Comparative Effects of Low-Intensity Blood Flow Restriction and High-Intensity Resistance Training on Pain Intensity in Individuals with Knee Osteoarthritis: A Randomized Controlled Trial

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Abstract:

Background: High-intensity resistance training (HI-RT) of the quadriceps, which is one of the primary treatment methods, can aggravate the pain of knee osteoarthritis (KOA) and cause the individual to abandon the exercise.

Objective: Evaluate the effects of progressive blood flow restriction training (BFRT) on pain intensity, functionality, and quality of life (QoL) in individuals with KOA and compare them with traditional HI-RT.

Design: Single-blinded, randomized controlled study

Methods: Individuals who were diagnosed with KOA were randomly assigned to the low-intensity BFRT (n=19) and HI-RT (n=19) groups by a blinded assessor. All participants performed the same strengthening exercise training at different resistance intensities (BFRT: 30% of 1-RM; HI-RT: 70% of 1-RM) for 24 sessions. Pain intensity measured by visual analog scale (VAS), Western Ontario and McMaster Universities Arthritis Index (WOMAC) for functionality and QoL by the short form (SF-36) were the outcome measurements applied at baseline and after 8 weeks of training.

Results: Thirty-eight participants completed the trial. Both BFRT and HI-RT significantly reduced pain and improved function and quality of life (all $p<0.05$). Activity pain decreased more with BFRT than HI-RT (time×group $F=5.91$, $p=0.020$). BFRT was well tolerated, with no adverse events; two HI-RT participants withdrew due to knee pain.

Conclusions: The present results support the notion that use of BFRT in individuals with KOA may show similar or even some superior effects to HI-RT. It has been demonstrated that the use of BFRT in clinics can be an effective, feasible, and safe method for the conservative treatment of painful OA who cannot tolerate high resistances.

Keywords: Blood flow, KAATSU, Osteoarthritis, Knee, Pain

1. INTRODUCTION

Knee osteoarthritis (KOA) is a major inflammatory joint disease that causes disability, inactivity, and pain. Rehabilitation is an integral part and the primary step of KOA treatment.[1] Strengthening the quadriceps is a key and proven practice by reducing pain and disability, increasing functionality. Most notably, quadriceps weakness is considered the main risk factor for KOA and an important indicator of KOA progression.[2]

The American College of Sports Medicine (ACSM) recommends a minimum resistance load of 70-85% of 1 maximum repetition (1-RM) for strength gain and 60-70% of 1-RM for muscle hypertrophy.[3] In painful arthritic knees, it may not be possible to exercise with high resistance; it may damage the joint, and movements with high loads may exacerbate pain, swelling, and inflammation.[4] Recently, the use of blood flow restriction training (BFRT) with low resistance loads, such as 30% of 1-RM, has been regarded as a practical approach in people who cannot tolerate high-load resistance training.[5]

BFRT involves placing a pneumatic cuff proximal to the target muscle during exercises. The cuff restricts arterial blood flow and venous return, causing more muscle fatigue than normal conditions with stimulus as a result of metabolic accumulation.[6] BFRT may be useful in KOA management because of the possibility of gains with lower levels of pain, overload, and joint stress compared with high-intensity (≥ 60% of 1-RM) resistance training (HI-RT).[7]

Although studies investigating BFRT and its effect on pain, function, quality of life, and hypertrophy in healthy and unhealthy individuals have been conducted, randomized controlled trials (RCTs) of KOA are scarce. More RCTs are, therefore, necessary to determine whether BFRT is applicable and beneficial for individuals with KOA. Hence, our aim in this study was to assess the effect of structured blood flow-restricting progressive exercise training on pain intensity, functionality, and quality of life (QoL) in individuals with chronic KOA and compare it with conventional high-intensity resistance training.

