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Effect of cryotherapy added to traditional physiotherapy on pain, function, and kinematic gait parameters in persistent patellofemoral pain syndrome: a randomized controlled trial

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ABSTRACT

Background: Patellofemoral Pain Syndrome is a prevalent orthopedic disorder, especially among young adults and athletes. It presents with anterior knee pain that is aggravated by activities including stair climbing, squatting, as well as prolonged sitting.
Purpose: This study was done to examine the impact of cryotherapy on pain intensity, knee function, along with kinematic gait parameters in patients suffering from chronic PFPS.
Materials and Methods: 60 individuals with a diagnosis of patellofemoral pain syndrome (both genders, aged 18–40 years, BMI 20–25 kg/m²) were randomized into two equivalent groups. Group A (control) was given traditional physical therapy, while Group B (study) was given the same treatment combined with cryotherapy. The intervention was done three times weekly for four weeks. The primary outcomes were kinematic gait parameters (step length, walking speed, step cycle, and step length coefficient of variation) measured via Biodex Gait Trainer. Secondary outcomes included pain intensity (Visual Analogue Scale) and knee function (Lower Extremity Functional Scale).
Results: According to Mixed MANOVA which was used for statistical analysis, both groups demonstrated significant improvements in all parameters after treatment, according to this study ($p < 0.001$). However, Group B revealed significantly greater improvements in step length (43.86% vs. 38.78%), walking speed (62.75% vs. 52.00%), step cycle (31.82% vs. 22.39%), and Lower Extremity Functional Scale (78.19% vs. 56.01%). A significantly greater reduction in step length coefficient of variation was observed in Group B (86.12% vs. 78.79), Visual Analogue Scale scores (58.55% vs. 49.81%).
Conclusion: Cryotherapy, when combined with traditional physical therapy, offers superior improvements in pain relief, knee function, and kinematic gait parameters in patients with chronic Patellofemoral Pain Syndrome compared to traditional therapy alone.

Keywords: *Cryotherapy, Patellofemoral Pain Syndrome, Gait Parameters, Visual Analogue Scale, Lower Extremity Functional Scale, Cold Compression Therapy.*

1. Introduction

The term "persistent patellofemoral pain syndrome" (PFPS) refers to the gradual onset of anterior knee or retropatellar pain that lasts longer than 6 weeks and is brought on by a minimum of two extended periods of sitting, kneeling, squatting, running, hopping, or stair climbing; patella tenderness upon palpation, or pain during a step-down or double-legged squatting; and the worst pain experienced during the previous week that is a minimum of 30 mm on a 100 mm visual analogue scale, aggravated by loaded patellofemoral joint movements

and diagnosed after the exclusion of other distinct knee pathologies. It is a prevalent musculoskeletal disorder that significantly impacts adolescents and young adults worldwide [13,42].

It is known to be the primary cause of anterior knee pain, particularly among physically active populations. According to recent epidemiological research, the PFPS yearly prevalence in adults is about 22.7%, and in adolescents, it could rise as high as 28.9% [1]. Notably, females are disproportionately affected, with prevalence rates more than double those observed in males, and adolescent girls are especially at risk, making PFPS the most common overuse injury in this group [1].

In specific populations such as amateur runners and military recruits, the incidence can be as high as 1080.5 per 1,000 person-years and 13.5%, respectively, underscoring the substantial burden of this condition in active individuals [1,2].

PFPS is clinically characterized by diffuse anterior knee pain where the patellofemoral joint is subjected to increased compressive forces during activities including running, squatting, climbing stairs, and sitting for prolonged periods of time [3].

The etiology of PFPS is multifactorial, involving a complex interplay of biomechanical, anatomical, and, to a lesser extent, psychosocial factors. Key risk factors include functional muscular weakness particularly of the quadriceps and hip musculature tightness of periarticular soft tissues, general ligamentous laxity, and biomechanical abnormalities such as excessive foot pronation and altered lower limb alignment [4].

Physiotherapy remains the cornerstone of PFPS management, with strong evidence supporting the effectiveness of exercise-based interventions targeting the quadriceps, hamstrings, and hip muscles. These interventions have been shown to significantly alleviate pain and enhance knee function, outperforming other conservative treatments such as rest, bracing, or nonsteroidal anti-inflammatory drugs (NSAIDs) in the long term. Other modalities, including patellar taping and foot orthoses, may provide immediate pain relief and enhance functional outcomes [4,5].

A primary functional consequence of PFPS is its significant detrimental impact on gait kinematics. The experience of pain leads to compensatory movement patterns, often resulting in an antalgic gait characterized by reduced step length, decreased walking speed, and increased stride-to-stride variability quantified as a higher coefficient of variation (CV) [3, 4]. This altered kinematics are not merely symptoms of pain but are core to the dysfunction, potentially perpetuating abnormal joint loading and contributing to the condition's chronicity.

Therefore, a critical goal of rehabilitation is not only to reduce pain but to restore normal, efficient, and stable gait mechanics. While exercise therapy is effective at addressing strength deficits, its direct and immediate impact on normalizing these specific gait parameters can be limited and gradual.

