# The effectiveness of adjunct cryotherapy along with an exercise on somatic symptoms in patients with knee osteoarthritis – a randomized controlled trial

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## Abstract

**Introduction:** Knee osteoarthritis (KOA) is a common joint condition associated with aging, leading to pain, functional limitations, disability, and reduced quality of life. This clinical randomized controlled trial aimed to investigate the effectiveness of a cryotherapy intervention in combination with a home-based conventional exercise (HBE) program in reducing somatic symptoms in patients with KOA.

**Material and methods:** Patients diagnosed with KOA were randomly assigned to 2 groups: an experimental group (n = 16) receiving HBE with cryotherapy and a control group (n = 15) receiving HBE alone for 2 months.

**Results:** The results showed that patients in the HBE with cryotherapy group had significantly lower scores on somatic symptoms (SDS) compared to those in the HBE group (2.00 vs. 4.53; mean difference: -2.53, 95% CI: -4.50 to -0.57) with a large effect size (Cohen's *d*: 0.94). Additionally, both the HBE and HBE with cryotherapy groups exhibited a significant decrease in SDS scores, 20.87–4.53 and 18.75–2.00, respectively (p < 0.001).

**Conclusions:** This study showed that combining HBE with cryotherapy is an effective approach for improving somatic symptoms in patients with KOA.

Key words: somatic symptoms, quality of life, complementary therapy.

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#### INTRODUCTION

Knee osteoarthritis (KOA) is a prevalent joint condition that commonly affects older individuals, causing symptoms such as pain, reduced function, and decreased quality of life (QoL) [1]. It is a leading cause of disability among the elderly, with a global prevalence of 22.9% in individuals aged 40 years and above, accounting for approximately 654.1 million cases worldwide [1]. The occurrence of KOA varies across countries and generally rises with age. Studies have indicated a gender disparity, with females (1.69) being more prone to the condition than males (1.39) [2]. In the Middle East and North Africa, there are approximately 24.6 million cases of osteoarthritis (OA), with a prevalence of 5342.8 per 100,000 individuals [3]. Women above the age of 50 years exhibit higher susceptibility to developing OA in comparison to men [4].

Knee OA represents the most prevalent form of OA [5], and its management focuses on enhancing

patients' health-related QoL. While pharmaceutical treatments can relief the symptoms, their long-term use may lead to poor tolerance and systemic side effects [6, 7]. Non-pharmacological interventions play a crucial role in slowing disease progression, alleviating symptoms, and improving knee function and health-related QoL [8]. Current clinical guide-lines recommend a combination of pharmacological and non-pharmacological therapies for managing KOA [9]. Home-based exercise (HBE) programs have shown positive effects on strength, function, and pain levels in knee OA patients [10].

Cryotherapy, a non-pharmaceutical therapy, is commonly utilized in the management of various rheumatic joint conditions due to its positive impact on pain, swelling, and inflammation. It can be employed either as a standalone treatment or in conjunction with other approaches [11]. However, there is no consensus in the literature regarding the effectiveness of cryotherapy. While some international guidelines endorse it as a viable treatment option [12–14], others do not recommend it due to limited evidence [15, 16]. Recent systematic reviews highlight the need for well-designed studies to determine the effectiveness of cryotherapy on pain, function, and health-related QoL in KOA patients [17, 18].

Limited research exists regarding the combined effects of HBE and cryotherapy on clinical outcomes and QoL in KOA patients [19]. Therefore, further studies are warranted to evaluate the effectiveness of this approach specifically for individuals with KOA. This study aimed to examine the impact of an HBE program in combination with cryotherapy for alleviating symptoms in KOA patients. The hypothesis points that patients receiving HBE with cryotherapy will experience greater relief from somatic symptoms after a 2-month period compared to those undergoing the HBE intervention alone.

