

Quadriceps strengthening with and without blood flow restriction in the treatment of patellofemoral pain: a double-blind randomised trial

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ABSTRACT

Background Quadriceps strengthening exercises are part of the treatment of patellofemoral pain (PFP), but the heavy resistance exercises may aggravate knee pain. Blood flow restriction (BFR) training may provide a low-load quadriceps strengthening method to treat PFP.

Methods Seventy-nine participants were randomly allocated to a standardised quadriceps strengthening (standard) or low-load BFR. Both groups performed 8 weeks of leg press and leg extension, the standard group at 70% of 1 repetition maximum (1RM) and the BFR group at 30% of 1RM. Interventions were compared using repeated-measures analysis of variance for Kujala Patellofemoral Score, Visual Analogue Scale for 'worst pain' and 'pain with daily activity', isometric knee extensor torque (Newton metre) and quadriceps muscle thickness (cm). Subgroup analyses were performed on those participants with painful resisted knee extension at 60°.

Results Sixty-nine participants (87%) completed the study (standard, n=34; BFR, n=35). The BFR group had a 93% greater reduction in pain with activities of daily living (p=0.02) than the standard group. Participants with painful resisted knee extension (n=39) had greater increases in knee extensor torque with BFR than standard (p<0.01). No between-group differences were found for change in Kujala Patellofemoral Score (p=0.31), worst pain (p=0.24), knee extensor torque (p=0.07) or quadriceps thickness (p=0.2). No difference was found between interventions at 6 months.

Conclusion Compared with standard quadriceps strengthening, low load with BFR produced greater reduction in pain with daily living at 8 weeks in people with PFP. Improvements were similar between groups in worst pain and Kujala score. The subgroup with painful resisted knee extension had larger improvements in quadriceps strength from BFR.

Trial registration number 12614001164684.

BACKGROUND

Patellofemoral pain (PFP) is a common source of anterior knee pain in active adolescents¹ and adults,² and often associated with weakness³ and atrophy of the quadriceps femoris.^{4 5} Quadriceps strengthening exercises reduce anterior knee pain, improve function^{6 7} and increase patellofemoral joint contact area for people with PFP.⁸ However, quadriceps strengthening exercises are thought to increase load through the patellofemoral joint, and clinicians administering these exercises need to exercise caution to avoid aggravating PFP symptoms.

The American College of Sports Medicine (ACSM) recommends loads of 60%–70% of the maximum load a person can lift (1 repetition maximum (1RM)) to develop muscle strength, and 70%–85% 1RM to produce muscle hypertrophy.⁹ Quadriceps strengthening exercises for PFP are typically consistent with the ACSM guidelines, and prescribed at 60%–70% 1RM.^{8 10 11} For many people with PFP, the joint loads from these exercises may cause symptoms to flare. Patients are therefore often advised to reduce resistance to a level that does not provoke symptoms,^{8 12} although these loads may not maximise muscle hypertrophy and strength gains.

Blood flow restriction (BFR) training, also known as Kaatsu training,¹³ involves placing a pneumatic cuff proximal to the target muscle during strengthening exercises. The cuff restricts arterial blood flow and venous return, causing a greater rate of muscle fatigue than normal conditions.¹⁴ Training with BFR at 20%–30% of 1RM can induce muscle hypertrophy and increase strength more than the same programme without BFR,¹⁵ although the improvements are not as substantial as with traditional strength training at 70% of 1RM.^{16–18} Greater muscular adaptation with the addition of BFR at low resistance may increase quadriceps strength without risking symptom flare in PFP. BFR could be particularly beneficial for a subgroup of people with PFP who cannot perform quadriceps strengthening exercises effectively due to pain.

Therefore, we compared the effects of quadriceps strengthening at low intensity with BFR with quadriceps strengthening at high intensity on improvements in pain, function, quadriceps muscle strength and quadriceps muscle size in individuals with PFP. A secondary aim was to examine whether the subgroup of patients who experienced PFP on resisted knee extension had greater change in pain and quadriceps strength from BFR than from the standardised quadriceps strengthening programme.

