALYSIS

The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement will guide this systematic review[14] and the study protocol is reported in a precise manner according to the guidelines of the PRISMA Protocols.[15] This protocol has been registered (with the registration number: CRD42024605189) in the International Prospective Register of Systematic Reviews in November 2024. The study is planned to start on 9 June 2024 and end on 9 September 2025. As this will be a systematic review of previously published studies and no new data will be gathered, ethical approval and patient consent are not required.

Search strategy and study selection

Comprehensive database searches will be performed in PubMed, Scopus, Ovid, Web of Sciences, EBSCO, Cochrane Central Register of Controlled Clinical Trials (CENTRAL), Physiotherapy Evidence Database (PEDro), and Google Scholar.

Manual search on the clinical trials registration website via US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov), WHO International Clinical Trials Registry Platform and International Standard Randomized Controlled Trials Number (ISRCTN), EU Clinical Trials Register and Iranian Registry of Clinical Trials (IRCT) will be carried out for relevant trials. Relevant systematic reviews and included studies reference lists will also be checked for missing studies.

If a full-text article is not available, the corresponding author(s) will be contacted. If unpublished papers are retrieved, the corresponding author(s) will also be contacted to see if they have republished the paper. Three emails to the corresponding author(s) are the limit. If there is no response, the study will be excluded.

Electronic search strategies will be developed according to the combination of keywords such as: *blood flow restriction, Kaatsu training, vascular occlusion* and *shoulder* with PubMed Medical Subject Headings (MeSH) and free-text terms. The developed strategy is then adapted for each electronic database. The search syntax for the PubMed database is described below.

((‘blood flow restriction’(tiab)) OR (bfr(tiab)) OR (bfrt(tiab)) OR (‘Regional blood flow’) OR (‘Blood Flow Restriction Therapy’(tiab)) OR (‘Restriction training’(tiab)) OR (‘blood flow restriction training’(tiab)) OR (‘blood flow restriction exercise’(tiab)) OR (‘BFR therapy’(tiab)) OR (‘Kaatsu training’(tiab)) OR (‘occlusion resistance training’(tiab)) OR (‘vascular occlusion’(tiab))) AND ((tendinopathy(tiab)) OR (‘Rotator Cuff’(tiab)) OR (shoulder(tiab)) OR (‘shoulder joint’(tiab)) OR (‘shoulder girdle’(tiab)) OR (tendinitis))

Eligibility criteria

All identified references will be transferred to EndNote software (V.X21; Clarivate Analytics, Philadelphia, Pennsylvania, USA) and the duplicate study will be discarded. All the study titles and abstracts will be assessed independently by three authors (TS, HH and MAG) based on the eligibility criteria. The full text of the retrieved studies will then be reviewed by the three authors in order to identify the final studies to be included. Consensus will be used to resolve disagreements at each stage. The PRISMA flow chart (figure 1) will fully summarise the process used to select trials.

Inclusion criteria

1. The study should be designed as a clinical trial or randomised controlled trial.
2. The studies used the BFRT method or pressure cuff on upper extremity (arm/elbow/hand) or neck or trunk.
3. The mentioned intervention method is used as a single session or multiple sessions with or without another treatment method.
4. Intervention on either healthy adults or athletes or patients with shoulder problems before or after surgery.

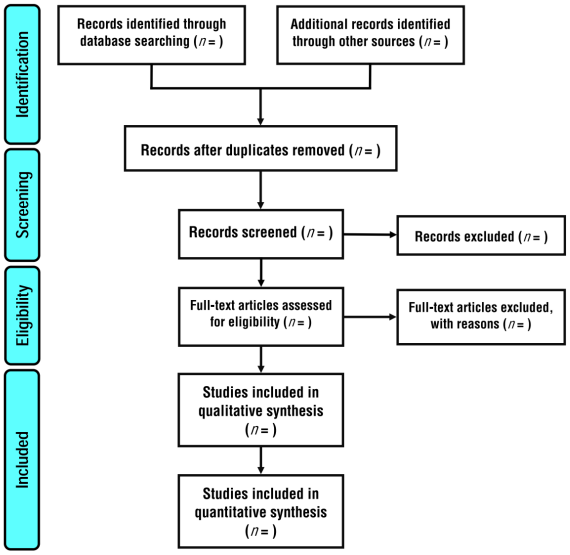

Figure 1 Preferred Reporting Items for Systematic Review and Meta-Analysis flowchart illustrating how to select a study.