This creates a clear rationale for investigating extra therapies that could facilitate immediate improvements in movement quality.

Among the various therapeutic modalities, cryotherapy, the application of cold to affected tissues, has been widely used to manage pain and inflammation in musculoskeletal conditions. Cryotherapy can be administered through various methods, including ice packs, ice baths, gel packs, and specialized devices, and is known to reduce pain, swelling, and muscle spasm by decreasing local blood flow, metabolism, and nerve conduction velocity [6,7].

Recent systematic reviews and meta-analyses have demonstrated the benefits of cryotherapy in decreasing pain and enhancing function in conditions such as knee osteoarthritis and chronic low back pain (LBP), as well as in enhancing muscle recovery following exercise [6,8,9,10].

Furthermore, cryotherapy has been shown to increase spinal reflex excitability and central activation of the quadriceps, which may facilitate more effective rehabilitation [4].

Despite the widespread use of cryotherapy in sports medicine and rehabilitation, there is a gap in research specifically evaluating its impacts on gait parameters in patients with PFPS. The effects of cold therapy on kinematic gait parameters in these patients have only recently been the subject of research, the evidence remains limited and inconclusive.

Therefore, this study was done to examine the impact of cryotherapy on pain intensity level, knee function level, and kinematics gait parameters in patients with patellofemoral pain.

We hypothesized that participants receiving adjunct cryotherapy would demonstrate significantly greater improvement in gait stability, as measured by a reduction in the step length coefficient of variation, compared to those receiving traditional physical therapy alone.

2. Material and methods

2.1. Study design

A controlled, randomized trial was carried out at Cairo University's Faculty of Physical Therapy outpatient clinic, using pre- and post-test measurements. Prior to its beginning, the study was given approval by a research ethics committee at Egypt's Faculty of Physical Therapy, Cairo University (NO: P.T.REC/012/004880). Before taking part, all participants were asked to sign an informed consent document. This research wasn't prospectively submitted in a public clinical trials registry, although being planned and carried out as a randomized controlled trial.

2.2. Participants

Sixty PFPS patients (both genders), aged between 18 and 40 years [11] with BMI ranging from 18 to 24.9 kg/m²[12], were recruited. Patients were randomly allocated into two equal groups (n=30 each). Group A (control group) was given traditional physiotherapy (Strengthening exercise, Stretching, ultrasound and electrotherapy). Group B (study group) was given the traditional treatment with the addition of cryotherapy. Treatment was administered three times per week for four weeks. 5 participants were excluded as they didn't mee the inclusion criteria (figure 1). Sample size determination was done using G*Power software with a power of 80% and α=0.05.

Inclusion criteria included clinical diagnosis of persistent PFPS, symptom duration of 4–5 weeks within the last six months as well as being brought on by two or more of the following: sitting for extended periods of time, kneeling, squatting, running, hopping, or climbing stairs; feeling pain while stepping down or squatting with both legs; and the worst pain experienced in the last seven days measuring 30mm on a 100 mm VAS, aggravated by loaded patellofemoral joint movements and diagnosed through Pain Provocation Test by palpating the posterior facets of the patella with the knee relaxed and slightly bent often reproduces the retropatellar pain. after the exclusion of other distinct knee pathologies. Unilateral or bilateral presentation [13].

Patients were excluded if they had any of the following: systemic rheumatic disease, recent knee surgery or injections, cognitive impairments, visual/hearing loss, uncontrolled diabetes, and contraindications to cryotherapy [14].

2.3.Randomization

Participants were randomized into two equal groups (Group A: control, Group B: study) using a computer-generated randomization sequence created in SPSS (version 20, IBM Corp., USA). To ensure group balance for potential confounding variables, the randomization was stratified by sex (male/female) and body mass index (BMI: 20-22.5 kg/m², 22.6-25 kg/m²) using a block size of 4.

Allocation concealment was strictly maintained using opaque, sealed, sequentially numbered envelopes. The randomization sequence was held by a statistician not involved in recruitment or assessment. After a participant provided informed consent and completed baseline assessments, an independent researcher who was blinded to the group assignments opened the next sequentially numbered envelope to reveal the group allocation.

The assessor responsible for collecting all post-treatment data (VAS, LEFS, Biodex gait analysis) was blinded to the group assignments of the participants. However, due to the nature of the intervention, the treating physiotherapists and the patients couldn't be blinded. This introduces a potential for performance bias; however, the use of objective, instrument-based primary outcomes (Biodex gait parameters) helps to mitigate the risk of assessment bias