2. PATIENTS AND METHODS:

2.1. Study Design

This study was designed as a single-blinded, prospective randomized controlled comparative study. It was conducted from December, 2020 to October 3, 2021 at the Divisions of Orthopedics in university hospital settings.

2.2. Participants

Of the 112 evaluated applicants, eligible 47 individuals aged between 40 to 65 who were diagnosed with primary KOA according to the criteria of the American College of Rheumatology were included in the study. These individuals were those who had Grade II and Grade III-KOA according to the Kellgren and Lawrence radiographic classification[8], and stated that the severity of knee pain measured by the visual analog scale (VAS) was at least 3 and at most 8. Potential participants were not eligible for the study if they had a history of knee surgery or physical therapy/intra-articular injection in the last 6 months, other sources of knee pain, were at risk for venous thrombosis and cardiovascular diseases, had other inflammatory metabolic disease, were anti-inflammatory drug users, or experienced fainting and dizziness during physical activity or exercise. Among the participants, those who were absent for more than 2 sessions in a row in 24 sessions of 8

weeks and those who showed COVID-19 symptoms or positive test results were excluded from the study. The flow of the study population is demonstrated in the CONSORT flow diagram **(Figure 1).** Randomization was performed using sealed and sequentially numbered envelopes for the groups. All procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. The institutional review board at Istanbul Medipol University approved all recruitment and testing procedures (Reference No. 10840098-772.02-E.34224).