METHODS

Trial design

This randomised controlled trial was registered with the Australian New Zealand Clinical Trials Registry, Trial Number 12614001164684, and took place from October 2014 to October 2015. Procedures were approved by La Trobe University Human Ethics Committee. Participants provided written, informed consent and were randomly



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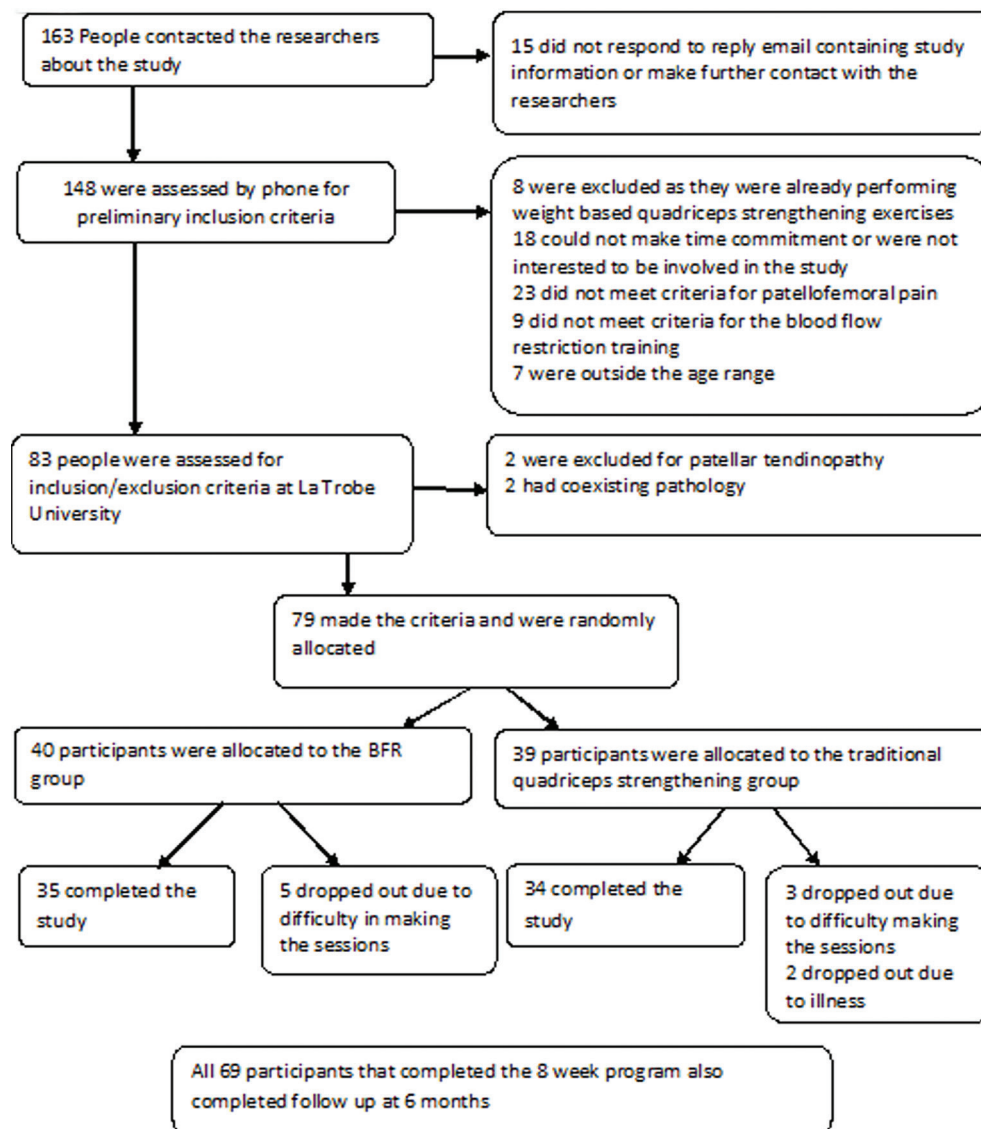


Figure 1 CONSORT statement. BFR, blood flow restriction.

allocated to a standardised quadriceps strengthening programme at high-intensity or low-intensity quadriceps strengthening with BFR, and performed the exercises three times per week over 8 weeks.

