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Effects of High-intensity Training and Electrical Stimulation on Pain, Disability, Knee Kinematic and Performance in Patellofemoral Pain: A Randomized Controlled Trial

Efectos del entrenamiento de alta intensidad y la estimulación eléctrica sobre el dolor, la discapacidad, la cinemática de la rodilla y el rendimiento en el dolor femororrotuliano: un ensayo controlado aleatorio

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Abstract. Patellofemoral pain (PFP) is a widespread problem in athletes who participate in jumping, cutting, and pivoting sports. Forty-four players participated in this study. They were divided into two groups: exercise plus Electro Myo Stimulation (EMS, G1) and exercise without EMS (G2), both with 12 women and 10 men. The exercise consisted of 8 weeks of a high-intensity strength program for 45-60 minutes, plus cooling and a warm-up phase. Visual analogue scale (VAS), disability (Kujala patellofemoral score), knee valgus angle (KVA) and single-leg hop (SLH) were tested before (pre-test) and after training (post-test at 8 weeks) using a within-between group analysis (ANOVA 2×2). At baseline, no differences between groups were found ($p > 0.05$). After the intervention, both groups improved VAS, KVA, SLH ($p < 0.001$), and disability ($p = 0.042$). G1 showed more improvements than G2 for VAS (- 63.4 vs - 51.5 %, $p = 0.021$, $\eta p2 = 0.13$), disability (+ 32.6 vs + 18.4 %, $p = 0.001$, $\eta p2 = 0.52$), KVA (+ 4.2 vs + 2.2 %, $p = 0.016$, $\eta p2 = 0.214$) and SLH (+ 12.3 vs + 6.0 %, $p = 0.003$, $\eta p2 = 0.20$) respectively. No differences were found between the sexes for each group. Despite both interventions being valid, high-intensity strength training combined with EMS improved pain, disability, knee kinematics, and lower extremity performance more than exercise alone in professional handball athletes with PFP.
Keywords: Electrical muscle stimulation, Rehabilitation, Musculoskeletal, Knee, Handball players

Resumen. El dolor patelofemoral (PFP) es un problema generalizado en los atletas que practican deportes de salto, corte y pivote. En este estudio participaron cuarenta y cuatro jugadores. Se dividieron en dos grupos: ejercicio más EMS (G1) y ejercicio sin EMS (G2), ambos con 12 mujeres y 10 hombres. El ejercicio realizado fue de 8 semanas de un programa de fuerza de alta intensidad durante 45-60 minutos, más una fase de enfriamiento y calentamiento. La escala analógica visual (EVA), la discapacidad (puntuación femororrotuliana de Kujala), el ángulo en valgo de la rodilla (KVA) y el salto con una sola pierna (SLH) se evaluaron antes (prueba previa) y después del entrenamiento (prueba posterior a las 8 semanas) utilizando un intervalo de -análisis entre grupos (ANOVA 2×2). Al inicio no se encontraron diferencias entre los grupos ($p > 0,05$). Después de la intervención, ambos grupos mejoraron EVA, KVA, SLH ($p < 0,001$) y discapacidad ($p = 0,042$). G1 mostró más mejoras que G2 en EVA (- 63,4 vs - 51,5 %, $p = 0,021$, $\eta p2 = 0,13$), discapacidad (+ 32,6 vs + 18,4 %, $p = 0,001$, $\eta p2 = 0,52$), KVA (+ 4,2 vs + 2,2 %, $p = 0.016$, $\eta p2 = 0.214$) y SLH (+ 12.3 vs + 6.0 %, $p = 0.003$, $\eta p2 = 0.20$) respectivamente. No se encontraron diferencias entre sexos para cada grupo. A pesar de que ambas intervenciones fueron válidas, el entrenamiento de fuerza de alta intensidad combinado con EMS mejoró el dolor, la discapacidad, la cinemática de la rodilla y el rendimiento de las extremidades inferiores más que el ejercicio solo en atletas profesionales de balonmano con PFP.
Palabras clave: Estimulación muscular eléctrica, Rehabilitación, Musculoesquelética, Rodilla, Jugadores de Balonmano