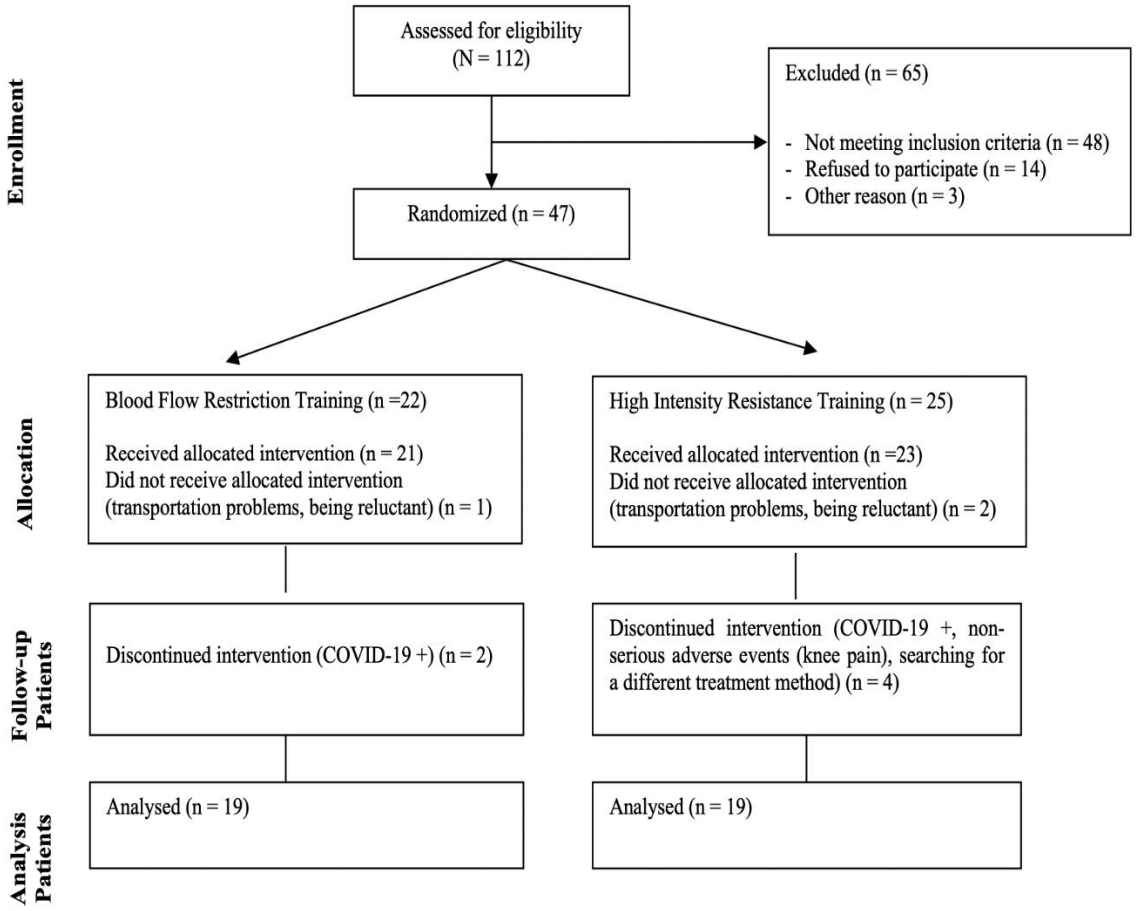

Figure 1. Flow diagram of the study representing enrollment, allocation, follow-up and analysis for both groups.

2.3. Demographic and Clinical Variables

Data were collected at baseline and at the end of the exercise (week 8). Demographic variables were documented prior to assessment. Pain intensity, functionality, and quality of life were assessed at baseline and at the end of the 8th week. The primary outcome was pain intensity, and secondary outcomes were functionality, and quality of life at the 4th week. The exercises were also evaluated for feasibility and safety.

Pain intensity: Participants were asked to mark activity pains (A-P) caused by daily living activities, pain at night (N-P) and pain at rest (R-P) on a 100-mm visual analog scale (VAS).

Function: WOMAC index is an OA-specific, self-reported, validated, and safe measurement

of KOA consisting of 24 items evaluating pain, stiffness and physical function on a scale of 100, high scores indicate worsening in physical function.[9]
Quality of Life: Short Form Health Survey Questionnaire (SF-36) which consists of eight scales, physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH), were used.[10]
Feasibility and Safety: The feasibility of the exercises was examined with 3-week strength gain rates based on the increase in 1-RM. Safety was monitored for exercise-related adverse events such as worsening of knee pain, falls, knee joint effusion, onset of pain in other joints in every session.

2.4. Experimental Condition

BFRT and HI-RT groups received the same structured progressive exercise under the supervision of a physiotherapist three days a week for eight weeks, with at least two days off between sessions. Exercises were developed based on previously established methodology.[11] The structured training protocol progression and doses of exercise in both groups of the study are shown in **Table 1.** Both groups started the session with 5- 10 minutes of warm-up with submaximal intensity of walking on the treadmill (*DKN EcoRun*), followed by stretching the lower extremity, and patellar mobilization then exercises focused on strengthening. Structured knee strengthening exercises consisted of four different phases that were progressed by adding new, proper exercises in each phase. The rest between sets was 30 seconds and 2 minutes between exercises. The BFRT group wrapped a 175 mm wide and 860 mm long occlusion cuff (*VBM Medizintechnik GmbH, Germany*) around the proximal thigh during the exercises. The cuff stayed inflated during the rest while deflating during the between-exercise period.
The exercise program was individualized by calculating the proper resistance. Tolerable resistance was defined as 1-RM=W/(1.0278-0.0278xR) using the Brzycki formula (W= weight used for the repetition, R= number of repetitions the test is left).[12] 1-RM calculations were repeated on the 1st day, 3rd week and 6th week of the treatment. Resistance was set at a load of 20% of one repetition maximum on BFRT and 70% of 1-RM on HI-RT. Initial resistance was reduced by 20% in the presence of high-intensity pain during training.
The auscultatory pulse was captured by the radiologist with a vascular Doppler probe (*GE Logiq P6 Ultrasound Machine, Tampa, USA*) over the tibial artery in the supine position. The cuff inflated until the pulse was completely lost, and this pressure was recorded as limb arterial occlusion pressure (AOP). To moderately restrict the blood flow to the muscle during exercises, restriction was settled at 70% AOP and increased to 80% on subsequent sets without deflating the cuff.