CONSORT statement and flow chart

This study has been designed and reported in line with the CONSORT and CONSORT PRO extension recommendations for reporting randomised trials (figure 1).

Participants

Participants with PFP responded to posters placed on social media (running groups, student groups, basketball and netball associations), sporting venues, physiotherapy and medical clinics.

Inclusion criteria

Participants between 18 and 40 years were included if they experienced PFP as evidenced by the following: atraumatic onset of anterior knee pain for greater than 8 weeks; pain with any two activities, including running, jumping, squatting, kneeling, stair ascent/descent or prolonged sitting; pain

with any two of patellar compression; palpation of the peri-patellar region; and resisted isometric knee extension when sitting.^{5 19 20}

Exclusion criteria

Participants were excluded if they had coexisting pathology around the knee, including patellar subluxation or dislocation, other sources of anterior knee pain (bursa, fat pad), knee surgery, or if they participated in weight training of the legs within the past 6 months (to not include previous non-responders). Participants were excluded on suspicion of patellar tendinopathy, with strong consideration of pain localised to the patellar tendon, increased symptoms with dynamic loads and pain reduction with sustained isometric contraction.²¹

Participants were excluded from the study if they were found to be at elevated risk of venous thrombosis (lower limb surgery in the past 6 months, cardiovascular conditions, including high blood pressure ($>140/90$)), diabetes, unexplained chest pain or heart condition, fainting or dizzy spells during physical activity/exercise that causes loss of balance, pregnancy,²² or if exercise was contraindicated.

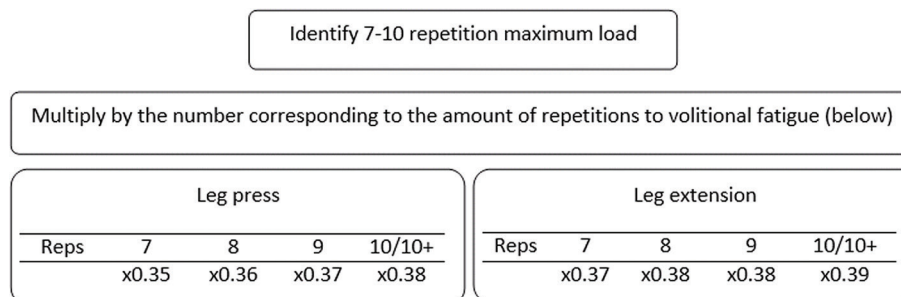


Figure 2 Identifying the load to be used with blood flow restriction training.

Randomisation and blinding

Participants were randomly allocated to one of the two treatment groups. The randomisation was performed by a person independent to the study in lots of 20 at a 1:1 ratio by drawing group allocation from a concealed box; the box was replenished before each lot had been used.

Participants presented to the university for baseline and 8-week assessments conducted by a physiotherapist blinded to treatment allocation. Additional follow-up questionnaires were administered at 6 months from baseline data (range: 5–12 months). Participants were blinded to group allocation, and both groups were informed they were receiving BFR.

Assessment procedures

Data on participants' age, height, weight, symptom duration, thigh circumference, Foot Posture Index,²³ knee swelling/crepitus and activity status (current running activity) were recorded at baseline. All other outcome measures were recorded at baseline and 8 weeks, and at 6 months (except muscle size and strength).