## MATERIAL AND METHODS

## Study design

The study randomly assigned the patients to two groups: an experimental group that received the HBE program along with cryotherapy and a control group that only received the HBE program. The experimental group will be referred to as "HBE with cryotherapy", while the control group will be referred to as "HBE". Both groups received education on the risk factors of KOA based on the guidelines provided by the "Specialized Centre of Rheumatic Diseases and Medical Rehabilitation". Patients visiting the centre underwent medical and clinical screening to determine their eligibility. Those diagnosed with KOA by a rheumatologist and meeting the inclusion and exclusion criteria, including age range, comorbidity, and body mass index (BMI) measurement, were randomly assigned to either the experimental or control group using pre-generated random numbers.

The study was conducted at a centre located in Duhok city, Iraqi Kurdistan, and included patients enrolled between 1 August 2021 and 1 June 2022. Both groups underwent a 2-month intervention period, and the outcomes were measured one week after 2 months. To ensure ethical standards, the study protocol received approval from the local ethics committee in Duhok city, which operates in collaboration with the University of Duhok and the Duhok General Directorate of Health. The trial was registered with reference number 13072021-7-27 (13 July 2021).

# Sampling technique and patients

A simple random sampling technique was used to select patients for the study. The centre provided

diagnostic and therapeutic services to the population of Duhok governorate in the Kurdistan Region. The first author collected general information about the target population, including gender, age, BMI, disease grade, and education, from the clinicians working at the centre. This information helped to estimate the target population and ensure a representative sample. The first author attended the centre twice a week for 6 months, including patients from different clinicians to enhance sample representativeness. The medical and clinical information of selected patients was checked to ensure accurate diagnosis and disease grading.

To assign eligible patients randomly to the experimental and control groups, pre-generated 2-group numbers were used. The total number of patients calculated through the sampling process was entered into statistical software (SPSS 25) to generate the random numbers. Patients were assigned to groups without using their names, and the group allocation was randomized to patient names to prevent bias. The random number generation was conducted by the second author, who had no knowledge of patient allocation. The clinicians were not involved in the intervention, outcome measurements, or patient allocation. Because the centre receives patients from different geographic areas within the Duhok governorate, allocation bias was minimized. However, two patients from the same family attended the centre, only the first case was included in the study based on the pre-generated random number, while the second patient was excluded to avoid allocation bias. Furthermore, the HBE patients were not informed about the cryotherapy. The researcher conducted weekly follow-ups with patients at their homes and through telephone calls.

## Sample size

The sample size for the study was determined based on the expected effectiveness of cryotherapy and HBE on outcomes in patients with KOA. Previous studies on KOA patients provided mean values that were used to estimate the effect size. The desired effect size was determined as a change from a mean value of 16.6 (SD: 9.86) to an expected mean value of 5.0 (SD: 1.2), with a Cohen's *d* of 1.65. To achieve a statistical power of 0.9562 (2-tailed test), an  $\alpha$  error probability of 0.05, and an allocation ratio (N2/N1) of 1. The required sample size for each group was calculated to be 11 patients. G\*Power 3.1.9 software was used to calculate the sample size based on these parameters.

# Eligibility criteria

To select patients for the study, the following eligibility criteria were applied:

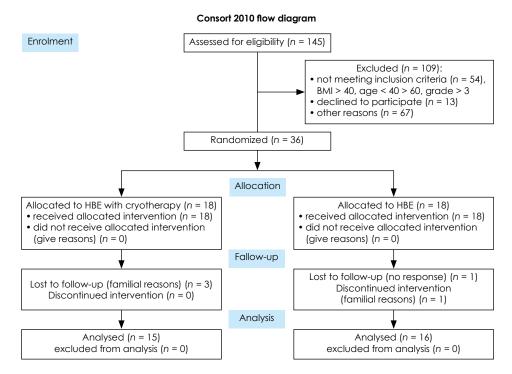


Fig. 1. Flow chart of patient recruitment

BMI – body mass index, HBE – home-based exercise

- 1. Diagnosis of KOA with a grade  $\leq$  3.
- 2. Presence of current joint symptoms.
- 3. Age between 40 and 60 years.
- 4. Experiencing knee pain on most days of the past month.
- 5. Average knee pain rated 3–7 on a visual analogue scale in the last week. We included the patients with pain scores 3–7 to enable the physical activity because the patients with higher levels of pain were unable to perform the physical as required.