2.5. Statistical Analysis

The statistical analysis was performed using IBM SPSS version 26.0 (SPSS Inc., Chicago, IL). The normality of the variables was checked using the Shapiro-Wilk test and histogram plots. Mann-Whitney U test, χ^2 and the Independent Sample-T Test were used for comparisons. The significance level was previously set at “p” less than 0.05. Time-dependent differences within groups were analyzed with two-way repeated measure ANOVA and Time*Group interactions between groups were analyzed with MANOVA.

Table 1. Progression of the structured knee osteoarthritis exercises protocol for groups.

Phases(week)	**1 (1w)**	**2 (2-3w)**	**3 (4-5w)**	**4 (6-8w)**
Exercises HI-RT& BFRT	Isometric quadriceps set Terminal knee extension Unilateral knee extension in sitting Isometric gluteus maximus exercises	1st phase exercises + 4 way straight leg raises Bridge exercises Toe raising Wall squat	2nd phase exercises + Mini squat Leg press Single leg bridge	3rd phase exercises + Climbing stairs Single leg toe raising Semi squat
Sets				
HI-RT	3	3	3	3
BFRT	4	4	4	4
Repetition				
HI-RT	30-45	30-45	30-45	30-45
BFRT	75	75	75	75
Resistance (%1-RM)				
HI-RT	%60	%70	%70	%70
BFRT	%20	%30	%30	%30
Rest between sets (s)	30	30	30	30

1-RM= 1 Repetition Maximum, BFRT= Blood Flow restriction Training, HI-RT= High Intensity Resistance Training, w=Week.

3. RESULTS:

3.1. Subjects' characteristics

In total, of the 47 individuals diagnosed with KOA, 38 successfully completed the 8-week-long 24 sessions of exercise intervention, with 3 and 6 dropouts in the BFRT (n = 19) and HI-RT (n = 19) groups, respectively. The mean age of the BFRT group was determined to be 53.26 (42-72) years and a BMI of 31.50 (24.16-40.00) kg/m^2, while the mean age of the HI-RT group was 54.00(45-72) years and BMI was 28.10 (20.08-40.00) kg/m^2. The groups had similar characteristics in terms of age (p=0.751) and BMI (p=0.333). The mean cuff pressure required to restrict blood flow during exercise training in the BFRT group was determined as 132.2±15.8 mmHg. Participants had not reported any serious exercise-related adverse effects in the BFRT group.

3.2. Within Group Findings

Both the BFRT and HI-RT groups demonstrated significant improvements after the 8-week intervention. In the BFRT group, activity pain (A-P) decreased from 5.05 ± 1.75 to 0.05 ± 0.22 (p<0.001), resting pain (R-P) from 5.89 ± 1.52 to 2.53 ± 1.78 (p<0.001), and night pain (N-P) from 1.84 ± 1.17 to 0.32 ± 0.95 (p=0.002). Similar significant within-group reductions were observed in the HI-RT group for A-P (3.89 ± 1.56 to 0.26 ± 0.45, p<0.001), R-P (6.63 ± 1.46 to 2.84 ± 1.64, p<0.001), and N-P (2.00 ± 0.88 to 0.15 ± 0.37, p<0.001). WOMAC total scores improved substantially in both groups (BFRT: 43.94 ± 18.85 to 16.92 ± 7.42, p<0.001; HI-RT: 42.03 ± 16.29 to 16.65 ± 7.56, p<0.001). SF-36 sub-scores, including physical functioning, role physical, bodily pain, general health, and role emotional, showed significant gains over time (p<0.05), while vitality, social functioning, and mental health remained unchanged. **(Table 2)**

Table 2. Within group CSA, QV, pain intensity, blood analysis, WOMAC and SF-36 score differences