Arterial occlusion pressure

Arterial occlusion pressure was measured by placing a pneumatic cuff on the proximal thigh in standing position. The participant lay supine and the pedal pulse was located with Acuson colour Doppler ultrasound (Mountain View, California, USA). Cuff pressure was increased until the pedal pulse could no longer be identified (maximum 250 mm Hg, velocity 92 cm/s), then

slowly released. The arterial occlusion pressure was recorded at the time when the pulse was restored. BFR was performed at 60% of the arterial occlusion pressure. This procedure has been described previously.²⁴

Outcome measures

PFP was measured by asking participants to indicate on a 100 mm Visual Analogue Scale (VAS) (1) their worst pain in the past week and (2) pain with activities of daily living (squatting, stair descent and after 30 min of sitting). Pain related to function was measured with Kujala Patellofemoral Score.²⁵ Test–retest reliability intraclass correlation coefficients (ICCs) are 0.76 (VAS worst pain), 0.83 (pain with activity) and 0.81 Kujala Patellofemoral Score.²⁶ Global perceived outcome was investigated at 6 months by asking participants to rate their pain compared with when they started the programme as much worse (1), worse (2), same (3), improved (4) or much improved (5).

Quadriceps muscle strength

Peak isometric knee extensor torque was measured bilaterally with a HUMAC NORM dynamometer (Computer Sports Medicine, Stoughton, Massachusetts, USA). Participants were seated at 105° hip flexion. Isometric peak torque was measured at 60° of knee flexion as knee extensor torque is near maximal in this position.²⁷ Straps placed over the thigh limited sagittal motion. Participants attempted to straighten their knee with maximal force. Peak knee extensor torque (Newton metres) was recorded over 3 × 5 s periods, with 30 s rest between attempts. Three submaximal practice repetitions were performed for familiarisation with the testing protocol. Participants reported whether they experienced pain during the testing (yes or no) and whether pain prevented them from pushing harder (yes or no). The test–retest reliability (ICC) of this measure is 0.94.²⁸

Quadriceps muscle thickness

Quadriceps muscle thickness was measured by a physiotherapist trained in real-time ultrasound. Previous research found a good correlation between ultrasound and MRI thickness measurement of vastus medialis (Pearson's $r=0.86$), vastus lateralis ($r=0.94$) and rectus femoris ($r=0.86$) muscle thickness.^{29–30} Measures were taken at the mid-belly of each of these muscles, and the sum of the measures was used to estimate quadriceps size.

Treatment procedures

Features common to BFR and standardised quadriceps strengthening

Each group performed 5 min of 'light' intensity exercise bike to warm up, leg press between 0° and 60° knee flexion and leg extension from 90° to 45° knee flexion. These ranges of motion were selected to minimise patellofemoral joint load.³¹

Table 1 Baseline characteristics

Group allocation	BFR (n=40)		SQS (n=39)		p Value
	Mean	SD	Mean	SD	
Age (years)	28.5	5.2	26.7	5.5	0.14
Gender (female/male)	24/16		19/20		0.31
Height (cm)	171.3	9.2	172.7	9.4	0.52
Weight (kg)	75.3	15.7	77.3	18.9	0.61
Unilateral/bilateral	8/32		10/29		0.55
Foot Posture Index	3.1	3.3	2.3	3.2	0.28
Symptom duration (months)	31.6	40.9	37.8	55.5	0.58
Audible crepitus (n)	11		12		
Pain with resisted knee extension (n)	20		19		
Pain limits knee extensor torque (n)	8		6		
Adherence to programme (% of sessions made)	83		80		

BFR, blood flow restriction; n, number of participants; SQS, standardised quadriceps strengthening.

Table 2 Overall effects of SQS (n=39) and quadriceps strengthening with BFR (n=40)

