

Feasibility of Combined BFR, Education and Physiotherapy Program for Patellofemoral Pain: A pilot study

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Abstract

Recent advancements in managing Patellofemoral Pain Syndrome (PFPS) highlight the potential of Blood Flow Restriction (BFR) training, education, and low-intensity exercises as innovative interventions. BFR with neuromuscular control has shown promise in enhancing strength at lower intensities. This study assessed the feasibility of incorporating BFR, education, and low-intensity physiotherapy exercises into PFPS rehabilitation, evaluating recruitment, retention, treatment delivery, and intervention implementation. While no statistically significant differences were found, clinically meaningful improvements in muscle strength, function, and quality of life were observed. These findings support the need for more extensive trials to refine and confirm the intervention's effectiveness in musculoskeletal rehabilitation.

Keyword: Patellofemoral pain; Feasibility; Blood Flow Restriction; Physiotherapy

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1.0 Introduction

Patellofemoral Pain Syndrome (PFPS) is a prevalent musculoskeletal condition linked to inflammation, muscle imbalances, or joint instability. During high-impact activities such as running and jumping, the pain typically worsens with repetitive stress on the knee (Fuhad et al., 2023; Reid et al., 2019). PFPS can significantly impair daily function, limiting physical activity and reducing overall quality of life (QoL).

Physiotherapy plays a crucial role in managing PFPS. The new emergence of rehabilitation for PFPS integrating physiotherapy and blood flow restriction (BFR) could be beneficial in promoting muscle hypertrophy & and strength at lower-intensity training. This makes it particularly helpful for individuals experiencing pain or physical deconditioning (Anderson et al., 2019). Since muscle weakness is a key contributor to PFPS, BFR is expected to enable rehabilitation progress with minimal knee strain, making it suitable for those with pain-induced limitations.

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Recent research, including Xu et al. (2024), underscores the importance of integrating multiple interventions such as BFR training, neuromuscular techniques, strengthening exercises, and postural education (ED) for effective PFPS management. These combined strategies not only improve physical function but also address psychological factors like Kinesiophobia, which frequently accompanies PFPS.

This study investigates the feasibility of a clinical trial integrating Blood Flow Restriction (BFR) training, education (ED), and low-intensity physiotherapy exercises for managing Patellofemoral Pain Syndrome (PFPS). Pilot studies on feasibility are crucial for determining whether interventions can be effectively implemented in clinical settings. The main objectives of the study are (1) to assess the feasibility of the trial by evaluating recruitment, retention, and data completion; (2) to monitor the implementation of the intervention, focusing on treatment delivery and adherence; and (3) to examine contextual factors influencing effectiveness through feedback from both patients and providers. Ultimately, this feasibility study creates a foundation for randomised controlled trials on a larger scale if the study seeks to refine future research and enhance clinical approaches to PFPS management.

2.0 Literature review

2.1 Blood Flow Restriction

Fuhad et al. (2024) and previous studies (Anderson et al., 2019; Hornikel et al., 2023; Schwiete et al., 2021; Zajac et al., 2021) explore Blood Flow Restriction (BFR) therapy for Patellofemoral Pain Syndrome (PFPS). While earlier research reports significant short-term benefits, Fuhad et al. (2024) find modest strength and muscle bulk improvements. Differences in methodology, therapy combination, and patient characteristics suggest further randomised controlled trials to optimise BFR's effectiveness (Fuhad et al., 2023).

2.2 Education

Education helps reduce kinesiophobia by correcting pain misconceptions and promoting rehabilitation adherence (Rim et al., 2022). Physiotherapy can also alleviate fear and improve musculoskeletal function (Fuhad et al., 2022). While these effects are well-studied in back pain, research on knee rehabilitation remains limited. Recent studies have shifted toward biomechanical analyses of knee osteoarthritis (KOA), highlighting altered gait, joint torque, and restricted motion (JAMDA). Bibliometric trends show a growing emphasis on comprehensive post-TKA rehabilitation (JOSR). Whittaker et al. (2022) identified key risk factors for post-traumatic KOA, while Li et al. (2014) explored the impact of joint loading. Standardised education may enhance outcomes (Grbavac et al., 2024).