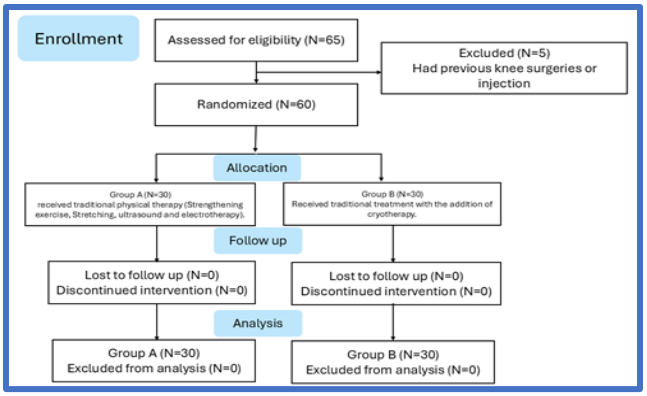

Figure (1) Consort flow chart

2.3. Assessment Instrumentation

1-Visual Analogue Scale: it is one-dimensional pain scale to keep monitor of how a patient's pain is changing over time or to compare the levels of pain in various individuals with the same medical condition. It is a simple, valid, as well as successful way to evaluate disease control, and it has been utilized extensively in varied adult groups [15]. There is strong evidence of test-retest reliability (ICC= 0.99, 95%CI 0.989–0.992). A 5-point verbal descriptive scale ("nil," "mild," "moderate," "severe," along with "very severe") demonstrated a strong correlation with VAS [15].

2-Lower extremity functional Scale:

This is a self-reporting questionnaire called the LEFS. Patients with musculoskeletal disorders affecting the lower extremities can assess their functional state using this patient-reported outcome measure. Minimal Clinically Important Difference (MCID) was defined as a rise of ≥9 points on an 80-point scale. When diagnosing musculoskeletal problems affecting the lower extremities in Arabic-speaking individuals, the 20-item LEFS-Ar might be used. LEFS-Ar acts as a valid measure of activity restriction because of its high test-retest reliability, minimal measurement error, in addition to excellent internal consistency [16]. Recent research has assessed and summarized LEFS's context-dependent measuring features, and it has been verified in a number of musculoskeletal disorders [16].

The patient's number is found at the page's end. A score of 80 indicates extremely high function, the highest level that may be achieved. Very low function is indicated by the lowest possible score of 0 points.

The LEFS has a high level of internal dependability (α=0.96). Results of test-retest reliability were R=.94 (95% CI=.89) for the subgroup of patients who had greater chronic illnesses (n=31) and R=.86 (95% CI=.80) for the overall sample (n=98).When contrasted with the SF-36, the LEFS is a valid instrument [16].

3-Biodex Gait Trainer

A Biodex Gait Trainer 3 treadmill (BIODEX MEDICAL SYSTEMS, INC., New York, NY, USA) that shows the length of each step in real time. Throughout the support phase, it was fitted with load sensors as well as software that showed the distribution of weight transmitted to each foot. Graphical representations of the foot's real position (foot contours) were shown to patients on the screen. The Biodex Gait Trainer is a validated instrument for the assessment of kinematic parameters [17]. While specific reliability data for a PFPS population is not available, the reliability of its measurements (e.g., high intraclass correlation coefficients for step length and walking speed) has been established in studies involving other musculoskeletal populations and healthy controls [17].

The gait impairments in PFPS, characterized by reduced step length and speed due to pain and altered neuromuscular control [3, 4], involve fundamental biomechanical parameters that this device is designed to measure accurately [22, 23]. Therefore, its established psychometric properties are considered generalizable to the present study's population.Five repeated-measures analyses of variance were used to examine the test-retest eliability of the results.A 2-way random effects model was used to calculate intraclass correlation coefficients (ICC [2,k]) for each performance measure to assess reliability. A reliability level of high, moderate, or poor was indicated by an ICC value of 0.80 or higher, 0.60 or lower, and less than 0.60. The intraclass reliability of the variables was determined by calculating the standard error of the measurement (SEM) values along with establishing 95% confidence intervals (CIs) for ICC values at the P less than.05 level of significance [17]. A reduction of ≥1.5 points (on the 10-point scale) was considered the Minimal Clinically Important Difference (MCID), indicating a change meaningful to the patient [43]

Throughout the assessment, the patient was shown visually where their feet should be placed and how long each step should be. Both baseline and after the treatment program, participants in this three-minute extended exam were given it.

For each trial, data was collected on the following parameters:

- Step length for the affected limb (cm)
- Load on the affected limb (%)
- Walking speed (km/h)
- Step length coefficient of variation (CV) calculated as (standard deviation / mean) × 100, which serves as a primary measure of gait stability, with lower values indicating more consistent and stable walking patterns.

The primary outcomes of this study were the kinematic gait parameters, assessed using the Biodex Gait Trainer. The primary outcome for the main hypothesis was the step length coefficient of variation (CV), as it most directly measures gait stability. Other primary kinematic outcomes included step length, walking speed, and step cycle.

Secondary outcomes included patient-reported measures of pain intensity, assessed using the VAS, and knee function, assessed using the LEFS.

B-Intervention Instrumentation

Cryotherapy Compression Machine

Local cryotherapy was applied using a cryocompression device (CTC-7; Daesung Maref, Gunpo, Korea). The device was configured with the manufacturer's designated knee wrap and set to deliver circulating fluid at a temperature of 10°C alongside intermittent compression. The compression pressure was set to 30 mmHg for a treatment duration of 20 minutes.

This cryocompression intervention was administered immediately prior to the traditional physical therapy exercise regimen during each treatment visit. The protocol was done 3 sessions per week for four successive weeks [18].

