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Research Article

Investigating the Effect of Iaraj Fiqra Capsule and Dry Cupping on Knee Osteoarthritis: A Clinical Trial Study

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Abstract

Introduction: Knee arthritis is a joint disease caused by the destruction of the underlying cartilage and bone. Common symptoms of this disease are stiffness and pain. Dry cupping and Iaraj Fiqra capsules are used in Persian medicine to treat knee arthritis. Therefore, the present study aimed to assess the effect of the Iaraj Fiqra capsule and dry cupping on arthritis and compare their effects.

Materials and Methods: This randomized, single-blind trial was conducted on 61 subjects aged 60 to 69 years old with knee osteoarthritis after obtaining informed consent. Patients were randomly assigned to two groups. One group received 500 mg/day of Iaraj Fiqra capsules for four weeks (n=31), and the other group received dry cupping on the knee for 10 min twice a week for four weeks (n=30). Patients completed the Knee Injury and Osteoarthritis Outcome Score questionnaire, which assessed five areas: pain, symptoms, daily activities, sports and recreation function, and knee-related quality of life, both before and after the study. Independent and paired t-tests, Fisher's exact test, and the Chi-square test were used to evaluate the data in GraphPad software (version 8).

Results: The results demonstrated that Iaraj Fiqra capsules and dry cupping for four weeks improved pain (Iaraj Fiqra capsule: before: 92.1±1.3 and after: 73.1±1.4, p=0.002, dry cupping: before: 96.6±2.3 and after: 83.0±3.1; P=0.02), symptoms (Iaraj Fiqra capsule: before: 84.12±3.1 and after: 73.23±1.5; P=0.005, dry cupping: before: 82.11±1.2 and after: 67.31±1.1; P=0.001), daily activities (Iaraj Fiqra capsule: before: 32.22±2.5 and after: 76.21±0.6; P=0.002, dry cupping: before: 34.15±1.4 and after: 72.12±1.2; P=0.001), sports performance (Iaraj Fiqra capsule: before: 92.1±1.3 and after: 73.1±1.4; P=0.002, dry cupping: before: 96.6±2.3 and after: 83.0±3.1; P=0.001,) and recreational (Iaraj Fiqra capsule: before: 24.21±1.2 and after: 68.11±0.5; P=0.002, dry cupping: before: 28.95±1.2 and after: 62.25±2.7; P=0.001), and knee-related quality of life scores (Iaraj Fiqra capsule: before: 31.11±0.6 and after: 82.32±11.4; P=0.002, dry cupping: before: 11.6±33.11 and after: 81.21±1.4; P=0.002). Furthermore, the results demonstrated that the pain score of patients improved significantly compared to the dry cupping group (P<0.05).

Conclusion: As evidenced by the obtained results, Iaraj Fiqra capsules and dry cupping can be used to improve the pain, symptoms, daily activities, sports and recreation function, and knee-related quality of life of individuals with knee osteoarthritis

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مقاله پژوهشی

بررسی تأثیر کپسول ایارج فیقرا و حجامت خشک بر آرتروز زانو: یک مطالعه کارآزمایی بالینی

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پرسش‌نامه KOOS

طب ایرانی

چکیده

مقدمه: آرتروز زانو یک بیماری مفصلی است که در اثر تخریب غضروف و استخوان زیرین ایجاد می‌شود. علایم شایع سفتی و درد است. از حجامت خشک و کپسول ایارج فیقرا در طب ایرانی برای درمان آرتروز زانو استفاده می‌شود؛ بنابراین، این مطالعه به بررسی تاثیر کپسول ایارج فیقرا و حجامت خشک بر آرتروز و مقایسه آثار آن‌ها پرداخته است.

روش کار: این کارآزمایی تصادفی یک‌سوکور پس از کسب رضایت آگاهانه بر روی ۶۱ فرد مبتلا به استئوآرتریت زانو در رده سنی ۶۰ تا ۶۹ سال انجام شد. بیماران به طور تصادفی به دو گروه تقسیم شدند. یک گروه (۳۱ نفر) ۵۰۰ میلی‌گرم در روز کپسول ایارج فیقرا را به مدت ۴ هفته و گروه دیگر (۳۰ نفر) حجامت خشک روی زانو را به مدت ۱۰ دقیقه دو بار در هفته به مدت ۴ هفته دریافت کردند. قبل و بعد از مطالعه، بیماران پرسش‌نامه نتیجه آسیب زانو و استئوآرتریت Knee Injury and Osteoarthritis Outcome Score (KOOS) که شامل ۵ سوال درد، علایم، فعالیت‌های روزانه، عملکرد ورزشی و تفریحی و کیفیت زندگی بود، تکمیل کردند. برای ارزیابی داده‌ها از آزمون تی مستقل و زوجی، آزمون فیشر دقیق و کای دو با استفاده از نرم‌افزار گراف پد نسخه ۸ استفاده شد.