## $6.\,\mathrm{BMI} < 40.$

Exclusion criteria were as follows:

- 1. Presence of rheumatoid arthritis or other systemic rheumatic diseases.
- 2. Diagnosis of the following psychiatric disorders: dementia, psychosis, or active substance abuse disorder.
- Acute or chronic diseases, lower limb or knee injuries, deformities, or recent lower limb or knee surgeries.
- 4. Severe hearing or visual impairments.
- 5. Patients who had been hospitalized for a cardiovascular condition, cerebral infarction (stroke), or arrhythmia within the preceding 3 months.
- 6. Participants who had experienced 3 or more falls in the recent past.
- 7. Patients who were currently participating in another OA intervention study.
- 8. Individuals with uncontrolled diabetes mellitus.
- 9. Patients who had received intra-articular knee injections within the past 6 months.

10. Participants who had contraindications to cryotherapy application, such as experiencing a high level of discomfort or pain during the application.

Before being enrolled in the study, all participants were required to provide written informed consent. The author of the study conducted baseline assessments on the participants. To prevent bias, individuals who did not meet the eligibility criteria were not assigned a number or included in the study, as depicted in Figure 1.

# Outcome measurements

The study outcomes were assessed at the end of the follow-up period. The interventions in both groups were administered by the first author, who is a nurse physiotherapist. Outcome measurements were conducted by a trained nurse who was unaware of the patients' group assignments to minimize bias. The nurse received training from the researchers to ensure consistent outcome measurement in both the HBE with cryotherapy and HBR groups. Preintervention and post-intervention measurements were conducted for all participants.

# Pilot study

A pilot study involving 5 patients diagnosed with KOA was conducted. The first 5 cases received interventions based on pre-generated random numbers. The purpose of the pilot study was to identify any potential difficulties or challenges associated with the main study. Initially uncertain about the study's feasibility, the researchers decided to proceed with the full study when no significant challenges or difficulties were encountered. Additionally, the reliability of the somatic symptom disorder (SSD) scale exceeded 0.6 for the first 5 cases.

## Interventions

## Home-based exercise with cryotherapy and home-based exercise groups

In the home-based exercise with cryotherapy group, patients received education on the risk factors of KOA during the first session. Individual sessions were conducted at the patients' homes to ensure uninterrupted education. The patients were also educated on HBE during the first session. The primary researcher assisted the patients in performing the HBE intervention as instructed in the provided booklet. Videos and booklets in Kurdish and Arabic languages were provided to ensure correct execution of the exercises. The researcher made weekly visits to supervise the exercise performance and prevent loss to follow-up. The patients continued performing the remaining HBE exercises independently. Cryotherapy was also administered to these patients as instructed by the researcher. The home-based exercise with cryotherapy group received HBE along with cryotherapy for 2 months. During the 8-week study period, the researcher visited participants' homes in weeks 1, 3, 5, and 7 to motivate adherence to the exercise regimen and prevent loss to follow-up. The health education session lasted approximately 30 minutes during the first visit. Each session included 70-75 minutes of exercise and 20 minutes of cryotherapy. Phone calls were made in weeks 2, 4, 6, and 8 to assess participants' progress and adherence to the home program. Participants were encouraged to comply with the exercise and cryotherapy program. The study spanned 8 weeks, with 3 sessions per week on non-consecutive days, totalling 24 sessions. The health education component covered topics such as clinical manifestations, risk factors, nursing care for KOA, benefits of exercise, and cryotherapy. For cryotherapy, reusable gel ice packs were applied to the patient's knee for 20 minutes, covering the anterior, posterior, medial, and lateral surfaces. Patients in the HBE group received similar education and HBE exercises to the HBE with cryotherapy group, but without cryotherapy. They were followed up in the same manner as the HBE with cryotherapy group.

## Assessment of outcomes

Patients' baseline data, encompassing demographic characteristics and pertinent medical information, were gathered and recorded using a pre-established questionnaire. The collected information included the following variables: age, gender, height, weight, BMI, marital status, educational level, occupation, smoking status, duration of the disease, history of falls within the past year, affected knees, disease grade, analgesic usage, cartilage drug usage, and presence of comorbidities.