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Introduction

Patellofemoral pain (PFP) or anterior knee pain is one of the most common lower extremity disorders that often affects young women athletes (Crossley et al., 2016; Witvrouw, Lysens, Bellemans, Cambier, & Vanderstraeten, 2000). In general population, the annual prevalence of PFP was around 22.7% with an incidence rate of 1080.5/1000 while in adolescents was around 28.9% with a percentage ranging from 5.1 to 14.9% for adolescent amateur athletes (Smith et al., 2018). PFP often limits participation in recreational and sports activities (Blond & Hansen, 1998), which is associated with the development of patellar osteoarthritis (Utting, Davies, & Newman, 2005; Witvrouw et al., 2000). While the underlying mechanisms are not yet well known, it is suggested that incorrect lower extremities biomechanics and increased knee valgus play a role in developing PFP (Willson & Davis, 2008). Along the same line, knee injuries may contribute to PFP (Galloway et al., 2018). They are prevalent in competitive sports that include stop-start actions, change of direction, jumps and lands with and without passing and/or shooting a ball (e.g., handball) (Hootman, Dick, & Agel, 2007; Myer et al., 2015; Weiss & Whatman, 2015).

The sport of handball includes many actions such as running, changing direction and jumping. These actions are vigorous and can be responsible for higher mechanical stress levels to the knee. Consequently, handball players are predisposed to developing osteoarthritic changes in the knee such as bone marrow edema, cartilage and patella damage, ligamentous damage, and meniscal tear (Vrezas, Elsner, Bolm-Audorff, Abolmaali, & Seidler, 2010).

A recent study showed that from 15783 athletes, 1392 male handball players presented an increased risk of full-thickness cartilage damage compared to male soccer athletes (Røtterud, Sivertsen, Forssblad, Engebretsen, & Årøen, 2011). Other research showed that participating in this sport was correlated with symptomatic knee osteoarthritis (OA) (Vrezas et al., 2010). In this regard, it has been shown that every 1000 hours of match-play contributes to a range between 2.5 to 108 injuries (Higashi et al., 2015; Yde & Nielsen, 1990) while reaching 0.8 for each player every year (Higashi et al., 2015).

According to evidence, knee joint injuries, including anterior knee pain, lead to muscular imbalances or weakness in patella malalignment (Boling, Bolgla, Mattacola, Uhl, & Hosey, 2006; Nejati, Forogh, Moeineddin, Baradaran, & Nejati, 2011) during knee flexion and extension movements (Rixe, Glick, Brady, & Olympia, 2013) can contribute to PFP (Boling et al., 2006). In addition, previous research stated that knee valgus can occur due to medial knee rotation, tibia abduction, and foot pronation caused by internal rotation and excessive hip adduction during weight-bearing (Bell, Padua, & Clark, 2008), a phenomenon associated with a hip strength reduction (Claiborne, Armstrong, Gandhi, & Pincivero, 2006; Hollman et al., 2009; Willson, Ireland, & Davis, 2006) and that may contribute to a higher knee injury risk.

The high prevalence of PFP and ineffective treatments have affected many people's activities and daily activities (Kooij et al., 2019). In this regard, the treatment principles for PFP are often mechanical and include lower limb exercises, stretching, tape, braces and orthoses (MacIntyre, Hill, Fellows, Ellis, & Wilson, 2006). One study showed that strength training alone affected lower back pain and performance in people with PFP (Shadloo, Kamali, & Dehno, 2021). Strength training has affected the strength of the knee muscles and has led to improved performance in PFP (Emamvirdi, Letafatkar, & Khaleghi Tazji, 2019).

Whole-body Electro Myo Stimulation (EMS) can complement strength training since it can be used in different ways (e.g., combined or separated from different training sessions (Berger et al., 2020). This stimulation uses several electrodes (Berger et al., 2020) that can be placed in different muscles and consequently, stimulate them simultaneously (Jee, 2018). Several improvements can be achieved with both high-intensity resistance training and whole-body EMS (Kemmler et al., 2016) and at the same time, EMS has been suggested to improve strength, muscle mass and jump ability (e.g., in volleyball and soccer players) among trained and elite athletes when combined with exercise training (Filipovic et al., 2019; Filipovic et al., 2016; Filipovic, Kleinoder, Dormann, & Mester, 2012; Kemmler et al., 2016). On the other hand, contraindications of this therapy were recommended for individuals with pacemakers, cardiac patients, epileptic patients, pregnant women, individuals with active phlebitis or thrombophlebitis, individuals affected by neoplasms or tumors) (Musumeci et al., 2018). Clinically, EMS has also been used for patients after injuries or surgeries in physiotherapy rehabilitation sessions, and several improvements were found in pain and muscle function (e.g., strength) in individuals with PFP (Glaviano & Saliba, 2016; Glaviano et al., 2019a; Glaviano et al., 2019b). Recently, the evolution of Bluetooth technology improved the EMS system, leading to more accessible and more comfortable devices for people with musculoskeletal diseases (Dey, Ashour, Shi, Fong, & Sherratt, 2017).