2.3 The Role of Core Strength in PFPS Management

Core strength is essential for stabilising the trunk and controlling lower extremity movements, as highlighted by Cobb et al. (2014), Rodrigues et al. (2021), and Stickler et al. (2015). Their biomechanical chain approach emphasises the interdependence of core and lower limb function in minimising knee stress. However, recommendations were insufficient for integrating core strengthening exercises into PFPS rehabilitation.

2.4 Muscular Imbalances and Their Impact on PFPS

Research suggests that hamstring flexibility and quadriceps stiffness influence PFPS. Lee et al. (2021) found that dynamic stretching improves hamstring activation, which is essential for knee and hip function. Quadriceps stiffness studies indicate imbalances contribute to patellar maltracking. However, research lacks focus on rehabilitation techniques like targeted stretching and strengthening.

2.5 Physiotherapy low-impact interval training

Low-intensity physiotherapy combined with Blood Flow Restriction (BFR) effectively reduces Kinesiophobia in PFPS rehabilitation (Fuhad et al., 2023). BFR enhances muscle strength at lower intensities, boosting patient confidence (Cognetti et al., 2022). However, long-term effects remain underexplored, necessitating further research on sustained outcomes and psychological factors in rehabilitation.

2.6 Assessment and Rehabilitation Approaches

The Knee Movement Functional Performance Test (KMFPT) effectively evaluates knee function but lacks measures for rotational stability and dynamic control in complex movements. While newer tests, like hopping assessments by Hammami et al. (2024), exist, they were not included in this 2023 study. While structured education is more effective than informal methods, research on PFPS rehabilitation's best formats and delivery methods is limited. Digital platforms may offer a flexible solution, especially for patients with time or physical constraints (de Oliveira Silva et al., 2020). Future studies should explore how education can complement strengthening exercises and psychological strategies like addressing Kinesiophobia.

3.0 Methods

3.1 Study design and setting

The rehabilitation program in this study integrates three core components: Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT), all tested in a pilot study. BFR targets muscle strength and hypertrophy, benefiting those with PFPS. ED educates participants on posture's role in knee function and musculoskeletal health, addressing PFPS's root causes. LIIT focuses on low-intensity movements to improve strength, flexibility, and recovery while reducing joint stress. This randomised controlled trial (RCT), registered under ClinicalTrials.gov (NCT06347406), follows CONSORT guidelines. Conducted in a Malaysian private physiotherapy centre, it ensures controlled, reliable, and consistent treatment protocols.

3.2 Participants

Participants, aged 18-59 with PFPS lasting at least four weeks, were recruited from a private physiotherapy centre. Exclusions included severe symptoms, NSAID use, non-compliance, and a history of knee surgery or trauma.

3.3 Randomisation and blinding

Computer-generated randomisation assigned participants to two groups, minimizing selection bias and confounding variables. Blinding and double-blinding of the allocation process reduced the influence of participant and assessor bias, maintaining study integrity..

3.4 Procedures

The experimental group received a comprehensive intervention addressing both the physical and psychological aspects of patellofemoral pain syndrome (PFPS). This included Blood Flow Restriction (BFR) training, Postural Care Education (ED), and Low-Impact Interval Training (LIIT). BFR, applied using a Recoverfun Air Cuff inflated to 80% of the lower limb's occlusion pressure (LOP) as measured by Doppler ultrasonography, enabled participants to train at lower intensities while promoting muscle hypertrophy and reduced joint stress, particularly beneficial for those with PFPS and deconditioning. LIIT exercises, including bridging, squats, and core strengthening, were combined with postural correction to improve stability. A structured program alternating activity and rest promoted strength and flexibility without increasing pain. Participants also received a brochure on posture and biomechanics. The control group received standard physiotherapy without BFR or targeted postural education. Outcomes were assessed at baseline and week four.

3.5 Recruitment and Retention

This phase assessed recruitment methods to ensure sufficient variability and adherence to inclusion criteria, focusing on adults with PFPS who could follow the protocol. The procedure was refined to identify qualified participants.