2.3. Procedures

A-Evaluation Procedures

All participants took a comprehensive evaluative protocol conducted before the initiation of treatment (baseline) and immediately following the final session (post-treatment). The primary aim of the assessment phase was to collect objective and subjective data regarding pain intensity, knee function, patellar alignment, and gait performance.

Initial Administrative Procedures

Participants were first oriented to the study environment and protocol by evaluating physical therapists. A full explanation of all assessment procedures, study objectives, and expected involvement was provided. Each participant's demographic details such as age, sex, height, weight, as well as BMI were recorded using a calibrated stadiometer and digital weighing Results scale.

Following verbal clarification, written informed consent was obtained Patellar Tilt Test To assess anatomical contribution to patellofemoral dysfunction, the Patellar Tilt Test was conducted. Each patient was positioned in a supine position with the knee in full extension and the quadriceps muscle relaxed. The examiner, positioned at the end of the treatment table, manually lifted the lateral border of the patella away from the lateral femoral condyle. A normal tilt angle is approximately 15°, with males typically displaying slightly lower values (around 10°). A decreased lateral lift suggests tightness of the lateral retinaculum and potential predisposition to patellofemoral pain syndrome. Care was taken not to apply medial or lateral translation, and all observations were recorded visually and noted manually [19].

Pain Intensity Assessment

Patients were requested to mark their level of knee pain along the line, and the distance from the “no pain” anchor point to the mark was measured in centimeters. This yielded a continuous pain score ranging from 0 to 10 [20].

Knee Functional Assessment

Functional limitations were evaluated using the LEFS. It is broadly utilized by clinicians to assess baseline function, monitor progress over time, and evaluate treatment outcomes. It is applicable for individuals with one or both lower extremity impairments.

The items are evaluated using a 5-point Likert scale, with 0 indicating "very difficult" or "not able to perform the activity" and 4 indicating "no difficulty." The highest possible score is 80. Higher scores indicate better function, while lower scores reflect greater functional disability.

Score Interpretation:

- 0–20: Severe functional limitations
- 21–40: Moderate to severe limitations
- 41–60: Moderate functional ability with some limitations
- 61–80: Mild to no functional limitations

Additionally:

- Minimal Detectable Change (MDC) = ±5.3 points
- MCID = 9 points
- % Maximal Function = (LEFS score ÷ 80) × 100 [21].

In the present study, the LEFS-Ar was utilized to assess knee function. This version was developed and validated by Korakakis et al. (2019) through a rigorous process of translation and cross-cultural adaptation into Modern Standard Arabic, guaranteeing its practicality and comprehensibility throughout the Middle East and North Africa area. The LEFS-Ar has shown excellent psychometric characteristics, such as an excellent degree of internal consistency (Cronbach's $\alpha = 0.965$), an excellent degree of test-retest reliability (ICC = 0.983), a measurement error (SEM) of 3.34 points, a minimum detectable change (MDC_{95}) of 9.26 points, along with a MCID of 9 points, confirming it as a robust and reliable tool for this patient population [16].

Gait Parameters Assessment

The treadmill used in the program was equipped with force sensors and software designed to track foot placement pressure during the stance phase for both the right and left legs. Patients received real-time visual feedback via foot-contour graphics displayed on a monitor. During training, they were instructed to match their step length to a task-specific target represented by two parallel lines, whose spacing corresponded to the therapist-defined step length. If the patient deviated from these lines, a sound signal alerted them, and corrective text feedback such as "right step longer" appeared when discrepancies were significant. Training began at a minimum walking speed of 0.14 m/s, and as patients progressed, therapists systematically increased treadmill speed and session duration according to their gait performance [22,23].

B-Treatment Procedure

-Cryotherapy compression machine protocol

The cryocompression device was applied to the affected knee. To protect the skin, a thin stockinette was worn under the designated knee wrap. The wrap was applied circumferentially to encompass the entire thigh and calf. The device was then set to deliver a temperature of 10°C with intermittent compression at 30 mmHg for the 20-minute treatment duration [18,24].

-Traditional Physical Therapy Treatment

"The traditional physical therapy program was a supervised, comprehensive regimen targeting hip and knee musculature, delivered twice daily, 3 sessions per week for 4 weeks. The protocol included strengthening of the hip abductors, hip external rotators, quadriceps (isometric and isotonic), and core stabilizers, alongside a stretching routine for the hamstrings, quadriceps, iliotibial band, and gastrocnemius.

Progression was standardized: exercise repetitions were increased by five per week for strengthening exercises, provided pain remained below 3/10 on the Visual Analogue Scale during activity.

Therapist Qualifications: All interventions were administered by licensed physiotherapists with over five years of musculoskeletal experience.