The purpose of EMS was to prevent muscle hypotrophism by causing involuntary muscle contractions (Hamada, Sasaki, Hayashi, Moritani, & Nakao, 2003) which are dependent on the used frequency. For example, above 70 Hz, deep muscles are activated through small motor neurons, while lower values provoke superficial contraction of the muscles which leads to the activation of large motor neurons (Doucet, Lam, & Griffin, 2012). When combined with exercise, fast-twitch fibers can be activated with lower effort levels (Paillard, 2018).

Beyond frequency, electrical stimulation can be mediated by waveform, intensity, and on/off ratio for the primary purpose of muscle strengthening and muscle retraining (Doucet et al., 2012; Maffiuletti, Vivodtzev, Minetto, & Place, 2014). This electric pad transmits current to the muscle in contact with the skin and subsequently causes muscle contraction (Lee, Park, & Chon, 2019), which can be performed during dynamic movement and in a static state (Huo, Mohammed, Moreno, & Amirat, 2014). Pichon et al. (Pichon, Chatard, Martin, & Cometti, 1995) reported that EMS was effective in isometric and isotonic contraction, and reported an overall improvement in muscle strength training with EMS. Recently the EMS has been proposed as an innovative electrostimulation technique because it can improve the performance of the body complex (Wirtz et al., 2019). However, while research has examined the effectiveness of the EMS (Filipovic et al., 2019), scarce literature has quantitatively measured its effects during dynamic movements (e.g., squat jump) (Filipovic et al., 2019), leaving the field of investigation also open in PFP. In particular, one study using superficial electromyography (EMG) combined with resistance training to rehabilitate patients with PFP revealed higher levels of strength while increasing type II fiber in soccer players (Filipovic et al., 2019). To the best of the authors' knowledge, no research on EMS combined with exercise in handball players with PFP was retrieved in the literature. Therefore, this study investigated the effects of high-intensity strength training, with or without EMS, on pain, disability, knee kinematics and lower extremity performance in professional handball athletes with PFP. It was hypothesized that strength-based treatment with EMS better affects pain, disability, knee kinematics, and lower extremity performance than exercising without EMS.

Material and Methods

Study Design

This research is a monocentric parallel randomized controlled trial (RCT) performed from 02/02/2021 to 31/01/2022. We adopted as a design a two-group study with exercise treatment delivered in two experimental groups with equal randomization (1 male, 1 female): exercise with EMS (G1) and exercise without EMS (G2). The intervention lasted 8 weeks.

This RCT report was prepared and reported following the CONSORT (Moher, 2010; Schulz Kenneth & Altman Douglas, 2010) and REPORT-PFP CHECKLIST (Barton et al., 2021) guidelines and was reported as Supplementary files. Professional instructors and participants were blinded to group assignments until the study had concluded.

Randomization

A blinded person generated a concealed allocation sequence, enrolled players, and assigned them to the groups. Two professional instructors, blinded to the group players' allocation and the research aims performed the assessments. These were the same who applied the training protocols.

Using equal randomization (ratio of 1:1), players were assigned to one of two groups by a blinded person to the study design and aims. Moreover, the randomization was made through 44 codes representing each participant and different sexes in a concealed envelope. Then, the blinded person placed 22 cards in both balls.

Participants

A total of 44 professional handball players with PFP with more than three years of experience playing in the professional league participated in this RCT. We considered professional players who trained three times a week for 3-4 hours each day in Iran's official national championship.

The sample size was also calculated for a priori F-test family (ANOVA: Repeated measures, within – between interaction) was calculated for α level = 0.05; effect size = 0.5; two G, which required a minimum of n = 16 by the G-Power (Faul & Erdfelder, 2007). This calculation achieved 96% of the actual power for the analysis.

Procedures

Before enrolling in the study, players were informed of the risks and benefits while signing an informed consent form according to the Helsinki Declaration (Winter & Maughan, 2009).