## Somatic symptom disorder

Somatic symptom disorder was assessed using the somatic symptom disorder-B criteria scale (SSD-12). The scale consists of 12 items rated from never (0) to very often (4). It is a reliable and valid self report measure designed to assess the psychological characteristics of DSM-5 Somatic Symptom Disorder. The individual item scores were summed to calculate the overall score, with higher scores indicating greater severity of somatic symptoms in patients [20].

## Statistical methods

The demographic characteristics and baseline information of the patients in the 2 groups were presented as means (SD) or numbers (%). Independent *t*-tests or Pearson  $\chi^2$  tests were used to compare the baseline information between the study groups, depending on the type of data. Somatic symptom disorder scores of patients with KOA in the study groups were compared using an independent *t*-test. Paired *t*-tests were used to analyse the comparisons of SSD scores within the HBE and HBE with cryotherapy groups at different study steps. Statistical significance was set at a *p* < 0.05. Statistical calculations were done using JMP Pro 14.3.0 software.

## Statement

This article is a complementary project of the main previously published study as: MohammedSadiq, Hawar Abdulrazaq; Rasool, Mohammad Tahir. Effectiveness of HBE and cryotherapy on daily living activities in patients with KOA: A randomized controlled clinical trial. Medicine 102(18):p e33678, May 05, 2023. | DOI: 10.1097/MD.00000000033678.

## RESULTS

The study found that both the HBE and HBE with cryotherapy groups had similar general and medical characteristics at the per-protocol and intention-to treat steps (Table 1). The study also showed that patients in the HBE and HBE with cryotherapy groups had similar somatic symptoms (SDS) scores at baseline (20.87 vs. 18.75; p = 0.5022). However, patients in

 Table 1. Comparison of baseline information of patients with knee osteoarthritis among the study group (per-protocol approach and intention to treat steps)

Socio-demographic characteristics	Study groups per-protocol No. (%)		p-value (2-sided)	Inte	Intention to treat No. (%)		
	HBE, n = 18	HBE with cryotherapy, n = 18		HBE, n = 15	HBE with cryotherapy, n = 16		
Age (years)ª Range	51.83 (7.99) 41–67	51.83 (6.33) 42–64	1.000	51.80 (7.79) 41–67	51.56 (5.82) 42–64	0.9237	
Age category <sup>b</sup>							
41–50	8 (44.44)	8 (44.44)	0.8752	6 (40.00)	7 (43.75)	0.8005	
51–60	7 (38.89)	8 (44.44)		7 (46.67)	8 (50.00)		
61–70	3 (16.67)	2 (11.11)		2 (13.33)	1 (6.25)		
Gender⁵							
Male	3 (16.67)	5 (27.78)	0.6906	3 (20.00)	4 (25.00)	1.0000	
Female	15 (83.33)	13 (72.22)		12 (80.00)	12 (75.00)		
BMIª	32.19 (3.91)	32.73 (4.02)	0.6812	31.95 (4.03) 25.22–38.29)	33.22 (3.90) 24.89–38.54)	0.3767	
BMI category <sup>b</sup>							
Normal weight	0 (0.00)	1 (5.56)	0.4868	0 (0.00)	1 (6.25)	0.4380	
Overweight	6 (33.33)	4 (22.22)		5 (33.33)	3 (18.75)		
Obese	12 (66.67)	13 (72.22)		10 (66.67)	12 (75.00)		
Marital Status <sup>6</sup>							
Married	12 (66.67)	14 (77.78)	0.3406	10 (66.67)	12 )75.00)	0.3175	
Single	2 (11.11)	0 (0.00)		2 (13.33)	0 (0.00)		
Widow	4 (22.22)	4 (22.22)		3 (20.00)	4 (25.00)		
Education <sup>b</sup>							
Illiterate	9 (50.00)	9 (50.00)	0.6892	8 (53.33)	8 (50.00)	0.7045	
Primary school	5 (27.78)	4 (22.22)		4 (26.67)	4 (25.00)		
Intermediate school	3 (16.67)	4 (22.22)		2 (13.33)	3 (18.75)		
Secondary school	0 (0.00)	1 (5.56)		0 (0.00)	1 (6.25)		
Institute/college	1 (5.56)	0 (0.00)		1 (6.67)	0 (0.00)		
Occupation <sup>b</sup>							
Mild mobility	4 (22.22)	5 (27.78)	0.2674	3 (20.00)	5 (31.25)	0.3784	
Moderate mobility	13 (72.22)	9 (50.00)		11 (73.33)	8 (50.00)		
High mobility	1 (5.56)	4 (22.22)		1 (6.67)	3 (18.75)		
Smoking <sup>b</sup>							
No	15 (83.33)	17 (94.44)	0.6026	13 (86.67)	16 (100)	0.2258	
Yes	3 (16.67)	1 (5.56)		2 (13.33)	0 (0.00)		
Disease duration <sup>a</sup>	8.78 (3.52)	11.06 (4.33)	0.0926	8.93 (3.61) 5–18	11.56 (4.32) 7–19	0.0774	
Fall history <sup>b</sup>							
No	17 (94.44)	18 (100)	1.0000	14 (93.33)	16 (100)	0.4839	
Yes	1 (5.56)	0 (0.00)		1 (6.67)	0 (0.00)		
Affected knees <sup>b</sup>							
One knee	13 (72.22)	16 (88.89)	0.4018	10 (66.67)	14 (87.50)	0.2200	
Two knees	5 (27.78)	2 (11.11)		5 (33.33)	2 (12.50)		
Disease grade <sup>b</sup>							
1	0 (0.00)	1 (5.56)	0.5488	0 (0.00)	1 (6.25)	0.6161	
2	15 (83.33)	15 (83.33)		13 (86.67)	13 (81.25)		
3	3 (16.67)	2 (11.11)		2 (13.33)	2 (12.50)		