Table (1) **Strengthening Exercise Protocol**

Exercise Target	**Exercise Description**	**Sets x Hold Time**
Hip Abductors	Standing hip abduction with elastic resistance to 30-35° [25]	1 x 3.5 sec
Hip External Rotators	Seated external hip rotation to ~30° with towel between thighs [26]	1 x 3.5 sec
Quadriceps (Isometric)	Supine isometric quad sets pressing into a towel [27, 28]	1 x 10 sec
Quadriceps (Isotonic)	Straight leg raise in supine (~6 inch lift) [29]	1 x 3 sec
Functional Strength	Wall mini-squats (30-45° knee flexion) [30]	1 x 10 sec
Knee Extensors	Short arc quadriceps exercises with elastic resistance [31]	1 x 3.5 sec

Stretching Routine: A stretching routine was performed twice daily. The stretches were held for 10 seconds each and performed at least three times per session [32, 33, 34].

Hamstrings: Supine stretch with knee extended and trunk flexed.

Quadriceps: Standing quadriceps stretch.

Iliotibial Band: Standing ITB stretch.

Gastrocnemius: Standing calf stretch with knee extended.

Progression Rules: Progression was criteria-based. Repetitions were increased weekly only if the patient's pain during the exercise was ≤3/10 on the Visual Analogue Scale (VAS). If pain exceeded this level, the current repetition volume was maintained until the next weekly evaluation.

Data Collection and Statistical Analysis

To compare the subject characteristics across the groups, we utilized an independent t-test, and to compare gender distribution, we employed a chi-squared test. The Shapiro-Wilk test was used to ensure that the data followed a normal distribution. The homogeneity of variances among groups was assessed using Levene's test. To examine the effects of each group on walking speed, step cycle, step length CV, VAS, along with LFS, a two-way mixed MANOVA was conducted. Bonferroni corrections were carried out for subsequent multiple comparisons. All randomized participants were analyzed according to the intention-to-treat principle. No missing data was observed; therefore, no imputation was required. A significance criterion of $p < 0.05$ was established for all statistical tests. Statistical analysis was carried out using SPSS version 25 for Windows, which is a program developed by IBM SPSS in Chicago, IL, USA

Results

No adverse events or intolerance to the cryotherapy application were reported or observed in any participants throughout the study period Subject characteristics and baseline clinical characteristics of subjects:

Table (2) shows the subject characteristics of group A and B. No significant difference was noted between groups in age, BMI and sex distribution ($p > 0.05$). In addition, there was no significant difference between groups in base line clinical characteristics ($p > 0.05$).

Table 2. Comparison of subject characteristics among group A and B

	Group A (n = 30)	**Group B (n = 30)**	**MD (95% CI)**	**p –value**
Age (years)	29.80 ± 6.57	28.90 ± 6.34	0.9 (-2.44: 4.24)	0.59
BMI (kg/m²)	22.78 ± 1.48	22.84 ± 1.43	-0.06 (-0.81: 0.69)	0.88
Sex, n (%)				
Males	11 (37%)	14 (47%)	0.62	0.43
Females	19 (63%)	16 (53%)		
Step length (cm)	35.07 ± 2.65	35.73 ± 3.12	-0.66 (-2.16: 0.83)	0.38
Walking speed (m/sec)	0.50 ± 0.05	0.51 ± 0.06	-0.01 (-0.04: 0.02)	0.55
Step cycle (cycles/sec)	0.67 ± 0.04	0.66 ± 0.05	0.01 (-0.02: 0.03)	0.62
Step length CV (%)	71.33 ± 12.30	70.63 ± 11.03	0.70 (-5.34: 6.74)	0.81
VAS	8.03 ± 1.35	8.13 ± 1.36	-0.10 (-0.80: 0.60)	0.78
LEFS	22.80 ± 4.37	22.60 ± 3.87	0.20 (-1.94): 2.34	0.85

Abbreviations: BMI, Body Mass Index; CV, Coefficient of variance; VAS, Visual Analogue Scale; LEFS, Lower Extremity Functional Scale; MD, Mean difference; CI, Confidence Interval; p, probability value.* Data are mean± SD

Effect of treatment on step length, walking speed, step cycle, step length CV, VAS and LEFS:

Assumptions of statistical analyses were examined. Box's M test indicated that the assumption of equality of covariance matrices was met ($p > 0.05$). Levene's test revealed that the assumption of homogeneity of variance was met across groups ($p > 0.05$). Multicollinearity was checked using tolerance and variance inflation factor values, with all variables falling within acceptable limits (tolerance > 0.2, VIF < 5). For repeated measures, Mauchly's test of sphericity was conducted; results indicated that the assumption of sphericity was met ($p > 0.05$).

Mixed MANOVA showed that there was a significant interaction of treatment and time (Wilk's A = 0.30, F (6, 53) = 20.28, p = 0.001, partial = 0.69). A significant main effect of time was reported (Wilk's A = 0.005, F (6, 53) = 1809.89, p = 0.001, partial = 0.99). There was a significant main effect of treatment (Wilk's A = 0.39, F (6, 53) = 4.09, p = 0.002, partial = 0.32).