3.6 Assessment of Outcomes

Monitoring vital signs was crucial to ensuring the safety and feasibility of the BFR, education, and low-impact interval training intervention. Blood pressure and heart rate were regularly assessed using a sphygmomanometer or automated device. Based on pilot study insights, Mean Arterial Pressure (MAP) was added to the main study to enhance cardiovascular monitoring. Adverse events, including discomfort, lightheadedness, or swelling, were promptly documented using standardised forms. Participants were encouraged to report symptoms, guiding protocol adjustments. Staff received specialised training and conducted emergency drills to ensure preparedness. These safety measures supported the safe and scalable application of the BFR intervention.

3.7 Assessment of Feasibility

Dropout rates and reasons for discontinuation were tracked to evaluate the scalability and effectiveness of the intervention; a centralised attendance log recorded session participation supported by automated reminders and follow-ups for missed sessions. Data on participant demographics, attendance, and reasons for withdrawal were collected. Discontinued participants were surveyed or interviewed to identify withdrawal factors such as time constraints, discomfort, adverse effects, or lack of motivation. Dropout rates were calculated, and associations with demographic factors and study variables, such as intervention difficulty, were explored statistically. Physiotherapist feedback, adherence rates, and participant acceptability were assessed to evaluate intervention feasibility.

3.8 Statical Analysis

Data were analysed using IBM SPSS Statistics 25 for descriptive and inferential statistics. Repeated measures ANCOVA assessed the intervention's effects on pain, strength, functional performance, and Kinesiophobia. A between-factors approach was chosen to compare groups (e.g., treatment vs. control) across dependent variables, making it more appropriate than a within-between interaction. The latter is suited for analysing within-subject changes over time but carries the risk of carryover effects, which are minimised in a between-factors design.

3.9 Outcome measures

After obtaining written informed consent, participants completed a demographic questionnaire covering age, gender, and health history. Pain-related inquiries followed, assessing frequency, severity, and triggers. Anthropometric data, including weight, height, and BMI, were recorded as baseline characteristics. Pain intensity was measured using the Numeric Pain Rating Scale (NPRS), and

Kinesiophobia was assessed with the TAMPA Scale for Kinesiophobia. Muscle strength was evaluated with a handheld dynamometer and functional performance was assessed through squats, balance tests, and reach assessments.