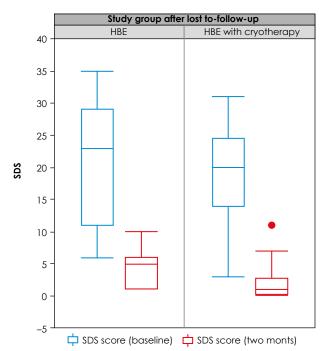
Socio-demographic characteristics	Study g	roups per-protocol No. (%)	p-value (2-sided)	Intention to treat No. (%)		p-value (2-sided)
	HBE, n = 18	HBE with cryotherapy, n = 18		HBE, n = 15	HBE with cryotherapy, n = 16	
Analgesics <sup>b</sup>						
No	1 (5.56)	2 (11.11)	1.0000	1 (6.67)	2 (12.50)	1.0000
Yes	17 (94.44)	16 (88.89)		14 (93.33)	14 (87.50)	
Cartilage drug <sup>b</sup>						
No	15 (83.33)	14 (77.78)	1.0000	13 (86.67)	12 (75.00)	0.6539
Yes	3 (16.67)	4 (22.22)		2 (13.33)	4 (25.00)	
Comorbidity <sup>b</sup>						
No	8 (44.44)	10 (55.56)	0.7395	6 (40.00)	9 (56.25)	0.4795
Yes	10 (55.56)	8 (44.44)		9 (60.00)	7 (43.75)	
Yes	. ,	<b>χ</b> ,		9 (60.00)	7 (43.75)	

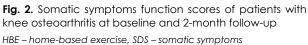
#### Table 1. Cont.