یافته‌ها: نتایج نشان داد که داروی ایارج فیقرا و حجامت خشک به مدت ۴ هفته باعث بهبود درد (ایارج فیقرا: قبل: ۱/۳ ± ۹۲/۱ و بعد: ۱/۴ ± ۷۳/۱؛ حجامت خشک: قبل: ۲/۳ ± ۹۶/۶ و بعد: ۳/۱ ± ۸۳/۰) شدند، هرچند نتایج نشان داد که ایارج فیقرا نمره درد بیماران را در مقایسه با گروه حجامت خشک به طور معناداری بهبود بخشید ($P<0.05$). از نظر تاثیر این دو روش درمانی بر علایم (ایارج فیقرا: قبل: ۳/۱ ± ۸۴/۱۲ و بعد: ۱/۵ ± ۷۳/۲۳، حجامت خشک: قبل: ۱/۲ ± ۸۲/۱۱ و بعد: ۱/۱ ± ۶۷/۳۱) و با ($p<.01$) تاثیر معناداری مشاهده شد. از نظر تاثیر این دو روش بر فعالیت‌های روزانه (ایارج فیقرا: قبل: ۲/۵ ± ۳۲/۲۲ و بعد: ۰/۶ ± ۷۶/۲۱؛ حجامت خشک: قبل: ۱/۴ ± ۳۴/۱۵ و بعد: ۱/۲ ± ۷۲/۱۲)، عملکرد ورزشی و تفریحی (ایارج فیقرا: قبل: ۱/۲ ± ۲۴/۲۱ و بعد: ۰/۵ ± ۶۸/۱۱؛ حجامت خشک: قبل: ۱/۲ ± ۲۸/۹۵ و بعد: ۲/۷ ± ۶۲/۲۵) و نمرات کیفیت زندگی (ایارج فیقرا: قبل: ۰/۶ ± ۳۱/۱۱ و بعد: ۱۱/۴ ± ۸۲/۳۲؛ حجامت خشک: قبل: ۱۱/۶ ± ۳۳/۱۱ و بعد: ۱/۴ ± ۸۱/۲۱) نیز با ($p<.001$) تاثیر مثبت قابل ملاحظه مشاهده شد.

نتیجه گیری: بر اساس نتایج، می‌توان از کپسول ایارج فیقرا و حجامت خشک برای بهبود درد، علایم، فعالیت‌های روزانه، عملکرد ورزشی و تفریحی و کیفیت زندگی افراد مبتلا به آرتروز زانو استفاده کرد.

Introduction

Osteoarthritis musculoskeletal system diseases present with degenerative changes in synovial joints, along with new ossification (1). This disease causes more disability and clinical symptoms in the knee than other joints and, according to the evidence in the world, is a major problem presented to health. Musculoskeletal pain is common in older adults (2). Some researchers consider aging to be associated with a reduction in musculoskeletal characteristics that results in pain, decreased physical function, and disability (3).

Research has indicated that 33.6% of individuals aged 65 and older experience knee osteoarthritis as a source of musculoskeletal pain (4). This disease is one of the leading causes of functional impairment significantly impacting people's lives, including mobility, independence, and daily activities, leading to limited recreational, sports, and occupational activities. Excessive pressure, overuse, and trauma to the joints are among the causes of joint damage and osteoarthritis (5).

Nonsteroidal anti-inflammatory drugs (NSAIDs) are medicines used most often for the relief of osteoarthritic symptoms (6). Although NSAIDs are relatively efficient, long-term use or use in susceptible individuals can cause serious side effects, such as gastrointestinal toxicity, cardiovascular events, edema development, reversible renal insufficiency, and a modest increase in blood pressure (7). Therefore, patients who experience adverse efficacy and side effects of conventional treatment try to overcome the current treatment deficiencies by taking complementary and alternative medicines (8, 9).