They were divided into two groups: group 1 (G1), n: 22, age: 25.3 ± 2.33 yr, height: 1.74 ± 0.08 m, weight: 66.72 ± 6.59 kg, and group 2 (G2), n: 20, age: 25.40 ± 2.83 yr, height: 1.70 ± 0.09 m, weight: 64.10 ± 10.55 kg). For each group, 22 players (12 women, 10 men) were allocated. MZ10023-3, ADE scale equipment was used to evaluate weight and height (Hien, Tam, Tam, Derese, & Devroey, 2018). In addition, these players reported unilateral PFP in the dominant leg, which was specified using the ball-kicking test (McCoy, 2017).

An orthopedic physician with 15 years of experience managing athletes with musculoskeletal complaints performed the eligibility criteria process, executing history taking and physical examination. From G2, two players were lost at follow-up for absence post-test and three non-consecutive training absences. Thus, 22 players in the G1 and 20 players in the G2, but according to the recommendations of intention-to-treat (ITT) analysis in RCT protocols (McCoy, 2017), for the players who were lost in this study, the mean of the relevant variables was used instead of the lost players in G2 (Elkins & Moseley, 2015).

The following eligibility criteria were applied:

Inclusion criteria: (1) symptoms of anterior knee pain for at least one month; (2) average pain level of ≥ 4 on a 10-cm visual analogue scale during squatting; (3) presence of at least two of the following clinical criteria: 1) pain during apprehension test, 2) pain during the patellar compression test, 3) crepitation during the compression test (Smith et al., 2012).

Exclusion criteria: (1) any history of knee surgery; (2) history of patellar dislocation, subluxation or ligament laxity; (3) orthopedic and nerve injuries; (4) history of other abnormalities such as leg length inequalities (> 2 cm); and (5) medication as a part of the treatment (Gorji, Mohammadi Nia Samakosh, Watt, Henrique Marchetti, & Oliveira, 2022). Players were also excluded from the study if they underwent other types of therapy, specific work activities, or regular treatments (e.g., stretching, tape, braces, orthoses and/or acupuncture) or if they failed in two consecutive sessions, three non-consecutive sessions or in the post-test phase.

Interventions

All professional handball players progressively completed a high-intensity exercise strength training program for 8 weeks. Players were blind to their intended intervention during the trial, and also the instructor delivering the interventions was blind to the players' intended intervention (neither the players nor the instructors can know about the applied treatment).

For the two groups, certified professional instructors (one man, one woman) with a background in PFP management and 7 years of experience handling handball players conducted each exercise training session three times a week on two non-consecutive days (Saturday, Monday and Wednesday) in the preseason during the morning. In addition, both groups performed face-to-face sessions consisting of 45-60 minutes of exercises, cooling and a warm-up phase. The training sessions were offered in Iran (Heaven Gym, Tehran), and the instructors trained the athletes individually.

In G1, players have been given variously sized EMS suits made of silicone conductive pad and wireless materials (Germany, vision body Powersuit pro system, the material of spandex/cotton/silver fiber) (Figure 1A). Moreover,

Bluetooth was used to control the electrical strength of the suit.

The EMS suit is equipped with 20 conductive panels located on the arms (4 panels), chest (2 panels), back (6 panels), abdomen (2 panels), buttocks (2 panels), and legs (4 panels) to stimulate the muscle belly of brachialis, triceps of the arm, pectoralis major, latissimus dorsi, rectus abdominis, gluteus maximus, rectus femoris, biceps of thigh and semitendinosus.

The whole body EMS was used according to the aim of the present study because disability, knee kinematics and lower extremity performance of handball players were important (Hewett, Briem, & Bahr, 2007). In addition, the EMS suit has benefits versus single muscle EMS; for example, EMS is suggested to activate the whole body, stabilize, and improve motor control, thus increasing the players' performance. In the context of the difference between wireless vs. wired EMS: first, wireless makes it simple to use an EMS via Bluetooth device on the go (freedom of movement), allowing participants to work out almost anywhere; second, multiple people can utilize wireless EMS devices with various channels at the same time (Filipovic et al., 2016; Hoffmann et al., 2014).

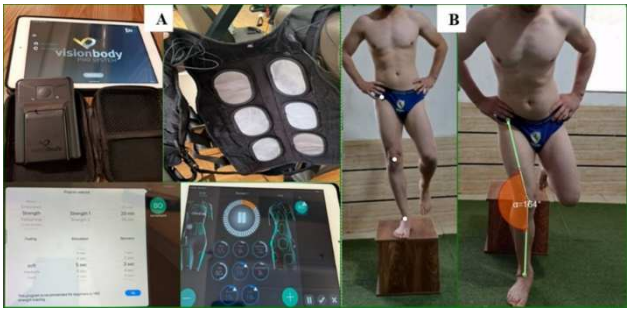

Figure 1. A) Electrical muscle stimulation vision body pro made in Germany, B) KVA with Kinvoa tools.