Between group comparison

Group B revealed a significant increase in step length (p = 0.001, partial η^2 = 0.22), walking speed (p = 0.001, partial η^2 = 0.28), step cycle (p = 0.003, partial η^2 = 0.15), and LEFS (p = 0.020, partial η^2 = 0.08) post treatment compared to group A. There was a significantly decline in step length CV (p = 0.001, partial η^2 = 0.42) and VAS (p = 0.001, partial η^2 = 0.19) in group B compared to group A post treatment. (Table 3)

Within group comparison

Groups A and B showed a significant improvement in their step length, walking speed, as well as step cycle after treatment as compared to before treatment (p < 0.001). The step length CV of both group A and B significantly decreased after treatments as compared to before treatment (p < 0.001). Groups A and B showed a significant decline in VAS and a rise in LFS after treatments as compared to before treatment (p < 0.001) (Table 4).

Table 3. Between groups changes after 4 weeks of intervention

Outcome	Group A (n = 30)	Group B (n = 30)	MD (95% CI)	F-value (df)	p value	partial η^2
Step length (cm)	48.67 ± 2.59	51.40 ± 2.65	-2.73 (-4.09: -1.38)	16.34 (1, 58)	0.001	0.22
Walking speed (m/sec)	0.76 ± 0.06	0.83 ± 0.05	-0.07 (-0.10: -0.04)	22.04 (1, 58)	0.001	0.28
Step cycle (cycles/sec)	0.82 ± 0.06	0.87 ± 0.04	-0.05 (-0.07: -0.02)	9.94 (1, 58)	0.003	0.15
Step length CV (%)	15.13 ± 2.96	9.80 ± 3.37	5.33 (3.70: 6.97)	42.50 (1, 58)	0.001	0.42
VAS	4.03 ± 1.22	3.37 ± 1.03	0.66 (0.08: 1.25)	13.17 (1, 58)	0.001	0.19
LEFS	35.57 ± 5.08	40.27 ± 4.95	-4.7 (-7.29: -2.11)	5.23 (1, 58)	0.02	0.08

Abbreviations: CV, Coefficient of variance; VAS, Visual Analogue Scale; LEFS, Lower Extremity Functional Scale; MD, Mean Difference; CI, Confidence Interval; p, probability value; p < 0.05 indicates statistical significance; Eta Squared. *Data are mean ± SD

Table 4. Within groups changes after 4 weeks of intervention.

Outcome	Group A			Group B		
	MD (95% CI)	%of change	p value	MD (95% CI)	%of change	p value
Step length (cm)	-13.60 (-14.31: -12.89)	38.78	0.001	-15.67 (-16.38: -14.96)	43.86	0.001
Walking speed (m/sec)	-0.26 (-0.27: -0.24)	52.00	0.001	-0.32 (-0.33: -0.30)	62.75	0.001
Step cycle (cycles/sec)	-0.15 (-0.17: -0.13)	22.39	0.001	-0.21 (-0.22: -0.18)	31.82	0.001
Step length CV (%)	56.20 (52.30: 60.10)	78.79	0.001	60.83 (56.93: 64.74)	86.12	0.001
VAS	4.00 (3.75: 4.25)	49.81	0.001	4.76 (4.52: 5.02)	58.55	0.001
LEFS	-12.77 (-13.42: -12.11)	56.01	0.001	-17.67 (-18.32: -17.01)	78.19	0.001

Abbreviations: CV, Coefficient of variance; VAS, Visual Analogue Scale; LEFS, Lower Extremity Functional Scale; MD, Mean Difference; CI, Confidence Interval; p, probability value; p < 0.05 indicates statistical significance