5. Shoulder strength or power measured by any type of dynamometer in the direction of flexion, abduction or scaption, or internal rotation and/or external rotation will be considered as primary outcomes. In addition, shoulder pain and function will be taken as secondary outcomes of the study.

Exclusion criteria

1. Case reports, case series and studies with a before–after design.
2. The studies for which the full text is not available.
3. The studies with non-extractable data.

Risk of bias assessment

Two reviewers (HH and MAG) will separately assess the risk of bias in the included studies using the Cochrane Collaboration's Risk of Bias 2 tool, which was developed to assess the risk of bias in randomised controlled trials. This checklist covers the following bias domains: randomisation-related bias, bias due to difference in intended interventions, bias due to missing data, bias in measuring outcomes, bias in the selection of reported outcomes and overall risk of bias. Ratings are 'low', 'some concerns', or 'high'. The two investigators will cross-check the risk of bias assessment and involve the third investigator (TS) if necessary.

Data extraction

Study data will be extracted independently by two reviewers (HH and MGH) by means of a data extraction form that was provided for this review. Information provided (1) study characteristics: author, year, quality, design and sample size; (2) participant characteristics: age, gender, health status (healthy adults/patients with pain or disorders/athletes); (3) details of intervention and controls: each group sample size, treatment sessions, treatment weeks, treatment time, intensity of BFRT used, blinding of participants, therapist and rater; and (4) strength or power of the shoulder (flexion, abduction, internal rotation and external rotation), devices used to measure shoulder strength or power, conflicts of interest, sources of funding and ethical approval. To check for missing studies or mistakes, one author (TS) will also recheck the data. If there is a disagreement, it will be resolved by consensus. We will contact the authors of the included studies if we need more information.

Data synthesis

When the outcome is the same across eligible studies, combined effects of continuous variables are estimated as Morris' delta (Morris' dppc)[16 17] using the effect size calculator from the Campbell Collaboration (http://www.campbellcollaboration.org/escalc/html/EffectSizeCalculator-SMD-main.php) and the online tool from Psychometrica (https://www.psychometrica.de/effect_size.html#cohc). Pooled effects will be calculated using Morris' dppc by first converting the different outcome measures to a 0–100 scale. Morris' delta is defined as small for a dppc of less than 0.40, medium for a dppc between 0.40 and 0.70 and large for a dppc greater than 0.70. If the effect size value is moderately large or greater, the effect is considered significant for the outcome.[17]

Heterogeneity assessment

Statistical heterogeneity of the included study will be assessed using the X^2 test and I^2 statistics.[18] An $I^2 > 50\%$ is defined as substantial heterogeneity. Sensitivity and subgroup and meta-regression analyses will be carried out to account for potential sources of heterogeneity.

Publication bias assessment

Begg[19] and Egger's linear regression methods[20] will be used to examine publication bias. And if the number of the available studies per primary outcome is more than 10, a funnel plot will be performed.[17] Furthermore, a 'trim and fill' procedure will be carried out to discover the possible impact of publication bias.[21] Publication bias will be evaluated via Stata software (V.14: Stata Corp, College Station, Texas, USA).

Sensitivity analysis

Sensitivity analyses will be performed using the leave-one-out method to identify the impact of studies on the overall results.[22] In addition, sensitivity analyses will be performed to check the robustness of the conclusions by including only high-quality studies in the meta-analysis if that is applicable. Sensitivity analysis will be provided by Stata software (V.14: Stata Corp., College Station, Texas, USA).

Summary of evidence

The Grading of Recommendations, Assessment, Development and Evaluation(GRADE) framework[23] will be used to rate the quality of evidence and the strength of recommendations for primary outcomes. GRADE considers five areas: study limitations (eg, 'risk of bias'), inconsistencies

(eg, 'differences in study outcomes'), indirectness of evidence (eg, 'including different patient groups or secondary outcomes'), inaccuracy (eg, 'small sample sizes') and reporting bias (eg, 'publication bias'). The quality of the evidence will be graded as high, moderate, low and very low.

Ethics and dissemination

The previously published papers will be used for all analyses in this study. Results will be disseminated through professional networks, presentations at conferences and publication in a peer-reviewed journal. No ethics approval is required.

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Contributors TS was responsible for conceptualisation, methodology and revising the manuscript. HH and MAG participated in methodology and drafting of the manuscript. All authors read and approved the final version of the manuscript and agree with the order of authorship. TS, the corresponding author, is the guarantor.

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