In G1, the selected frequency was in the automatic range of 70-100 Hz, the impulse width at soft grade, pulse duration of 3 s, and recovery time of 1 s (Kostrzewa-Nowak et al., 2015). The impulse rise is a rectangular application and variable electrostimulation intensities relative to the maximum peak voltage (Kostrzewa-Nowak et al., 2015). This study used 1 maximal tolerance (MT) as the maximum peak voltage, similar to calculating the maximal voluntary contraction as one maximal repetition. Each 1 MT of the upper and lower body was measured and stored in Bluetooth, and the intensity was adjusted for each individual during training. To prevent the patients from being surprised or uncomfortable with the electrical stimulus, the 1 MT level was gradually increased while providing a low stimulation current (Park, Na, Choi, Seon, & Do, 2021). The electric stimulation was stopped at players' requests when reaching an unbearable level on the RPE scale (Jee, 2018). The intensity of the electrical workout was different from 1 MT. Both G1 and G2 were assigned 60% of 1 MT from the baseline to week 2, 70% of 1 MT from week 3 to week 5, and 80% of 1 MT from week 6 to week 8.

For both groups, high-intensity strength training was based on the rating perceived exertion (RPE) scale of a range between 12 to 15 arbitrary units (AU) (Borg, 1982). The RPE ranged from a minimum of six (meaning "no exertion at all" and a maximum of 20 AU (meaning "maximal exertion") (Borg, 1982).

The protocol of exercises was developed following the existing evidence in the treatment of PFP (Emamvirdi et al., 2019; Filipovic et al., 2016; Valli, Boldrini, Bianchedi, Brizzi, & Miserocchi, 2002) and adapted to handball players for this RCT. The characteristics of the training program are reported in Table 1.

Table 1.
Exercises for G1 and G2 following evidence on PFP.

Weeks	Set	R/S	Exercises			
1-2 Weeks	3	10	 Leg extension	 Squat	 Bridge	 Hamstring curl
Description			First, the chair was adjusted to fit the players, then the players were asked to do the exercise on the whole range, the initial angle of the knee at the beginning of the movement is 90 degrees.	For this exercise, the players spreads her legs shoulder-width apart and begins to squat, so that the amount of bending of the knee should not exceed 90, and the direction of the patella should not extend beyond the tip of the toe.	The players first assumes a supine position, then begins to move so that the thighs, hips and trunk should be in line in the last step.	At the beginning of this exercise, first, the chair was adjusted according to the player, the initial angle of the knee was adjusted to 135 degrees at the beginning of the movement, then the players were asked to perform the exercise.

3-4 Weeks	3	10			 	 
			Squat with resistance band	Single leg bridge	Side-lying hip abduction	Supine hip adduction
Description			In addition to squatting, this exercise is also performed by hip abduction exercise with a resistance band, so that the abduction movement is performed in the lowering phase.	In this exercise, the players performs this exercise with her/his dominant leg.	First, the players assumes a side position and then begins to lift the leg away from the body.	In supine position, the players begin to move hip adduction. Note: The leg is not on the ground.
5-6 Weeks	4	15	 	 	 	 
			Standing hip adduction with band	Bridge on bosu ball	Bridge with squeeze the ball	Standing hip abduction
Description			The players stand on one leg and with the other leg perform the exercise of adduction hip, in this exercise band is used.	This exercise is done with the help of Bosu ball, the player puts the heels of her/ his feet on the ball and starts moving the bridge, the final phase of this table exercise is like a bridge.	This exercise is done with the help of medicine ball, then the bridge starts to move, in all phases of the exercise, the players press the ball so that the ball does not fall.	When standing on one leg, the other players begin to move the abduction hip.
7-8 Weeks	5	15	 	 	 	 
			Long stride lunges	Side lunges exercise	Squat jump	Modified single-leg squat with resistance band
Description			In this exercise, players in the lounge start to move so that the length of the steps in this exercise is such that the front knee is bent 90 degrees.	The players start moving the lounge from the side so that the length of the steps in this exercise is such that the guide knee is bent 90 degrees.	The players assume the squat position, performing this exercise in the ascending phase with the jump.	Modified forward lunge with elastic around the knee that is ahead (constant muscle activation of abductors and lateral rotators of the hip and training of motor control during the execution of the activity, performed on stable terrain).