	Baseline measure			8-Week measure			0–8 Week changes			6-Month measure		0–6 Month results			
	Group	Mean	SD	Levene's (F)	Mean	SD	Levene's (F)	Sig (p) b/w group	Sig (p) within group	Mean difference in change b/w groups (95% CI)	Effect size (d)	Mean	SD	Levene's (F)	Sig (p) b/w group
VAS worst pain in past week (mm, range: 0–100)	BFR	55.7	13.9	0.26	27.4	20.1	3.51	0.237	<0.001	6.0 (–4.1 to 16.2)	0.27	28.1	25.5	0.03	0.752
	SQS	51.4	15.3	p=0.61	29.2	25.6	p=0.06		<0.001			25.8	27.1	p=0.90	
Kujala Patellofemoral Score (0: most affected; 100: least affected)	BFR	73.6	9.9	0.05	86.5	10.5	1.04	0.308	<0.001	2.4 (–2.2 to 7.0)	0.23	84.4	12.0	1.98	0.351
	SQS	72.6	10.5	p=0.83	83.2	12.3	p=0.31		<0.001			85.9	13.3	p=0.16	
VAS with ADL (stairs, squat or sitting) (mm, max 100)	BFR	58.2	17.5	2.92	21.6	25.0	0.359	0.022	<0.001	12.1 (1.8 to 22.3)	0.53	31.7	26.6	0.14	0.175
	SQS	42.5	22.8	p=0.09	23.5	24.1	p=0.55		<0.001			23.9	25.4	p=0.71	
Knee extensor torque (Nm)	BFR	131.2	61.9	0.42	166.4	59.4	<0.01	0.073	<0.001	13.0 (–0.2 to 26.2)	0.48	N/A	N/A	N/A	N/A
	SQS	135.1	55.1	p=0.52	158.7	57.4	p=0.96		<0.001						
Quadriceps size (cm)	BFR	7.9	1.3	0.05	8.0	1.1	0.126	0.195	0.507	0.2 (–0.11 to 0.53)	0.30	N/A	N/A	N/A	N/A
	SQS	7.7	1.4	p=0.83	7.9	1.2	p=0.73		0.018						
ADL, activities of daily living; BFR, blood flow restriction; b/w, between; sig, significance; SQS, standardised quadriceps strengthening; VAS, Visual Analogue Scale; N/A, not applicable.															

ADL, activities of daily living; BFR, blood flow restriction; b/w, between; sig, significance; SQS, standardised quadriceps strengthening; VAS, Visual Analogue Scale; N/A, not applicable.

All exercises were performed with little pain, and if pain was reported to be greater than 2/10 on the VAS the load was reduced by 20%. Six rehabilitation sessions were performed with one-on-one supervision from the physiotherapist (three sessions in the first week, then at 2-week intervals), and the remainder of the sessions were performed under group supervision. Participants were permitted to maintain current activity, unless knee symptoms were aggravated. After 8 weeks, participants could continue exercises of their own volition.

To identify the load participants used during the rehabilitation exercises, the maximum load that could be lifted for 7-10 repetitions (7-10RM) was used instead of direct 1RM measurements because pain was likely to interfere with 1RM (figure 2). The 7-10RM is highly predictive of 1RM leg press ($r=0.98$)³² and leg extension ($r=0.94$).³³

BFR training

Participants in the BFR group placed the cuff on the proximal thigh and inflated to the prescribed pressure in the resting position of the exercise to be performed (leg press or leg extension). The exercises were performed at approximately 30% of 1RM with the BFR cuff inflated. One set of 30 repetitions (or volitional fatigue), then three sets of 15 repetitions were performed.^{34 35} The cuff remained on for the 30s rest between sets and was removed after the exercise was completed.

Standardised quadriceps strengthening

The standardised quadriceps strengthening group performed three sets of 7-10 repetitions (approximately 70% of 1RM) with placebo BFR. The placebo was a 5 cm elastic cuff placed firmly around the proximal thigh, with enough room for two fingers between the skin and the cuff. This did not affect the amount of repetitions performed during strength training in preliminary testing.

Adherence to programme

Participants recorded each of the scheduled sessions that they attended, and the percentage of attended sessions was calculated.

Statistical analysis

All statistical analyses were performed with IBM SPSS V.20. Analysis was performed on an intention-to-treat basis.