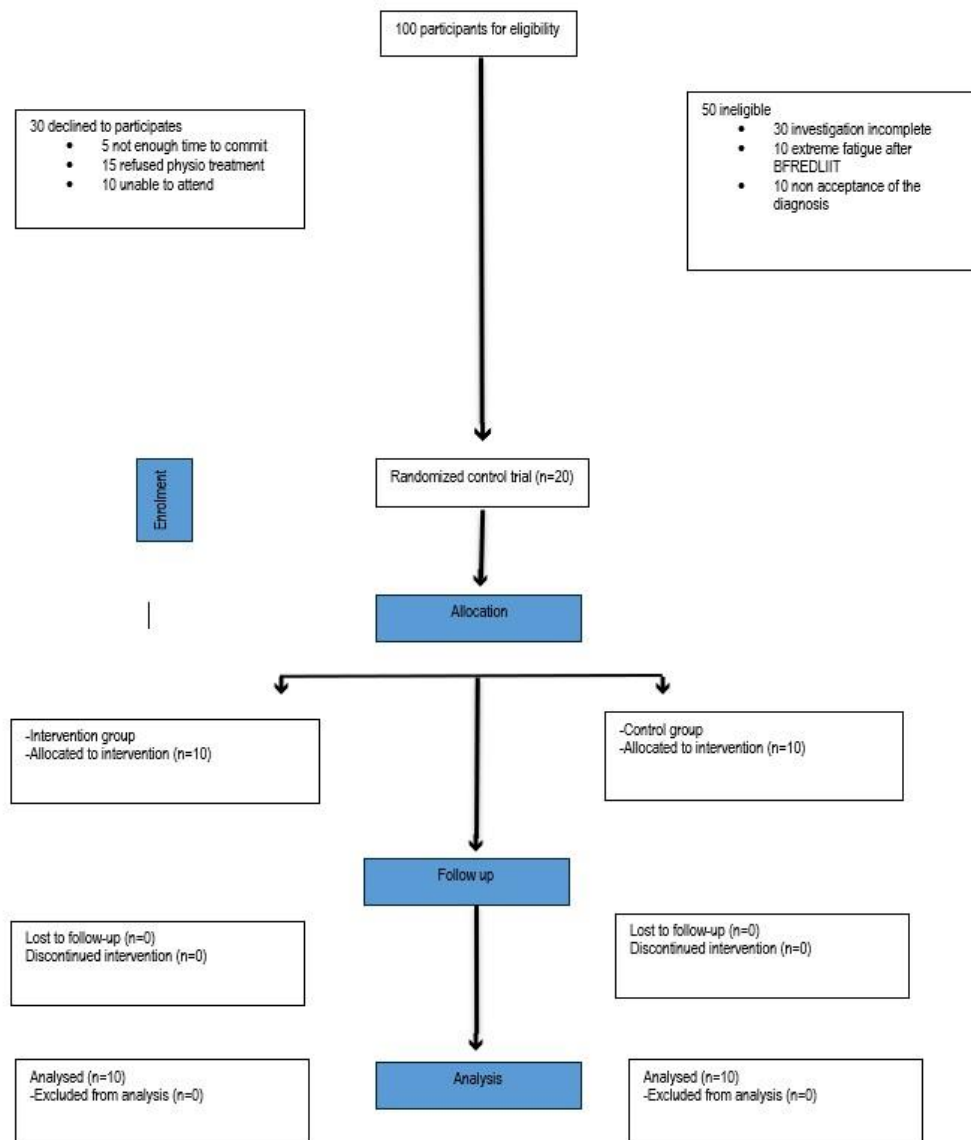


Figure 1: Study flow chart of the study for Feasibility study

4.0 Results

4.1 Participants

Data from 20 older individuals were analysed in this study. The participants had a mean age of 39.75 years, ranging from 18 to 59. Of the participants, 12 (60%) were male, and 8 (40%) were female, all reporting having PFPS. The characteristics of the participants are summarised in Table 1.

Table 1: Demographic data of sociodemographic characteristic

Demographic	Experimental n (%)	Physiotherapy n (%)	Mean ± SD	Total n (%)	Significant
Gender					$X^2=0.8$, $p=0.37$
Male	7 (70)	5 (50)		12 (60)	
Female	3 (30)	5 (50)		8 (40)	
Race					$X^2=24.100$, $p<0.001$
Malay	1 (10)	1 (10)		2 (10)	
Chinese	8 (80)	9 (90)		17 (85)	

Indian		0	0 (0)	
Others	1 (10)	0	1 (5)	
Status				$\chi^2=1.8, p=0.18$
Single	7 (70)	6 (60)	13 (65)	
Married	3 (30)	4 (40)	7 (35)	
Divorce	0	0	0 (0)	
Widow	0	0	0 (0)	
Age		39.75±9.031		$t=2.4, p=1.00$
Young Adult (19-39)	5 (50%)	5 (50)	10 (50)	
Adult (40-59)	5 (50%)	5 (50)	10 (50)	
Type of physical activities				$\chi^2=3.5, p<0.001$
Once a month	1 (10)	1 (10)	2 (10)	
Once a week	3 (30)	2 (20)	5 (25)	
Everyday	4 (40)	1 (10)	5 (25)	
Two to three times a week	2 (20)	4 (40)	6 (30)	
No	0	2 (20)	2 (10)	
Smoking				$\chi^2=12.80, p<0.001$
Yes	0	2 (20)	2 (10)	
No	10 (100)	8 (80)	18 (90)	
Climbing stairs				$\chi^2=12.8, p<0.01$
Yes	9 (90)	9 (90)	18 (90)	
No	1 (10)	1 (10)	2 (10)	
Toilet				$\chi^2=5.0, p=0.025$
Sitting	7 (70)	8 (80)	15 (75)	
Squatting	3 (30)	8 (80)	7 (35)	$\chi^2=1.8, p=0.18$
Health status				$\chi^2=9.7, p=0.008$
Very Good	0	0	2 (10)	
Good	2 (20)	5 (50)	13 (65)	
Moderate	8 (80)	5 (50)	5 (25)	
Walking				$\chi^2=5.0, p=0.25$
Very Good	3 (30)	2 (20)	5 (25)	
Good	7 (70)	8 (80)	15 (75)	