Legend: S = Second, R = Repetition.

Outcomes

Primary and secondary outcomes were tested on all players and assessed at baseline (pre-test) and 8 weeks after training (post-test). Before the tests, players performed a standardized 5-minute warm-up which consisted of double leg squats (2 sets of 8 repetitions), double leg maximum jumps (2 sets of 5 repetitions), calf-stretching with a straight and bent knee (Mohammadi Nia Samakosh, Brito, Shojaedin, Hadadnezhad, & Oliveira, 2022).

Primary outcomes

- *Visual Analog Scale (VAS)* measured the players' pain severity during squatting trials. VAS consists of a 10 cm horizontal strip starting from 0 (meaning no pain) to 10 (meaning the most severe pain possible). This is one of the most reliable quantitative scales for musculoskeletal literature (Scrimshaw & Maher, 2001).

- *Disability* was assessed using the Iranian version of the Kujala Patellofemoral Score, which consists of 13 items (Kujala et al., 1993). These items request information about the perception of pain during walking up and down stairs, squatting, running, jumping, or prolonged sitting with the knee in flexion; if there is limping, swelling, or subluxation of the patella; the amount of hypotropia in the quadriceps muscle, flexion deficiency, pain, and whether there is a need for a walking aid. The total score ranged from 0% (meaning more disability) to 100% (meaning less disability) (Negahban et al., 2012).

Secondary outcomes

- *Single-Leg Landing (SLL) Task (Kinematic)* asked players to perform a 3 unilateral hop landing task. After the participants were comfortable with the task, 3 familiarization SLL on the dominant leg were performed. The hop landing task involved the subject hopping off a 30 cm high box, landing with the same leg onto a mark 30 cm from the bench and holding the position on landing for 3 s (Herrington, 2014). A two-dimensional method was used to analyze the kinematics of the knee. The two-dimensional frontal projection plane angles (FPPA) of knee valgus alignment were measured (Dingenen et al., 2015; Herrington, 2014). A digital video camera (Canon Powershot SX620HS) with a capability of 50 frames per second was placed at the height of the subject's knee, 3 m anterior to the subject's landing target, and aligned perpendicular to the frontal plane (Dingenen et al., 2015). The digital images were imported into a digitizing software program (Kinovea) (Sañudo, Rueda, Pozo-Cruz, De Hoyo, & Carrasco, 2016) (Figure 1.B). The videos were coded. The angle subtended between the lines formed between the markers at the anterior superior iliac spine and middle of the tibiofemoral joint and that formed from the markers on the middle of the tibiofemoral joint to the middle of the ankle mortise was recorded as the valgus angle of the knee. The three markers were placed on all players by the same individual. The angle was captured at the point corresponding to the lowest point of the landing descent phase (Valli et al., 2002). The same individual digitized all the data from all subjects. The average FPPA angle value from three trials was used for analysis (Herrington, 2014); The rest time was 60 s between three attempts, and the rest time was 120 s between this test and the next test (Single Leg Hop (SLH)).

- *Single Leg Hop Test* consisted of performing one unilateral hop while achieving the farthest distance possible and landing on the same foot for at least 3 s. Again, hand movements could be used to maintain balance. After performing 2 or 3 attempts, the participant performed a single leg hop twice for the dominant leg, and the total distance traveled was recorded. This test used a narrow measuring tape of 6 meters (Swearingen et al., 2011).

Statistical Analysis

The Shapiro–Wilk test and Levene's tests confirmed the normality and homogeneity of the dependent variables, respectively. Then, a 2×2 ANOVA (treatment group versus time) with Bonferroni correction post hoc was conducted with a mixed model analysis design. Mean and standard deviation (SD) were used to characterize all variables. The percentage of change and effect size (ES) with 95% CI was used for between-group comparison. A p-value < 0.05 was used to determine significant results, while Partial Eta Squared (hp^2) values were calculated as ES, which was considered as 0.2 = small effect, 0.5 = moderate effect, and 0.8 = large effect based on the study of Cohen (Keselman et al., 1998). Data was analyzed through IBM SPSS Statistics for Windows (version 26, IBM Corp., Armonk, NY, USA).

Table 2.
Anthropometric data (mean ± standard deviation).