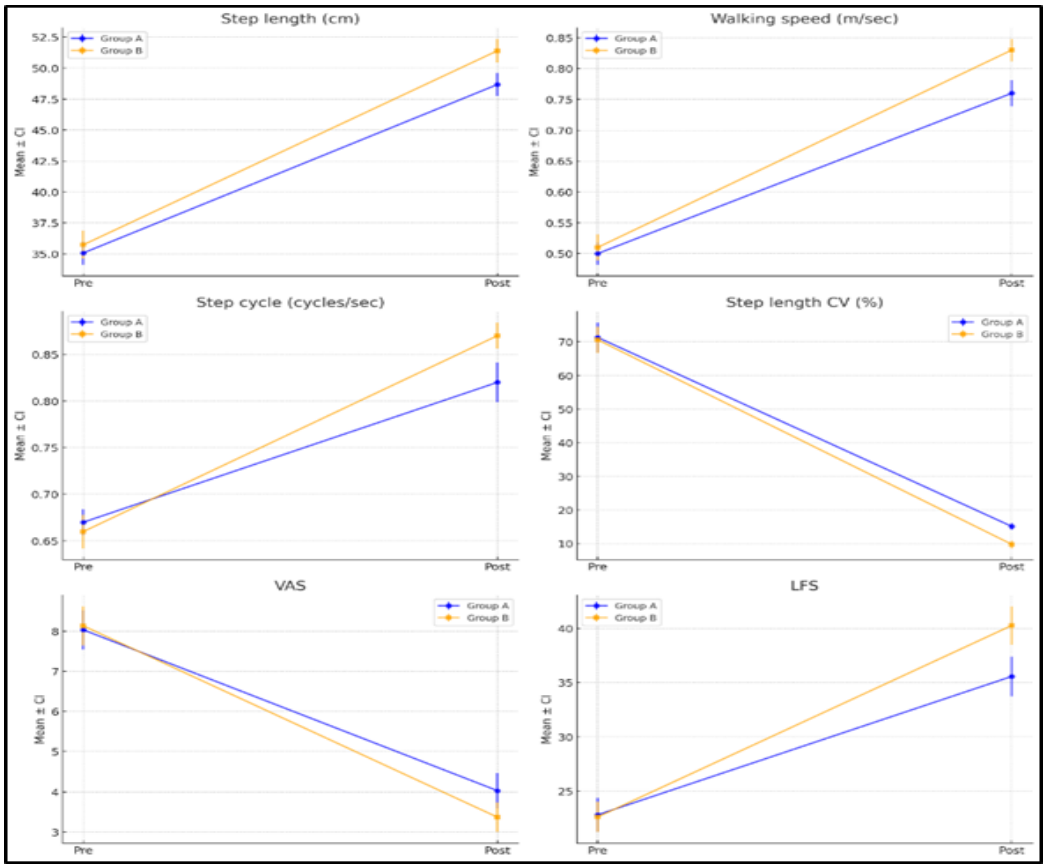

Figure (2) Mean step length, walking speed, step cycle, step length CV, VAS and LFS pre and post treatment in group A and B.

Discussion

This study aimed to investigate the effect of cryotherapy combined with traditional physical therapy on pain intensity level, knee function level, and gait kinematics parameters in individuals with chronic patellofemoral pain syndrome (PFPS). Sixty patients from both genders with PFPS participated in this study. They were recruited from the outpatient clinic of Faculty of Physical Therapy, Cairo University. They were randomized into two equivalent groups, Group A (control group) thirty patients was given traditional physical therapy (Strengthening exercise, Stretching, ultrasound and electrotherapy). Group B (study group) thirty patients was given the same conventional treatment with the addition of cryotherapy. They were aged from 18 to 40 years old and their BMI was from 20 to 25 kg/m2. Regarding outcome measures, pain intensity level was measured by VAS, Knee function level by LEFS and kinematic gait parameters by biodex gait parameters pre and post treatment after 4 weeks of treatment.

The primary mechanistic rationale for these results is that cryotherapy-induced analgesia, through reduced nerve conduction velocity and modulation of nociceptors, likely created a window of opportunity for more effective engagement with the subsequent strengthening and gait training exercises.

This reduction in pain potentially mitigates arthrogenic muscle inhibition, facilitating greater motor unit recruitment and improved neuromuscular control during functional tasks. An important caveat to this mechanism is that the same reduction in nerve conduction can cause transient sensory dampening and impair proprioception.

Between-group comparisons showed that Group B, which received cryotherapy in addition to traditional physical therapy, achieved significantly greater improvements across all outcome measures post-treatment compared to Group A. Group B showed a higher percentage of improvement in step length (43.86% vs. 38.78%; $p = 0.001$), walking speed (62.75% vs. 52.00%; $p = 0.001$), and step cycle (31.82% vs. 22.39%; $p = 0.003$). Furthermore, Group B exhibited a more substantial reduction in step length CV (86.12% vs. 78.79%; $p = 0.001$), suggesting superior enhancement in gait consistency. Pain levels in Group B decreased more markedly than in Group A (58.55% vs. 49.81%; $p = 0.02$), and functional gains measured by LEFS were also higher in Group B (78.19% vs. 56.01%; $p = 0.001$).

Regarding Effect of cryotherapy on pain intensity level

The results indicated a statistically significant reduction in pain intensity. However, Group B showed greater pain reduction compared to group A (Control group). The explanation of these results are consistent with prior research demonstrating cryotherapy's capacity to reduce nociceptive transmission by decreasing nerve conduction velocity and modulating sensory input from peripheral nociceptors [35,6]. Furthermore, the analgesic effects observed in this study align with other studies in other musculoskeletal conditions where cryotherapy was shown to reduce pain and inflammation effectively as shown by He et al., 2025, A meta-analysis of 11 randomized controlled trials, has concluded that whole-body cryotherapy (WBC) can reduce the inflammatory response in humans. The study found that WBC lowered levels of IL-1β and increased levels of IL-10, suggesting a potential benefit for athletes and obese individuals and other studies evaluated the efficacy of whole-body cryotherapy (WBC) in managing chronic LBP. When compared to baseline data, the research indicated that those who received WBC had significantly fewer pain and disability.

These findings suggest that WBC may be an effective non-pharmacological intervention for enhancing pain and function in individuals with chronic LBP [7,10].

The primary mechanistic rationale for these results is that cryotherapy-induced analgesia, through reduced nerve conduction velocity and modulation of nociceptors, likely created a window of opportunity for more effective engagement with the subsequent strengthening and gait training exercises. This reduction in pain potentially mitigates arthrogenic muscle inhibition, facilitating greater motor unit recruitment and improved neuromuscular control during functional tasks. An important caveat to this mechanism is that the same reduction in nerve conduction can cause transient sensory dampening and impair proprioception.

Nevertheless, some researchers have noted transient sensory impairments following cryotherapy, raising concerns about proprioceptive acuity during physical activity [36,37]. These concerns did not manifest clinically in the present study, possibly due to the structured timing of cryotherapy before functional tasks.