Notes: p-value < 0.05 showed statistically significant M= Mean, SD= Standard deviation

4.2 Outcome of Intervention

The measures were taken at baseline and after the fourth week of intervention (post-test) (Table 2).

Table 2: The Results of Pre-Test, Post-Test, and Changes (%) Between Pre and Mid Tests, Mid and Post Tests and Pre and Post Tests Following 12 Weeks of Interventions For Pain

GROUP		Weeks of intervention	Pre-test (M±SD)	Post-test (M±SD)	% of changes in post-test
Pain	BFREDLIIT pain		2.7±1.7	0.4±2.7	-2.3%
	Physiotherapy management		3±0.9	1.6±1.8	-1.4%
Quality of Life	BFREDLIIT		81.81±18.40	90.98±9.08	9.17%
	Physiotherapy management		77.95±14.92	85.2±14.45	7.25%
Kinesiophobia	BFREDLIIT		40.1±7.68	22.4±6.65	-18.1%
	Physiotherapy management		41.6±5.66	24.8±6.88	-16.8%
Strength	BFREDLIIT	Right Hamstring	28.07±11.76	28.73±11.85	0.64
		Left Hamstring	25.67±11.68	26.40±12.18	0.73
		Right Quadriceps	28.63±9.47	30.65±8.80	2.02
		Left Quadriceps	29.63±12.16	31.30±10.18	1.67
	Physiotherapy management	Right Hamstring	27.57±12.06	27.97±11.91	0.4
		Left Hamstring	27.97±11.91	27.39±10.14	-0.58
		Right Quadriceps	24.63±10.42	25.13±10.57	0.5
		Left Quadriceps	22.57±9.50	22.94±9.68	0.37
Muscle Bulk	BFREDLIIT	Right RF	8.9±2.75	10.12±2.62	1.2
		Right VL	15.12±4.6	14.6±3.8	-0.5
		Right VMO	13.47±3.95	15.36±4.04	1.89
		Right VI	11.26±3.4	12.20±3.5	0.94
		Left RF	9.1±3.25	10.78±3.42	1.68
		Left VL	13.7±2.99	14.01±2.85	0.31
		Left VMO	12.99±5.14	14.4±5.18	1.41
		Left VI	11.5±2.93	12.43±2.81	0.93
	Physiotherapy management				