BMI – body mass index, HBE – home-based exercise

<sup>a</sup> independent t-test

 $^{\scriptscriptstyle b}$  Pearson  $\chi^2$  tests were performed for statistical analyses





the HBE with cryotherapy group had significantly lower SDS scores compared to patients in the HBE group (2.00 vs. 4.53; mean difference: -2.53, 95% CI: -4.50

to -0.57) with a large effect size (Cohen's *d*: 0.94) (Fig. 2, Table 2). The pain severity of both the HBE and HBE with cryotherapy groups was similar at bassline (Table 2). The somatic symptoms scores of patients in both the HBE and HBE with cryotherapy groups significantly decreased: 20.87–4.53 and 18.75–2.00, respectively (p < 0.001). Large effect sizes were observed in both the HBE and HBE with cryotherapy groups (2.95 and 2.25, respectively) (Table 3). The correlations of the pain at baseline with SDS scores of patients with KOA within the HBE and HBE with cryotherapy groups showed no statistically significant association (Fig. 3, Table 4).

## DISCUSSION

The research findings indicate that the implementation of HBE alongside cryotherapy demonstrated a significant improvement in SDS severity scores compared to patients who only received HBE intervention after 2 months. The effectiveness of combining HBE with cryotherapy for patients with KOA has not been extensively studied before. MohammedSadiq *et al.* [19] conducted a study in which they applied HBE with cryotherapy to KOA patients and compared the outcomes in terms of health-related QoL (daily functioning) with pa-

Table 2. Comparisons of somatic symptoms scores of patients with knee osteoarthritis among the study group at baseline

SDS	Study group mean (SD)		Mean diff		p-value
-	HBE (n = 15)	HBE with cryotherapy (n = 16)	- (95% CI)	(Cohen's d)	(2-sided)
SDS (baseline)	20.87 (9.05)	18.75 (8.29)	-2.12 (-8.49 to 4.25)	0.24	0.5022
SDS (2 months)	4.53 (3.09)	2.00 (2.22)	–2.53 (–4.50 to –0.57)	0.94	0.0134
VAS pain (baseline)	5.93 (0.80)	5.38 (1.02)	–0.56 (–1.24 to 0.12)		0.1029

HBE – home-based exercise, SDS – somatic symptoms, VAS – visual analogue scale An independent t-test was performed for statistical analyses

Groups	Time		Mean diff (95% CI)	Effect size	p-value	
	Baseline	Two-month follow-up	-	(Cohen's d)	(tow-sided)	
HBE	20.87 (9.05)	4.53 (3.09)	-16.33 (-20.29 to -12.38)	2.95	< 0.0001	
HBE with cryotherapy	18.75 (8.29)	2.00 (2.22)	-16.75 (-20.82 to -12.69)	2.25	< 0.0001	

 Table 3. Comparisons of somatic symptoms scores of patients with knee osteoarthritis between baseline and follow-up times in each group

HBE - home-based exercise

A paired t-test was performed for statistical analyses

tients who only received HBE intervention. The results showed that the group receiving HBE with cryotherapy experienced notable enhancements in daily activities, particularly in pain (2.22 vs. 4.81; p < 0.0001), stiffness (0.39 vs. 1.56; p < 0.0001), physical function (5.72 vs. 13.31; p < 0.0001), and overall score (8.33 vs. 19.69; p < 0.0001) at the 2-month mark. Additionally, patients receiving HBE with cryotherapy exhibited lower balance scores compared to those who received only HBE, and this pattern persisted at the 3-month follow-up.

The effectiveness of HBE with cryotherapy in the study was attributed to the anti-inflammatory effects of cryotherapy. Cryotherapy has been shown to have several mechanisms that contribute to its anti--inflammatory properties. It can reduce inflammation and pain by decreasing local metabolism, which leads to decreased cellular energy demands and secondary tissue injury caused by hypoxia [21]. Additionally, cryotherapy can help reduce fluid filtration into interstitial tissue by inducing vasoconstriction and preventing significant increases in microvascular permeability [22]. This can contribute to the reduction of swelling and inflammation. Evidence suggests that cryotherapy is beneficial in reducing pain, swelling, and inflammation in KOA. When combined with manual therapy or kinesiotherapy, cryotherapy may further enhance the health benefits for patients with knee OA [23, 24]. Furthermore, studies using a rat model of post-traumatic knee OA have indicated that cryotherapy has the potential to reduce synovial inflammation by decreasing inflammatory cytokine concentration and limiting leukocyte migration to the knee joint cavity [25]. These findings support the role of cryotherapy in mitigating the inflammatory processes associated with knee OA.