Regarding the Effect of cryotherapy on Knee Function level

Functional improvement was significantly higher in Group B compared to Group A. These results indicate that cryotherapy not only alleviated pain but may have facilitated greater participation in and effectiveness of the rehabilitation exercises, potentially by reducing arthrogenic muscle inhibition [38]. These findings are in line with the conclusions of a recent clinical trial was done by MohammedSadiq and Rasool 2023 that demonstrated enhanced daily performance in knee osteoarthritis patients treated with cryotherapy and conventional therapy [14].

This is also supported by reports from studies on cryo-compression and post-surgical rehabilitation, which have shown that cryotherapy improves functional outcomes when combined with therapeutic exercise [24, 39].

Regarding the Effect of cryotherapy on Kinematic Gait Parameters

Significant improvements were recorded in step length, walking speed, and step cycle in both groups post-treatment. However, Group B achieved notably greater improvements, with walking speed increasing by 62.75% and step cycle by 31.82%, compared to 52.00% and 22.39%, respectively, in Group A. The significantly greater reduction in the step length coefficient of variation (CV) observed in Group B indicates a superior improvement in gait stability and rhythmicity. This suggests that cryotherapy, by reducing pain and potentially mitigating arthrogenic muscle inhibition, allowed patients to adopt a more confident and consistent walking pattern, thereby reducing stride-to-stride variability. This suggests that cryotherapy enhances neuromuscular performance during dynamic activities [5]. These findings agreed with previous work that was done by Kullenberg et al., 2006 and Alexander et al., 2022 demonstrating improved locomotor performance following cryo-compression therapy in athletic and clinical populations [18,40].

Regarding the Effect of cryotherapy on Gait Stability (Step Length CV)

Group B exhibited a greater reduction in the coefficient of variation of step length (CV), indicating improved gait consistency and neuromuscular control. A reduction in variability is clinically relevant as it reflects improved motor planning and proprioceptive integration [22].

The findings of this study aligned with Waterman et al., 2012 who investigated the effectiveness of combined cryotherapy and compression compared to cryotherapy alone following anterior cruciate ligament (ACL) reconstruction. The study found that combined cryotherapy and compression showed significantly better objective patient outcomes compared to cryotherapy alone. Specifically, the study observed improvements in pain levels and other objective measures in the group using the combined approach [24]. Additionally, studies in similar patient populations (e.g., anterior cruciate ligament rehabilitation and knee osteoarthritis) that were done

by Hohenauer et al., 2015 and Fukuda et al., 2010 support the synergistic benefits of cold therapy when integrated with active rehabilitation protocols [41,9]. However, it is important to consider studies that have cautioned against the use of cryotherapy immediately before balance-dependent activities due to temporary sensory dampening [36,37].

Limitations

Although the results of this study are promising, several limitations must be acknowledged to contextualize the findings. First, the study duration was limited to four weeks with no follow-up period, which restricts conclusions regarding the long-term efficacy and durability of the effects. Second, participants were restricted to a narrow age (18-40 years) and BMI (18 to 24.9 kg/m²) range, limiting the generalizability of our findings to adolescents, older adults, and individuals with higher or lower body weight. Third, the sample was not stratified by sex during randomization, and the influence of sex on treatment response could not be analyzed. Fourth, the risk of performance and detection bias is present, as previously discussed. Fifth, the cryotherapy parameters, such as optimal timing relative to exercise and individual response variability, were not explored. Sixth, the potential for placebo effects must be considered, as the control group did not receive a sham cryotherapy treatment. Seventh, we did not formally assess participant adherence to the prescribed exercise regimen outside of the supervised sessions. Eighth, the analysis of multiple secondary outcomes without statistical adjustment increases the risk of Type I error (multiplicity inflation). Finally, the trial was not pre-registered in a public repository.

Conclusion

Based on the scope and findings of this study, we concluded that this four-week randomized controlled trial demonstrated that supplementing traditional physical therapy with cryotherapy produced statistically and clinically greater short-term improvements in pain, function, and gait parameters for patients with persistent patellofemoral pain syndrome compared to traditional physical therapy alone. The between-group differences were supported by a significant treatment effect (Partial $\eta^2 = 0.32$, $F = 4.09$, $p = 0.002$) and significant improvements in all primary outcomes, with large effect sizes (e.g., Cohen's *d* for between-group differences in LEFS = 0.94 [95% CI: 0.33 to 1.54] and for VAS = 0.59 [95% CI: -0.02 to 1.20]). Critically, the mean improvements in both the VAS ($\Delta = 4.10$ points) and LEFS ($\Delta = 31.28$ points) far exceeded their established Minimal Clinically Important Difference thresholds of 1.5 and 9 points, respectively. Therefore, cryotherapy added to traditional PT appears to be a beneficial short-term strategy. However, these conclusions are tempered by the study's limitations, including the lack of long-term follow-up and participant/therapist blinding. Longer-term, multicenter trials with blinded assessors, a pre-registered protocol, a sham-controlled design, and extended follow-up are warranted to confirm the durability of these effects and establish optimal clinical implementation guidelines.

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