The sources of Persian medicine have recommended the use of dry cupping and herbal medicines. Multiple types of cupping therapy are described in the literature, including dry cupping therapy, wet cupping therapy, medicinal cupping therapy, and moving cupping therapy (10). Cupping therapy is already employed for shoulder and neck pain as a complementary medicine (11). Dry cupping is a treatment in traditional medicine in which a negative pressure is applied to the skin by a suction cup (12). According to previous studies, dry cupping can reduce pain by increasing capillary blood flow, improving tissue perfusion, and improving venous drainage (13).

Another common treatment in traditional medicine is the use of herbs. Iaraj Fiqra capsule is a product derived from Persian medicine, scientifically prepared and formulated from *Rosa domestica* L., *Cinnamomum verum*, *Zingiber officinalis* L., and *Aloe vera*. The key phytochemicals in this product include Aloin and Emodin from the yellow saber, flavonoids, and anthocyanides along with kaempferol and quercetin from rose, proanthocyanidins and catechins from cinnamon, and gingerol, paradol, and zingerone from ginger. As illustrated in previous studies, it has been demonstrated that these plants individually have anti-inflammatory and soothing effects on osteoarthritis (14-17).

According to the literature, no study has been performed to investigate the effect of the Iaraj Fiqra capsule and dry cupping on the treatment of patients with knee osteoarthritis. Therefore, for the first time, the present study aimed to assess the effect of dry cupping and Iaraj Fiqra capsules on the treatment of patients with knee osteoarthritis and compare their effects.

Materials and Methods

This study was a single-blinded, randomized, parallel-group trial that lasted from 2019-10-07 to 2020-08-20 at Arak University of Medical Sciences and Valiasr Hospital. The Ethical Committee of the Arak University of Medical Sciences approved this study (IR.ARAKMU.REC.1397.54). After acquiring the IRCT code (www.irct.ir; NO: IRCT20180610040049N1), this study was performed on patients with knee osteoarthritis to evaluate the effect of Iaraj Fiqra capsules and dry cupping and compare the two treatments. Informed consent was first obtained from individuals. It is noteworthy that patients participated in the study voluntarily, and before entering the study, they were given a consent form to sign.

Inclusion and exclusion criteria

The inclusion criteria were as follows: an age of over 40 years, a history of intra-articular injection of corticosteroids or NSAIDs during the last four months, a history of knee pain and osteoarthritis in the last six months (diagnosed by an orthopedic specialist), non-use of herbal medicines or cupping during for the last four months, ability to read and write, and the provision of written consent to participate in the study. On the other hand, the exclusion criteria were as follows: allergies to herbal capsules during the study, receiving physical medicine, leeches, and acupuncture during the last four months, and unwillingness to cooperate in the study.

Randomization, blinding, and grouping

A total of 70 patients were enrolled according to the inclusion criteria. The participants were selected by an orthopedic and a Persian medicine specialist. To assign patients to each group, 20 blocks of 4 were formed and written on paper, and the papers were then placed in an envelope. The papers were randomly extracted from the envelope so that each participant could be assigned to either the Iaraj Fiqra capsule or the dry cupping group. Sampling was performed at Kosar Clinic. Statistical analyzers were blinded to grouping until the results were completed and analyzed. As illustrated in Figure 1, 70 patients were enrolled in the study at first, 2 of whom did not qualify according to the inclusion criteria, and two did not want to continue the study. Therefore, the study started with 66 patients (2 groups of 33 patients each), and in the continuation of the study, two patients in the Iaraj Fiqra group and three patients in the dry cupping group were excluded from the study for personal reasons.