Differences between groups in baseline characteristics (age, body mass index and symptom duration) were assessed with independent samples t-test and χ^2 test (gender and unilateral/bilateral symptoms). The differences between groups over time in worst pain in the past week (VAS), pain with daily activity (worst VAS score from squatting, stair descent or prolonged sitting), knee-related function (Kujala Patellofemoral Score), muscle size and muscle strength were analysed with a repeated-measures analysis of variance (ANOVA) with group allocation (BFR, standardised quadriceps strengthening) as the independent factor, and time (baseline, 8-week and 6-month follow-up for all outcomes, and baseline and 8 weeks for muscle size and strength only) as the dependent factor. Global change in pain was investigated with the Mann-Whitney U test. Effect size descriptors were based on recommendations by Rubin as Cohen's d: weak <0.2, weak to moderate 0.2-0.4, moderate 0.4-0.65, moderate to strong 0.7 and strong >0.8.³⁶ Participants who experienced pain with knee extensor torque testing were included in an a priori planned subgroup analysis. A repeated-measures ANOVA was performed for worst pain in the past week and knee extensor torque. Group

Table 3 Effects of SQS (n=19) and BFR (n=20) in people with pain with resisted knee extension

Outcome measure	Baseline measure				8-Week measure				Between-group effects (0–8 weeks)			6-Month measure				Between-group effect (0–6 months)	
	Mean	SD	Levene's F	Sig (p)	Mean	SD	Levene's F	Sig (p)	Mean difference in change (95%CI)	Sig (p)	Effect size (d)	Mean	SD	Levene's F	Sig (p)	Sig (p)	Levene's F
VAS worst pain in past week (mm, range: 0–100)	57.7	13.4	0.35 p=0.56		25.0	15.8	3.07 p=0.09	0.266	7.7 (–6.1 to 21.5)	0.266	0.36	29.8	26.6	0.06 p=0.81	0.708		
Knee extensor torque (Nm)	117.5	54.9	0.05 p=0.83		161.0	53.3	0.34 p=0.56	0.003	24.1 (8.9 to 39.4)	0.003	1.02	N/A	N/A	N/A	N/A		

BFR, blood flow restriction; Nm, Newton metre; sig, significance; SQS, standardised quadriceps strengthening; VAS, Visual Analogue Scale; N/A, not applicable.

allocation was the independent factor, and pain and strength at baseline, 8 weeks and 6 months were the dependent factors.

Assumptions of normality (Levene's test) and sphericity (Mauchly's test) were met for all analyses.

Sample size

Required sample size was calculated a priori based on the results (mean SD) of previous studies that measured the effects of quadriceps strengthening on VAS (worst pain in past week) at the 8-week mark^{37 38} and Kujala Patellofemoral Score at the 4-week mark.³⁹ To achieve a power of 0.8 in detecting a difference between groups of 15 mm (SD±22) points on the VAS and 8 points (SD±11.6) on the Kujala Patellofemoral Score, 58 and 68 participants were required, respectively.

RESULTS

Of the 79 participants who started the programme, 10 were lost to follow-up (5 in the BFR group and 5 in the standardised quadriceps strengthening group), leaving 69 completed participants (87%) at 8 weeks, all of whom completed follow-up at 6 months. Of the non-completers, two withdrew due to illness and eight cited difficulty in making it to the exercise sessions. The last reported scores of the non-completers were carried forward. Data from participants who did not complete the programme were not included in the subgroup analysis.

There was no significant difference between groups at baseline for age, gender, height, weight, unilateral/bilateral symptoms, Foot Posture Index or symptom duration (table 1).

Baseline characteristics

Baseline VAS with activities of daily living (ADL) scores were significantly higher (13.7 mm) in the BFR group than the standardised quadriceps strengthening group (p=0.001) (table 2).

No statistically significant difference in change was found between groups over 8 weeks in worst pain or Kujala Patellofemoral Score. There was a 93% greater reduction in pain with ADL (p=0.022) over 8 weeks in the BFR group relative to the standardised quadriceps strengthening group (table 2). A 49% greater improvement in knee extensor torque in the BFR group approached, but did not reach, significance (p=0.073). No significant change in quadriceps muscle thickness was found between groups. From baseline to 6 months, no significant difference was found between groups for change in worst pain, pain with ADL or Kujala Patellofemoral Score (table 2).