Variable	Sex	G1 (N= 22, F= 10, M=12)	G2 (N= 20, F= 12, M=10)	p-value
Age (yr)	Female	25.20 ± 2.16	25.66 ± 3.05	0.70
	Male	25.33 ± 2.18	25.00 ± 2.61	0.76
	Total	25.27 ± 2.33	25.40 ± 2.83	0.87
Height (m)	Female	1.67 ± 0.04	1.64 ± 0.06	0.13
	Male	1.80 ± 0.05	1.79 ± 0.05	0.79
	Total	1.74 ± 0.08	1.70 ± 0.09	0.12
Weight (kg)	Female	61.20 ± 3.32	56.86 ± 6.52	0.07
	Male	71.33 ± 4.81	75.00 ± 3.02	0.07
	Total	66.72 ± 6.59	64.10 ± 10.55	0.33
BMI ($kg.m^{-2}$)	Female	21.70 ± 0.61	21.09 ± 1.79	0.32
	Male	21.89 ± 0.46	23.25 ± 1.57	0.06
	Total	21.80 ± 0.53	21.96 ± 1.99	0.72
Pain Duration (month)	Female	13.10 ± 1.01	12.83 ± 1.19	0.59
	Male	13.25 ± 0.96	13.87 ± 1.35	0.24
	Total	13.18 ± 1.00	13.25 ± 1.32	0.85
EE (yr)	Female	4.60 ± 1.07	4.83 ± 0.83	0.97
	Male	4.58 ± 1.16	4.62 ± 1.18	0.64
	Total	4.59 ± 1.09	4.75 ± 0.96	0.40

N; Number. F; Female. M; Male, BMI; Body mass index, EE; Exercise Experience; G1; group 1 - Exercise with EMS, G2; group 2 - Exercise without EMS.

RCT and Ethics

Before starting the study, a clinical trial registry (UMIN000047921, https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000054632 was made,

and ethical approval was obtained by the Ethics Committee of the Polytechnic Institute of Santarém (N°6-2022ESDRM).

Results

Participants' characteristics

All 44 participants participated in this RCT's phases (e.g., allocation, follow-up), thus permitting data analysis (Figure 2). Table 2 lists the general characteristics of the players while comparing both groups.

Outcomes

Table 3 presents the analysis of the variance with a 2×2 ANOVA (treatment group × time) that showed significant group interactions over time and group for all variables ($p < 0.05$) while interaction time x group denoted no differences.

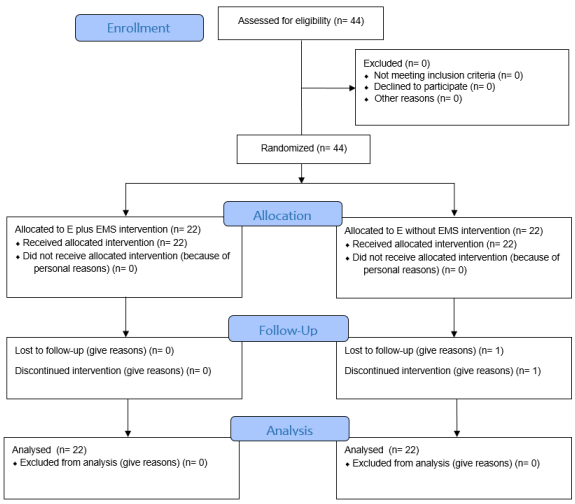

Figure 2. CONSORT flow diagram of the study

Table 3.
Baseline and post-test comparisons between groups.

Variables	Group	Baseline Mean ± SD	Post-test Mean ± SD	Δ Pre-Post	ES 95 % CI	Main effect :Time			Main effect :Group			Interaction :Time × Group		
						F	p	ηp^2	F	p	ηp^2	F	p	ηp^2
VAS (AU)	G1	4.95 ± 0.72	1.81 ± 0.58	↓ 63.43	2.24 (1.49 – 2.99)	449.89	<0.001 *	0.92	10.03	<0.001*	0.20	5.74	0.021*	0.13
	G2	4.85 ± 0.67	2.35 ± 0.48	↓ 51.54	3.99 (3.65 – 6.08)									
Disability (AU)	G1	66.54 ± 5.74	88.22 ± 2.74	↑ 32.58	-5.08 (-6.56 – -4.08)	4.76	0.042*	0.20	207.42	<0.001*	0.91	20.86	<0.001 *	0.52
	G2	68. 55 ± 5.31	81.15 ± 4.83	↑ 18.38	-2.98 (-3.87 – -2.09)									
KVA (de)	G1	166.45 ± 4.02	173.39 ± 3.29	↑ 4.16	-2.42 (-2.39 – -0.89)	69.35	<0.001 *	0.63	4.90	0.033*	0.11	6.38	0.016*	0.14
	G2	167.37 ± 3.47	171.07 ± 3.48	↑ 2.21	-1.09 (-1.76 – -0.43)									
SLH (cm)	G1	157.63 ± 22.14	177.00 ± 18.63	↑ 12.28	-1.22 (-1.86 – - 0.58)	83.18	<0.001 *	0.68	4.42	0.042*	0.10	10.12	0.003*	0.20
	G2	155.25 ± 18.92	164.60 ± 19.59	↑ 6.02	-0.5 (-1.13 – 0.13)									