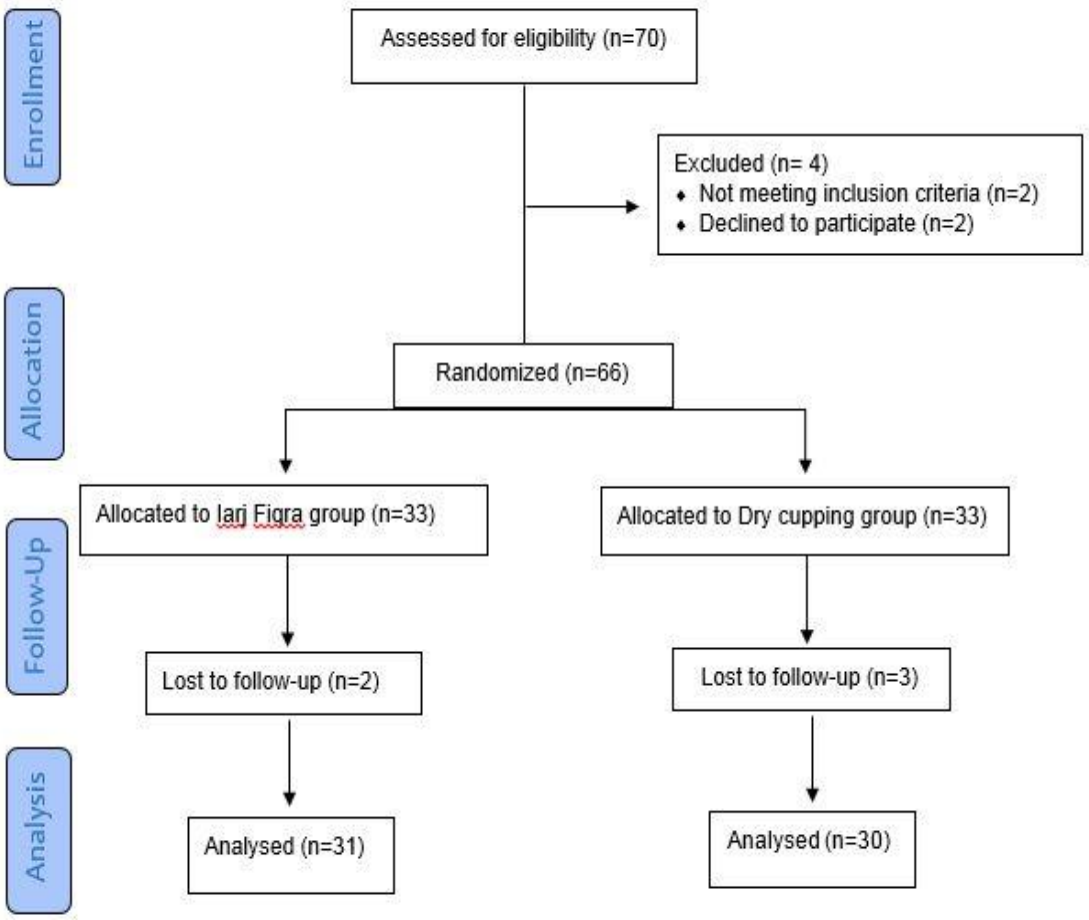

Figure 1: Summary of patient flow diagram

Procedure

Iaraj Fiqra capsule (500 mg/Kg) group: This group received Iaraj Fiqra capsule for four weeks and three times a day. The Iaraj Fiqra capsule was produced from *Rosa domestica* L., *Cinnamomum verum*, *Zingiber officinalis* L., and *Aloe vera* by the Sanabel Drug Company. Dry cupping group: This group received dry cupping on the knee for 10 min twice a week for four weeks at the specified points (SP9، SP10، ST36). Dry cupping with a big adaptable silicone cup (vacuum: 100-200 mbar, interval: 2 seconds, pulse: 30-50%) on the knee was performed by a specialist in Persian medicine.

Data collection tools

The demographic information of the participants was evaluated by a Persian medicine specialist. The Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire was used to evaluate the effect of the Iaraj Fiqra capsule and dry cupping. The KOOS questionnaire includes five subscales: pain (9 items), symptoms of the dry knee (7 items), daily activities (17 items), sport and recreation function (5 items), and knee-related quality of life (4 items). Each item was rated on a five-point Likert scale. Each subscale is calculated separately between 0 and 100, with 100 indicating the absence of problems and 0 denoting the worst problems. Salavati et al. reported that the KOOS was valid (7.44) and reliable (0.7) (18, 19).

Statistical analysis

Data were presented as mean and standard error mean (SEM). Shapiro-Wilk test was applied to check the normal distribution of data. Pain, symptoms, daily activities, sport and recreation function, and knee-related quality of life were compared between the two treatment groups using paired t-test, Fisher's exact test, and the Chi-squared test. Data were analyzed in GraphPad statistical software (version 8).

Results

Demographic information of the participants in the study

As tabulated in Table 1, the age, weight, and body mass index (BMI) of the participants in the Iaraj Fiqra group were not significantly different from those of their counterparts in the dry cupping group ($P>0.05$). The majority of participants in this study were female (64.51% for the Iaraj Fiqra group and 63.33% for the dry cupping group). All participants in both groups were married. Moreover, 10 (32.25%) members of the Iaraj Fiqra group and 12 (38.70%) members of the dry cupping group were smokers. The majority of participants in the study had elementary education.