Worst pain, Kujala Patellofemoral Score, pain with ADL and knee extensor torque improved significantly in both groups over 8 weeks. Quadriceps muscle thickness increased significantly over 8 weeks in the standardised quadriceps strengthening group (4.0% increase, p=0.018) and not in the BFR group (1.1% increase p=0.507).

No significant difference in global perceived change in pain was identified between groups at 6 months (BFR group: median 4 (range: 3–5); standardised quadriceps strengthening group: median 4 (range: 1–5), p=0.879).

Subgroup analysis

Participants with painful resisted knee extension (n=39) in the BFR group had a significantly greater increase in knee extensor torque than those in the standardised quadriceps strengthening group (table 3). The participants with painful resisted knee extension in the standardised quadriceps strengthening group who experienced pain with resisted knee extension had the least change in knee extensor torque of any of the participants

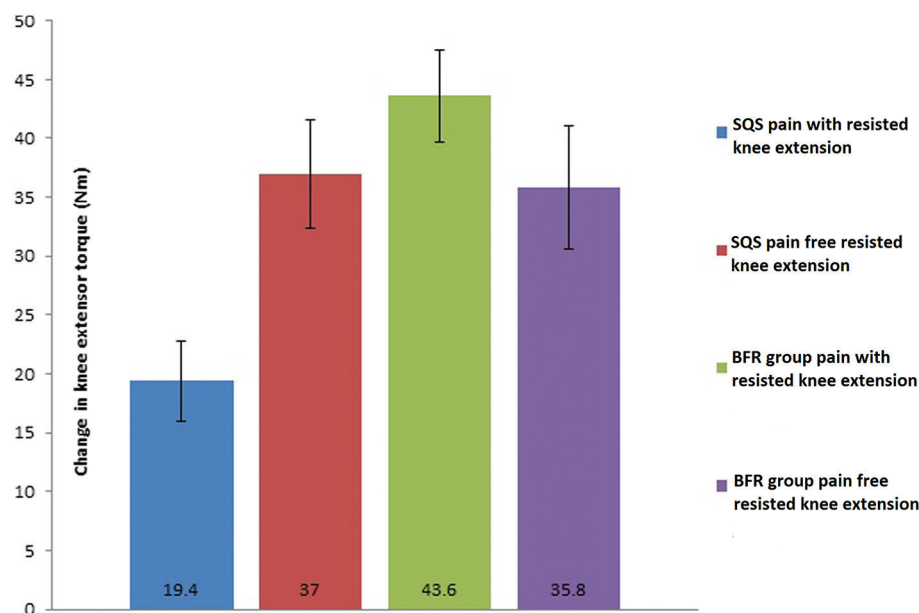


Figure 3 Change in knee extension torque (Newton metre) by group allocation and pain response to resisted knee extension. Error bars are SE in measurement. BFR, blood flow restriction; SQS, standardised quadriceps strengthening.

(figure 3). No significant difference in global perceived change in pain was identified between groups at 6 months for people with painful knee extension ($p=0.365$).

DISCUSSION

In patients with PFP, we identified a significantly greater reduction in pain with daily activities in the BFR training group relative to the standardised quadriceps strengthening programme over 8 weeks. There was no difference in change in worst pain, pain-related function (Kujala Patellofemoral Score), muscle size or strength among groups. No difference was found between groups for any outcome at 6 months. A subgroup of patients with PFP who had pain with resisted knee extension had greater improvement in quadriceps strength with BFR than with standardised quadriceps strengthening, but no difference in worst pain.