		Pre-training M ± SD	Post-training M ± SD	Mean difference	Confidence of Interval (Lower to Upper)	t	p value
R-P	BFRT	5,89± 1,52	2,53± 1,78	-3.37	-4.51 to -2.22	-6.22	<0.001*
	HI-RT	6.63±1.46	2.84±1.64	-3.79	-4.77 to -2.80	-8.08	<0.001*
A-P	BFRT	5,053±1,75	0,052±0,23	5.00	4.15 to 5.85	12.35	<0.001*
	HI-RT	3.89± 1.55	0.26± 0.45	3.63	2.81 to 4.45	9.28	<0.001*
N-P	BFRT	1,84± 1,17	0,32 ± 0,95	1.53	0.63 to 2.43	3.56	0.002*
	HI-RT	2.00± 0.88	0.15± 0.37	1.84	1.41 to 2.28	8.94	<0.001*
WOMAC							
General	BFRT	43.94±18.84	16.91±7.41	27.02	19.47 to 34.57	7.52	<0.001*
	HI-RT	42.02±16.28	16.65±7.56	25.38	19.07 to 31.67	8.47	<0.001*
Pain	BFRT	10.36±4.47	4.00±2.58	6.37	4.78 to 7.95	8.45	<0.001*
	HI-RT	10.68±4.26	4.42±3.07	6.26	5.22 to 7.30	12.66	<0.001*
Stiffness	BFRT	4.10±1.88	2.47±1.61	1.63	0.95 to 2.32	5.00	<0.001*
	HI-RT	3.73±1.59	2.00±1.10	1.74	0.92 to 2.55	4.47	<0.001*
Function	BFRT	28.68±14.52	9.68±3.94	19.00	12.48 to 25.52	6.13	<0.001*
	HI-RT	26.00±12.06	9.52±3.74	16.47	-11.39 to 21.54	6.82	<0.001*
SF-36							
PF	BFRT	26.31±22.78	53.94±26.69	-27.63	-39.61 to -15.65	-4.85	<0.001*
	HI-RT	30.26±25.79	55.26±28.35	-25.00	-38.32 to -11.57	-3.94	0.001*
RP	BFRT	56.64±46.58	92.98±17.84	-33.34	-56.06 to -10.62	-3.08	0.006*
	HI-RT	52.63±48.83	96.49±10.49	-43.86	-67.84 to -19.88	-3.84	0.001*
BP	BFRT	55.52±17.39	59.73±17.35	-4.21	-6.52 to -1.90	-3.83	0.001*
	HI-RT	61.57±17.08	65.52±17.47	-3.95	-6.15 to -1.73	-3.75	0.001*
GH	BFRT	69.13±15.76	72.63±14.49	-3.5	-6.33 to -0.67	-2.60	0.018*
	HI-RT	76.50±12.15	79.78±8.48	-3.29	-6.35 to -0.22	-2.25	0.037*
VT	BFRT	61.47±16.32	67.11±16.23	-5.64	-14.13 to 2.84	-1.40	0.179
	HI-RT	69.02±1.98	69.08±17.84	-0.60	-7.93 to 7.81	-0.02	0.988
SF	BFRT	52.12±20.32	78.55±17.38	-26.43	-34.15 to -18.71	-7.19	<0.001*
	HI-RT	59.90±18.93	82.36±18.07	-22.47	-29.55 to -15.38	-6.66	<0.001*
RE	BFRT	62.63±14.37	64.73±13.69	-2.11	-3.96 to -0.25	-2.39	0.028*
	HI-RT	68.68±10.11	71.84±7.30	-3.16	-5.96 to -0.35	-2.36	0.030*
MH	BFRT	44.73±27.10	48.68±25.64	-3.95	-8.46 to 0.57	-1.84	0.083
	HI-RT	52.63±27.50	61.84±24.10	-9.21	-16.41 to -2.01	-2.69	0.015*