Table 1: Demographic comparison of participants

Characteristic	Iaraj Fiqra (n=31)	Dry cupping (n=30)	P-value [a]
Age*# (years)	61.32±2.11	62.96±1.41	0.82
Weight*# (kg)	69.31±1.15	72.21±2.11	0.83
BMI*δ # (kg/m^2)	25.31±0.15	27.12±0.37	0.39
Gender^ (Male/Female), n (%)	36.6%/66.6%	40%/60%	
Smoking^, n (%)	10 (32.25%)	12 (38.70%)	
Married^, n (%)	31 (100%)	30 (100%)	
Education^, n (%)			
High	1 (3.22%)	2 (6.66%)	
Intermediate	2 (6.45%)	2 (6.66%)	
Primary	28 (90.32%)	26 (86.66%)	

*Data are presented as means±SEM. δBMI: Body mass index. #Independent t-test. [a]P-value < 0.05 was considered statistically significant. ^The Fisher's exact and Pearson χ 2 tests were used to analyze the demographic.

Results of the effects of Iaraj Fiqra capsule and dry cupping

Upon the completion of the study (30 days), the results demonstrated that the administration of Iaraj Fiqra capsules significantly improved the pain score (P=0.002), symptom score (P=0.005), daily activities score (P=0.003), sport and recreation function score (P=0.002), and knee-related quality of life score (P=0.002) compared to before the study (Table 2). Furthermore, our results illustrated that four weeks of dry cupping significantly improved pain score (P=0.01), symptom score (P=0.001), daily activities score (P=0.005), sport and recreation function score (P=0.001), and knee-related quality of life score (P=0.001) compared to before the study (Table 3).

Comparison of the effect of Iaraj Fiqra capsule and dry cupping at the end of the study

As presented in Table 4, Iaraj Fiqra capsules significantly reduced the pain score (P=0.1) compared to dry cupping. Nonetheless, there was no significant difference between the effect of Iaraj Fiqra capsules on symptom score (P=0.1), daily activities score (P=0.2), sport and recreation function score (P=0.3), and knee-related quality of life score (P=0.2) compared to the dry cupping.

Table 2: Comparison of capsule effects before and after the study

Characteristic	Iaraj Fiqra (n =31)^		P-value*
	Before	After	
Pain score#	92.1±1.3	73.1±1.4	0.002
Symptom score#	84.12±3.1	73.23±1.5	0.005
Daily activities score#	32.22±2.5	76.21±0.6	0.003
Sport and recreation function score#	24.21±1.2	68.11±0.5	0.002
Knee-related quality of life score#	31.11±0.6	82.32±11.4	0.002

^Data are presented as means±SEM. *Significantly different compared with the placebo group. #Paired t-test analysis. P-value < 0.05 was considered statistically significant.

Table 3: Comparison of dry cupping effects before and after the study

Characteristic	Dry cupping (n=30)^		P-value *
	Before	After	
Pain score#	96.6±2.3	83.0±3.1	0.02
Symptom score#	82.11±1.2	67.31±1.1	0.001
Daily activities score#	34.15±1.4	72.12±1.2	0.005
Sport and recreation function score#	28.95±1.2	62.25±2.7	0.001
Knee-related quality of life score#	33.11±11.6	81.21±1.4	0.001

^Data are presented as means±SEM. *Significantly different compared with the placebo group. #Paired t-test analysis. P-value < 0.05 was considered statistically significant.

Table 4. Comparison of the effect of Iaraj Fiqra capsule and dry cupping at the end of the study #

Characteristic	Iaraj Fiqra^	Dry cupping^	P-value*
Pain score#	73.1±1.4	83.0±3.1	0.1
Symptom score#	73.23±1.5	67.31±1.1	0.1
Daily activities score#	76.21±0.6	72.12±1.2	0.2
Sport and recreation function score#	68.11±0.5	62.25±2.7	0.3
Knee-related quality of life score#	82.32±11.4	81.21±1.4	0.2

^Data are expressed as mean±SEM. *Significantly different compared with the placebo group. #Independent t-test analyses. P-value < 0.05 was considered statistically significant.

Discussion

This clinical trial is the first study that assessed the effect of Iaraj Fiqra capsules and dry cupping on keen osteoarthritis and compared their effects. The results of our study revealed that Iaraj Fiqra capsules and dry cupping had significant effects on the improvement of pain, symptoms, daily activities, sports and recreation function, and knee-related quality of life scores in these patients. However, the effect of the Iaraj Fiqra capsule in the reduction of pain was more significant compared to the dry cupping group. Nevertheless, in terms of the symptoms, daily activities, sport and recreation function, and knee-related quality of life scores, there was no significant difference between Iaraj Fiqra and dry cupping.