Effects of standardised quadriceps strengthening exercises and BFR on PFP

Reducing pain and improving function are fundamental goals of PFP rehabilitation. No clinically relevant effect or significantly greater improvement in worst pain in the past week or Kujala Patellofemoral Score was found with BFR compared with standardised quadriceps strengthening.²⁶ The BFR group had a significantly greater reduction in pain with daily activities than the standardised quadriceps strengthening group over 8 weeks, which exceeded the recommended amount to achieve clinical relevance (13 mm on VAS for activity measures in PFP),²⁶ but this was not maintained at 6 months. Overall these results suggest that BFR has a similar effect to standardised quadriceps strengthening in reducing worst pain and pain related to function, and may have a greater effect in reducing pain with daily activity.

Muscle strength and size

Increasing quadriceps strength is a fundamental aim of PFP rehabilitation as quadriceps weakness is associated with PFP^{3 40} and may increase the risk of developing knee osteoarthritis.⁴¹ Greater increase in knee extensor torque over 8 weeks that

may be clinically relevant (49% greater, moderate effect size) but was not statistically significant was observed in the BFR group compared with the standardised quadriceps strengthening group. In this study the reduction in load to keep the exercises pain-free may have reduced the load to less than 70% 1RM for many people in the standardised quadriceps strengthening group, resulting in submaximal quadriceps strength gains. The trend towards greater gains in the BFR group is consistent with previous studies reporting that resistance training at lower loads with BFR produces greater gains in muscle strength than at low loads without BFR,⁴² which could explain the greater strength gains in the BFR group. Central and neural adaptations to the training could explain why the BFR group improved in muscle strength but not size.⁴³ Strengthening programmes greater than 8 weeks might be required to identify detectable changes in muscle size.⁴⁴

Effect of pain on outcomes

People with PFP who experience pain with quadriceps contraction may be particularly susceptible to flare with the load used in standardised quadriceps strengthening, and therefore may not perform these exercises effectively. The significantly greater increase (strong effect) in knee extensor torque with BFR than standardised quadriceps strengthening in people with painful resisted knee extension supports this hypothesis and suggests BFR may be beneficial for quadriceps strength gains for this population. The differences in quadriceps strength were not reflected in differences in pain for this subgroup.

LIMITATIONS

Participants in the BFR group had significantly more pain with daily activity than the standardised quadriceps strengthening group at baseline. This difference provided greater potential for pain reduction in the BFR group, and reduces confidence that results are due to intervention rather than baseline differences. Sample size was calculated for a moderate effect size on the VAS, and smaller effects with potential clinical implications may have been detected with a larger sample. Non-completers were

subject to intention-to-treat analysis with baseline score carried forward. This reduced the chance of type 1 error but increased the chance of type 2 error.

CONCLUSION

Quadriceps strengthening at low load with BFR was more effective in reducing pain with daily activity than standardised quadriceps strengthening exercises in people with PFP. It produced similar improvement in worst pain and pain related to function. In people with painful resisted knee extension, BFR was more effective than standardised quadriceps strengthening at increasing quadriceps strength, but this did not result in a greater improvement in pain. BFR training may be a useful alternative to standardised quadriceps strengthening for people with PFP who have poor tolerance to heavy resistance training due to pain.

What are the findings?

- Blood flow restriction (BFR) training at 30% 1RM reduced pain with daily activity more than standardised quadriceps strengthening (70% 1RM) over 8 weeks in people with patellofemoral pain (PFP). There was no significant difference in worst pain or Kujala Patellofemoral Score.
- People with PFP who have pain with resisted knee extension achieve greater improvement in quadriceps strength by performing exercises with BFR than standardised quadriceps strengthening.

How might it impact on clinical practice in the future?

- Both standardised quadriceps strengthening and BFR can be used to reduce pain from PFP and increase quadriceps strength.
- BFR may be a useful alternative for people with PFP who are not tolerating the load of standardised quadriceps strengthening programmes due to pain.

Correction notice This paper has been amended since it was published Online First. The corresponding author's email address has been updated.

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Contributors LG, JM, KEW and JLC contributed to the conception and design of the study. LG performed all assessments, extracted and analysed the data, and wrote the manuscript. JM, KEW and JLC critically revised the manuscript for important intellectual content.

Competing interests None declared.

Ethics approval La Trobe University Human Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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