management				
	Right RF	9.2±4.4	9.76±4.56	0.56
	Right VL	13.5±3.2	13.4±3.3	-0.1
	Right VMO	12.19±3.7	12.93±3.9	3.23
	Right VI	9.7±2.2	9.81±2.24	0.11
	Left RF	7.39±2.21	7.90±2.08	0.51
	Left VL	11.81±3.61	12.53±3.16	0.72
	Left VMO	12.6±5.99	13.25±5.86	0.65
	Left VI	10.3±2.4	10.85±2.25	0.55
Muscle Length	BFREDLIIT			
	Right RF	189.88±6.45	190.57±3.7	0.69
	Right VL	192.08±0.6	191.99±0.64	-0.09
	Right VMO	192.42±1.05	192.03±0.77	-0.39
	Right VI	193.01±1.34	193.05±1.41	0.04
	Left RF	192.04±0.72	191.85±0.90	-0.19
	Left VL	191.24±3.00	191.65±2.24	0.41
	Left VMO	192.39±1.40	191.86±1.17	-0.53
	Left VI	192.92±1.24	192.64±1.50	-0.28
	Physiotherapy management			
	Right RF	191.07±2.11	191.17±2.12	0.1
	Right VL	191.15±2.4	191.17±2.4	0.02
	Right VMO	192.09±2.35	191.46±2.14	-0.63
	Right VI	192.41±3.69	192.41±3.69	0
	Left RF	191.12±2.40	191.02±2.37	-0.1
	Left VL	191.41±2.08	191.43±2.08	0.02
	Left VMO	191.71±2.64	191.63±2.63	-0.08
	Left VI	192.54±3.02	192.4±3.93	-0.11
Knee Muscle Performance	BFREDLIIT			
	Squat	11.9±5.7	14.1±4.2	2.2
	Physiotherapy management			
		9.4±5.5	10.8±4.1	1.4
	BFREDLIIT			
	Right Anterior medial lunge	8.46±4.2	10±4.7	1.54
	Physiotherapy management			
		6.2±4.0	7.1±3.7	0.9
	BFREDLIIT			
	Left Anterior medial lunge	8±3.71	9.5±3.98	1.5
	Physiotherapy management			
		6.2±3.4	6.7±3.6	0.5
	BFREDLIIT			
	Right step down	7.6±3.6	11.4±3.0	3.8
	Physiotherapy management			
		7.6±2.9	8.9±2.8	1.3
	BFREDLIIT			
	Left step down	7.4±3.6	11.4±2.99	4
	Physiotherapy management			
		7.8±2.7	8.9±2.77	1.1
	BFREDLIIT			
	Right Balance and reach	17.2±12.5	18.2±12.5	1
	Physiotherapy management			
		11.8±10.1	11.8±10.1	0
	BFREDLIIT			
	Left Balance and reach	19.5±12.12	20.0±11.65	0.5
	Physiotherapy management			
	Squat	12.5±11.56	12.5±11.43	0

4.2.1 pain

Levene's test showed no significant differences ($p=0.21$). The experimental group showed a reduction of -2.3%, while the physiotherapy management group had a 1.4% reduction after 4 weeks of intervention.

4.2.2 Quality of Life

experimental group resulted in a 9.17% improvement, compared to a 7.25% improvement observed in the physiotherapy management group.

4.2.3 Kinesiophobia

Levene's test yielded no significant result ($p = 0.357$). BFREDLIIT showed an 18% improvement, while physiotherapy management showed a 16.8% improvement.

4.2.4 Muscle Functions

4.2.4.1 Strength

The experimental group showed notable muscle strength improvements, with increases in right hamstring (0.64%), left hamstring (0.73%), right quadriceps (2.02%), and left quadriceps (1.67%). In contrast, the physiotherapy group showed minimal changes across these measures.

4.2.4.2 Muscle Bulk

The results indicated that the experimental group achieved more significant improvements in muscle bulk across several muscle groups than the physiotherapy management group. Notably, the BFREDLIIT group showed more significant increases in right Rectus Femoris (RF) bulk (1.2% vs 0.56%), right Vastus Medialis Oblique (VMO) bulk (1.89% vs 3.23%), and left RF bulk (1.68% vs 0.51%). Conversely, reductions were observed in right Vastus Lateralis (VL) bulk (-0.5% vs -0.1%), right Vastus Intermedius (VI) bulk (0.94% vs 0.11%), left VL bulk (0.31% vs 0.72%), left VMO bulk (1.41% vs 0.65%), and left VI bulk (0.93% vs 0.55%).

4.2.4.3 Flexibility

The experimental group demonstrated improvements in Right Rectus Femoris (RF) length (0.69%), Right Vastus Intermedius (VI) length (0.04%), and Left Vastus Lateralis (VL) length (0.41%), while reductions were observed in other muscle lengths. Similarly, the physiotherapy management group showed slight improvements in Right RF length (0.1%) and right VL length.

4.2.5 Knee Muscle Performance Test

The experimental group demonstrated improvements in squat performance (2.2%), right and left anterior medial lunge (1.54% and 1.5%, respectively), step downs (3.8% and 4%), and balance and reach (1% and 0.5%) compared to the physiotherapy management group.