Knee osteoarthritis is commonly referred to as a degenerative joint disease. This disease is the result of the gradual destruction of articular cartilage, which is common in older adults (20). The most important risk factors of this disease include age, heredity, gender, repetitive stress injuries, athletics, and other illnesses (21). Studies have indicated that inflammatory factors,

including interleukin-1β, tumor necrosis factor-alpha (TNF-α), and metalloproteinases 1, have a role to play in the development of osteoarthritis (22). Therefore, treatments based on the suppression of inflammatory factors can improve knee osteoarthritis. Today, anti-inflammatory drugs, such as NSAIDs, are used to reduce pain in these patients; however, these drugs have several side effects (23). Therefore, it is more important to use traditional medicine drugs that have been commonly used for many years and are free from side effects (24).

Today, the use of herbal medicines is increasing owing to their fewer side effects (25). The results of our study based on the KOOS questionnaire pointed out that the Iaraj Fiqra capsule improved knee osteoarthritis compared to before the intervention. To the best of our knowledge, no study has been performed on Iaraj Fiqra capsules. This capsule is a combination of *Rosa domestica* L., *Cinnamomum verum*, *Zingiber officinalis L.*, and *Aloe vera*. Shishehbor et al. reported that Cinnamon supplementation can be an adjunct therapy to improve rheumatoid arthritis and significantly decrease C-reactive protein and TNF-α (26). *Aloe vera* is one of the most commonly used herbs in alternative medicine and is available in multiple forms, such as pills, powder, gels, and the whole leaf. Bałan et al. have reported that *Aloe vera* has strong anti-inflammatory effects (27). In a similar vein, Cowan, in a review article, concluded that *Aloe vera* was suitable for osteoarthritis (17).

Zingiber officinalis L. is used in Persian medicine to treat inflammation and arthritis. Dehghan et al. pinpointed that *Zingiber officinalis* L. gel can reduce pain caused by knee osteoarthritis (28). In another study, Altman et al. reported that oral consumption of *Zingiber officinalis* for six weeks significantly improved knee osteoarthritis (29). To the best of our knowledge, there has been no reported research on the impact of *Rosa domestica* on knee osteoarthritis; nonetheless, it has been noted for its anti-inflammatory effects. In general, the common feature of these four plants is their anti-inflammatory properties. This can be the reason for the improvement of knee osteoarthritis.

Cupping is one of the treatments of traditional medicine. In Persian medicine texts, cupping therapy has been recommended to reduce pain (30). The results of our study suggested that dry cupping for four weeks and two times a week significantly reduced pain and significantly improved symptoms compared to before the intervention. In line with the results of the current research, in a study by Almeida Silva et al., it was shown that dry cupping for eight weeks improved lower back pain (31). Along the same lines, a study by Pontes et al. reported that dry cupping twice a week for six weeks reduced the pain of knee osteoarthritis (32). In a study by Teut et al. on patients with chronic low back pain, it was reported that pulsatile dry cupping decreased pain compared to the control group (33). Various mechanisms have been proposed for the therapeutic effect of cupping, including dilating the superficial arteries, accumulating blood at the site, excretion of lactic acid, reducing pressure on the nerves of the muscle tissue, relieving muscle spasms, and enhancing local blood flow by invading defense cells and anti-inflammatory factors to the site (34). As a result, these factors collectively increase oxygen and nutrients, decrease inflammatory factors, and alleviate inflammation, leading to a reduction in pain and fatigue (35).

Furthermore, the post-intervention comparison of the two groups indicated that the effect of the Iaraj Fiqra capsule on the reduction of pain was significant compared to the dry cupping group, which can be attributed to the stronger anti-inflammatory effects of the plants in the Iaraj Fiqra capsule. This finding warrants further investigation. The main limitations of our study were the small sample size and the short duration of the treatment phase. Therefore, the impacts of Iaraj Fiqra capsule and dry cupping therapy in knee osteoarthritis patients should be further evaluated in a larger sample size with a longer duration of therapy.

Conclusion

As evidenced by the results of this study, Iaraj Fiqra capsules and dry cupping can be used to improve the pain, symptoms, daily activities, sports and recreation function, and knee-related quality of life of people with knee osteoarthritis.

Akcnowledgments

We sincerely thank and appreciate all the people who participated in this study.

Ethical considerations

This study is approved by the Ethics Committee of the Physical Education Research Institute (code: IR/SSRI.REC.2023.15667.2440).

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