*A-P=Activity pain, BFRT=Blood Flow Restriction Training, BP=Bodily pain, GH=General Health, HI-RT=High Intensity Resistance Training, M=Mean, MH=Mental Health, N-P=Night Pain, PF= Physical Functioning, R-P= Resting Pain, RE=Role Emotional, RP=Role Physical, SF=Social Functioning, SD= Standard Deviation, VT=Vitality, *p<0.05*

3.3. Between Group Findings

At baseline, the BFRT group reported higher activity pain compared to HI-RT (5.05 ± 1.75 vs 3.89 ± 1.56; p=0.038, d=0.7), but other variables did not differ significantly. Over time, there was a significant time × group interaction for activity pain favoring BFRT (F=5.91, p=0.020, partial $\eta^2 \approx 0.14$), indicating a larger reduction in A-P compared with HI-RT. No significant time × group differences were found for resting or night pain, WOMAC total or subscales (p>0.05, η^2 small), or for most SF-36 domains(p>0.05, η^2 small). BFRT was well tolerated, with no serious adverse events; in contrast, two participants in the HI-RT group discontinued due to knee pain. **(Table 3)** The post-treatment A-P change graph is shown in **Figure 2.**

Table 3. Between group differences

	Baseline			End of 8 Weeks Exercise			Time*Group Interaction			
	BFRT (n=19)	HI-RT (n=19)	p	BFRT (n=19)	HI-RT (n=19)	p	Mean Difference (Confidence of interval) BFRT-HIRT	F	Effect size (Cohen's d)	p
	M ± SD	M ± SD		M ± SD	M ± SD					
R-P	2.52 ± 1.78	2,84 ± 1,64	0.573	5.89 ± 1.52	6.63 ± 1.46	0.137	-0.526 (-1.293 to 0.240)	0.345	0.010	0.560
A-P	5,05 ±1.75	3,89 ±1.56	0.038*	0.05±0.22	0.26 ±0.45	0.079	0.474 (-0.070 to 1.017)	5.907	0.141	0.020*
N-P	1.84 ± 1.17	2.00 ± 0.88	0.641	0.32 ± 0.95	0.16 ± 0.37	0.503	0.000(-0.334 to 0.334)	0.441	0.012	0.511
WOMAC										
General	43.94± 18.85	42.03± 16.29	0.740	16.92± 7.42	16.65± 7.56	0.913	1.091 (-6.445 to 8.627)	0.124	0.003	0.727
Pain	10.37± 4.47	10.68± 4.27	0.825	4.00± 2.58	4.42± 3.08	0.651	-0.368 (-2.616 to 1.879)	0.014	0.000	0.908
Stiffness	4.11± 1.88	3.74± 1.59	0.519	2.47± 1.61	2.00± 1.11	0.298	0.421 (-0.477 to 1.319)	0.043	0.001	0.837
Function	28.68± 14.52	26.00± 12.07	0.539	9.68± 3.94	9.53± 3.75	0.900	1.421 (-3.669 to 6.511)	0.413	0.011	0.525
SF-36										
PF	56.32± 13.21	63.16± 10.70	0.088	78.16± 9.01	82.37± 5.37	0.089	-5.526 (-11.301 to 0.248)	0.723	0.020	0.401
RP	26.32± 22.78	30.26± 25.79	0.620	53.95± 26.70	55.26± 28.36	0.884	-2.632 (-17.383 to 12.119)	0.095	0.003	0.759
BP	59.65± 46.59	52.63± 48.83	0.635	92.98± 17.84	96.49± 10.50	0.465	1.753 (-15.136 to 18.641)	0.448	0.012	0.507
GH	55.53± 17.39	61.58± 17.08	0.286	59.74± 17.36	65.53± 17.47	0.312	-5.921 (-17.217 to 5.375)	0.030	0.001	0.864
VT	69.13± 15.77	76.50± 12.16	0.115	72.63± 14.50	79.79± 8.48	0.071	-7.263 (-15.593 to 1.067)	0.011	0.000	0.916
SF	61.47± 16.32	69.03± 10.99	0.103	67.12± 16.24	69.08± 17.85	0.724	-4.761 (-13.346 to 3.825)	1.027	0.028	0.318
RE	52.13± 20.33	59.90± 18.93	0.230	78.56± 17.39	82.37± 18.08	0.512	-5.792 (-17.019 to 5.435)	0.632	0.017	0.432
MH	62.63± 14.37	68.68± 10.12	0.142	64.74± 13.69	71.84± 7.30	0.054	-6.579 (-14.120 to 0.962)	0.432	0.012	0.515
	44.74± 27.10	52.63± 27.51	0.379	48.68± 25.65	61.84± 24.11	0.112	-10.526 (-27.221 to 6.168)	1.694	0.045	0.202