4.3 Adherence and Compliance

Tracking session attendance and adherence was vital in assessing the feasibility of the BFR intervention. Logs or automated systems recorded participation, duration, and exercise completion. Adherence to intensity, duration, and equipment use was monitored. Post-intervention interviews identified challenges and improvements, ensuring better engagement and effectiveness for larger-scale applications.

4.4 Feasibility test

The study results indicate a promising level of feasibility for the trial. Recruitment targets were met within the expected timeframe, retention rates were high, and data completion exceeded anticipated thresholds, suggesting strong participant engagement and effective study procedures. Implementation of the intervention was carried out successfully, with consistent treatment delivery and high levels of adherence among participants. Additionally, feedback from both patients and providers highlighted supportive contextual factors such as ease of integration into existing workflows and perceived benefits of the intervention, which may contribute positively to the intervention's overall effectiveness in a larger trial.

5.0 Discussion

The feasibility study adhered to the CONSORT 2010 extension guidelines for pilot trials, assessing key progression criteria, including recruitment, adherence, retention, data completeness, and protocol implementation. It evaluated the effectiveness of Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT) compared to standard physiotherapy, showing promising preliminary results. High adherence rates and successful protocol implementation indicated the intervention's feasibility. However, validating these findings will require a larger sample size and extended study duration.

This study offers valuable insights into the practical application of BFR, ED, and LIIT, participant adherence, and any immediate safety concerns. It also aids in refining the study design by highlighting challenges related to recruitment, data collection, and participant compliance. Although a sample size of 20 may not be sufficient to confirm the feasibility of studies with high variability or multiple subgroups, the pilot effectively tested logistics, recruitment strategies, and intervention acceptability.

High recruitment and retention rates demonstrated strong participant acceptance, with no serious adverse events reported. However, some participants experienced temporary exacerbations of chronic fatigue, resolving within a few days. Future studies will exclude individuals with chronic pain or fatigue as primary concerns to enhance participant safety and intervention effectiveness.

This research is the first to integrate BFR, ED, and LIIT into a comprehensive rehabilitation strategy, addressing physiological and behavioural aspects of recovery for Patellofemoral Pain Syndrome (PFPS). It hypothesises that this multimodal approach (BFREDLIIT) enhances pain relief, physical function, and long-term self-management by targeting physiological and psychological factors. If validated, this approach could offer an effective rehabilitation strategy for PFPS. Future research should explore the underlying mechanisms and assess long-term benefits across diverse patient populations.

5.1 Limitations

This study acknowledges several limitations. It was not specifically designed or powered to detect a definitive treatment effect. However, given the lack of controlled trials in the existing literature, reporting the outcomes was deemed valuable in providing preliminary insights. Despite promising trends, the study faced constraints such as a small sample size, limited statistical power, and a four-week intervention period.

The relatively short duration may not have been sufficient to capture significant long-term improvements in muscle strength and QoL. While early indicators suggest potential benefits, extended follow-up periods and larger sample sizes would be necessary to confirm these findings with more excellent reliability. Future research should refine the study protocol, incorporating more extended intervention periods and larger cohorts to strengthen statistical validity and better assess the sustained effects of Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT) on PFPS management.

6.0 Conclusion & recommendation

In conclusion, the pilot study demonstrates the feasibility of the Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT) program for PFPS rehabilitation. While limited by sample size, the promising results warrant a larger-scale study to further evaluate and refine the intervention. Future research should focus on optimising the program's components and assessing its broader clinical applicability in musculoskeletal rehabilitation.

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Paper Contribution to related field of study

The Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT) program offers a promising approach to managing PFPS by combining low-load resistance training, patient education, and rehabilitation. It strengthens key muscles like the quadriceps, hamstrings, and gluteals, reducing joint strain, which is especially beneficial in early rehabilitation phases. Its adaptability suits athletes and inactive individuals, improving recovery and clinical efficiency. The program's time efficiency is ideal for clinics with high patient volumes. Blood Flow Restriction (BFR), Postural Care Education (ED), and Physiotherapy Low-Impact Interval Training (LIIT) may reduce reliance on surgery and painkillers, promoting non-invasive rehabilitation. For effective deployment, physiotherapists need specific training, and patient safety requires proper screening and monitoring during sessions.

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