The effectiveness of cryotherapy as a standalone treatment has been explored in other RCTs. For instance, Dantas *et al.* [26] conducted a study on 30 patients to evaluate the effects of cryotherapy using crushed ice packs. While they did not find a significant difference in pain reduction between the cryotherapy group and the control group, they did observe positive effects on function and health-related QoL. The efficacy of cryotherapy for KOA lacks consensus among international organizations such as the International Osteoarthritis Research So-

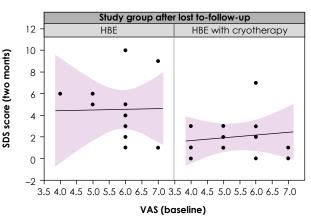


Fig. 3. Scatter plot of correlations of pain at baseline with somatic symptoms scores within the home-based exercise and home-based exercise with cryotherapy groups

 $\ensuremath{\mathsf{HBE}}$  – home-based exercise,  $\ensuremath{\mathsf{SDS}}$  – somatic symptoms,  $\ensuremath{\mathsf{VAS}}$  – visual analogue scale

**Table 4.** Effect of the pain at baseline on somatic symptomsscores of patients with knee osteoarthritis within the home-based exercise and home-based exercise with cryotherapygroups

Parameters	Correlations SDS score (2 months)	p-value (2-sided)			
HBE					
VAS (baseline)	0.0154 (-0.5008 to 0.5236)	0.9565			
HBE with cryotherapy					
VAS (baseline)	0.1172 (-0.4019 to 0.5792)	0.6656			

 $\mbox{HBE}$  – home-based exercise,  $\mbox{SDS}$  – somatic symptoms,  $\mbox{VAS}$  – visual analogue scale

Bivariate correlation was performed for statistical analyses.

ciety, the "European League against Rheumatism", and the "Ottawa Panel". These organizations did not reach a consensus in their final recommendations regarding cryotherapy for KOA [15, 27]. However, the "American College of Rheumatology" and the "National Institute for Health and Care Excellence" conditionally recommend cryotherapy as a complementary treatment option for knee OA [14].

A systematic review conducted by Brosseau *et al.* [28] examined 3 RCTs that had varied designs, treatment methods, and overall methodological quality. One of the trials investigated the effectiveness of ice massage compared to a control group and found that ice massage significantly increased quadriceps strength compared to the control group [29]. Another study evaluated the effects of ice packs and reported a statistically significant but not clinically significant difference in pain compared to the control group after 3 weeks of treatment [30]. A study combined HBE with cryotherapy to evaluate its effects on patients with KOA. Home-based conventional exercise intervention was based on a previous quasiexperimental study that assessed its impact on elderly patients with KOA [31]. In the experimental group, participants received HBE and health education, while the control group received only health education for a duration of 12 months. The results demonstrated that the combination of HBE and health education led to a reduction in pain intensity and joint stiffness, and improvement in muscle strength, balance, mobility, and overall health-related QoL in elderly patients with KOA.

## Strengths and limitations

The study possessed several strengths, including the utilization of a representative sample and the inclusion of comprehensive general and medical information of patients diagnosed with KOA. The randomized process employed in the study helped reduce potential biases, and efforts were made to minimize the number of lost-to-follow-up patients. However, there were certain limitations to the study. One such limitation was the exclusion of patients with higher BMIs, which makes it challenging to compare the results with studies that solely focused on cryotherapy. In future research, it would be beneficial to include participants with higher BMIs to broaden the applicability of the findings. Additionally, future studies could explore the use of crushed ice as an alternative to commercial gel for cryotherapy. This investigation may help enhance the therapeutic effects and further refine the application of cryotherapy in the management of KOA.

#### CONCLUSIONS

In conclusion, the study demonstrated that combining HBE with cryotherapy is an effective approach to improving somatic symptoms among patients with KOA. Cryotherapy is effective in alleviating the somatic symptoms among KOA patients. Cryotherapy is effective in improving QoL among KOA patients. Home-based exercise improves the somatic symptoms of KOA patients.

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