A-P=Activity pain, BFRT=Blood Flow Restriction Training, BP=Bodily pain, GH=General Health, HI-RT=High Intensity Resistance Training, M=Means, MH=Mental Health, N-P=Night Pain, PF= Physical Functioning, R-P= Resting Pain, RE=Role Emotional, RP=Role Physical, SF=Social Functioning, SD= Standard Deviation, VT=Vitality, *p<0.05

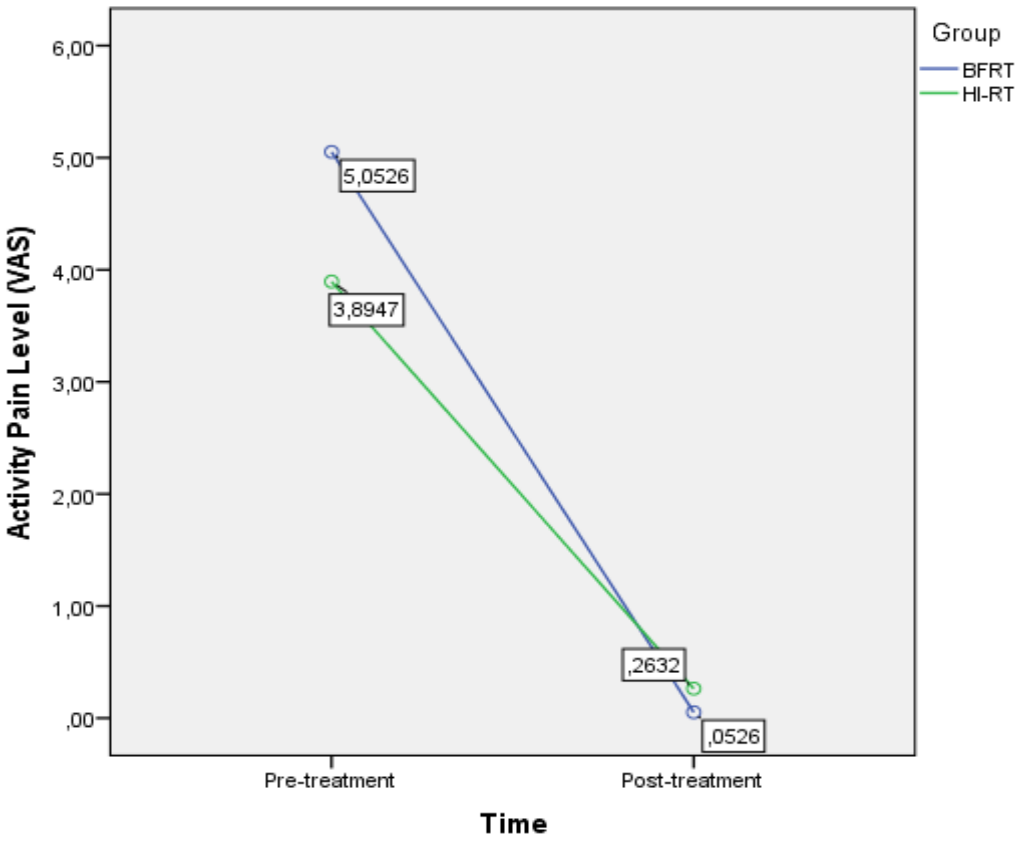

Figure 2. Post-Treatment activity pain intensity (A-P) change graph

4. DISCUSSION:

The purpose of this study was to investigate the effect of structured progressive BFRT on pain intensity, functionality, and QoL in individuals with chronic KOA and compare it with conventional HI-RT. Results showed that both groups improved in terms of pain intensity, WOMAC, and SF-36 scores after 8 weeks of training. No difference was found after the training in terms of vitality sub-score of SF-36. There was difference in activity pain intensity by time in favor of BFRT. In conclusion, HI-RT and BFRT may have similar improvements in pain, functionality, and QoL while BFRT has superior results in activity pain intensity at the end of the 8 weeks of treatment.

In ACLR patients, acute knee pain decreases by BFRT compared to HI-RT, perhaps due to the hypoalgesia effect of BFRT.[13] Although this effect is not fully known, ischemia and pressure-induced muscle pain are often stimuli for conditional pain modulation and alter pain sensitivity and and may contribute to the antinociceptive response.[25] BFRT reduced pain levels in patellofemoral pain[14], ACLR[15] and KOA[7], and its use was recommended for pain-free function. Although this study showed a significant decrease in pain intensity in both groups, activity pain intensity was less in the BFRT group than in the HI-RT group.Another important result of our study is that two participants withdrew due to knee pain caused by severe resistance training with HI-RT. It should be noted that low-intensity resistance training with BFRT can produce adaptations similar to HI-RT for populations where resistance exercises may be hard to perform due to pain.[16] It is also possible with BFRT to create lower joint stress during activity in individuals with KOA and to provide

long-term compliance to exercise with less pain. Among our possible expectations were an increase in exercise compliance and an improvement in functionality and QoL. Decreased physical function is directly related to the restriction of daily activities for independent living and is considered an indicator of disability.[17] For this reason, maintaining physical function in individuals with OA will increase the QoL. Studies have reported positive effects of BFRT exercises on QoL parameters.[18] In this study, improved QoL results were observed after 8-week exercise sessions.

This study is not without limitations. First, participants were not included in the long-term follow-up examination. As it is important to examine the post-exercise gains as a result of 8 weeks of exercise, it is also important to maintain the long-term gains. In addition to all these limitations, this study also includes strengths. First, the current study had sufficient statistical power to reduce the probability of type 2 error. Second, our study is a single-blinded RCT which reduces the risk of selection bias. Finally, participants were evaluated using reliable tools and diagnostic imaging methods that allowed us to make objective measures of improvement.

Considering all these results, the use of BFRT in painful KOA can be included in rehabilitation as an effective and reliable application that can lead to positive results in hypertrophy, pain, functionality and QoL. Lastly, it needs to be mentioned that our findings from adult individuals (40-65 years old) with KOA may not be representative of findings in healthy populations or individuals from different aging groups.

5. CONCLUSIONS

The results of this study indicate that the use of BFRT may show similar or even superior effects to HI-RT in improving functionality and quality of life while reducing pain intensity in individuals with KOA. This revealed that the clinical use of BFRT can be an effective, feasible, and safe method for the management of painful OA.

Research Highlights

- LI-BFRT improved pain intensity, and function in individuals with KOA.
- LI-BFRT showed pain reduction during activity than HI-BFRT.
- Both LI-BFRT and HI-BFRT improved function, but LI-BFRT had broader QoL benefits.
- LI-BFRT may offer a joint-sparing alternative to high-load resistance training in KOA.

IRB approval/research ethics committee

This study was approved by the ethics committees of the participating research institutions. Written, informed consent was obtained from all participants.

Role of the funding source

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Declaration of competing interest

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