Δ; percent change (↓decrease, ↑increase), ηp^2; partial eta squared (effect size). VAS; scores range from 0 ("no pain") to 10 ("high pain"); KVA, Knee Valgus angle, AU; Arbitrary Units, de; degree; SLH; Single Leg Hop Test, cm; centimeter, ES; Effect Size, CI; confidence interval. * Significant differences ($p \leq 0.05$) group 1 (G1 - Exercise with EMS) versus between group 2 (G2 - Exercise without EMS)

Overall, both groups had significant improvements between baseline and after eight weeks. Figure 3 shows VAS and disability results between groups and between pre versus post-tests. Figure 4 compares the same variables between the sexes.

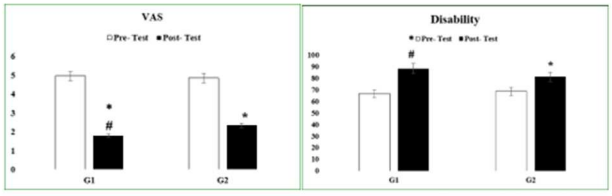

Figure 3. Pre- to post-test of VAS scores (range from 0, "no pain" to 10, "high pain") and disability. * denotes the difference between pre to post-test ($p < 0.05$). # denotes the difference between G1 versus G2 ($p < 0.05$)

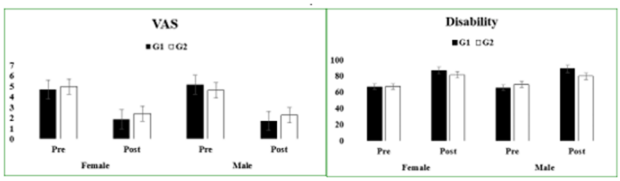

Figure 4. Pre- to post-test VAS and disability scores in two groups - G1 versus G2 and difference between females and males.

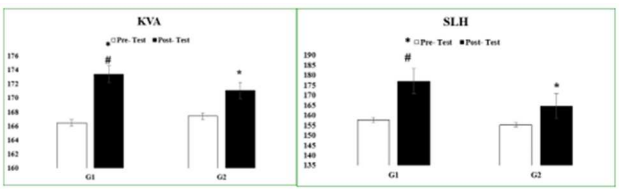

Figure 5. Pre- to post-test of KVA and SLH. * denotes the difference between pre to post-test ($p<0.05$). # denotes the difference between G1 versus G2 ($p < 0.05$).

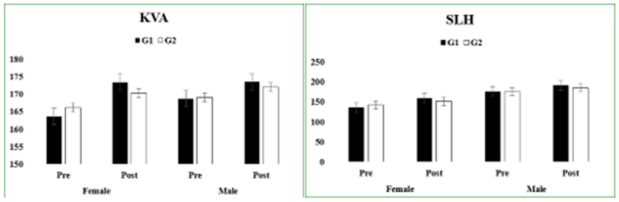

Figure 6. Pre- to post-test of KVA and SLH in two groups – G1 versus G2 and difference between female and male. KVA, SLH.

Figure 5 shows KVA and SLH results between groups and between pre versus post-tests. Figure 6 displays the comparisons for the same variables between the sexes.

Discussion

The main findings showed significant effects of both interventions after 8 weeks. Also, the comparison of the two exercise programs showed a greater effect for G1 when compared with G2 on pain (VAS, mean difference: -1.54 points), disability (Kujala Patellofemoral Score, mean difference: 7.07 points), knee valgus (KVA, mean difference: 2.32 degree), and lower extremity performance (SLH, mean difference: 12.40 cm).

Effect on the pain and disability

Our study results agreed with previous evidence reporting pain and disability improvements with exercise without EMS (Bily, Trimmel, Mödlin, Kaider, & Kern, 2008; Emamvirdi et al., 2019; Frye, Ramey, & Hart, 2012; Prieto-García, Cortés-Reyes, Lara-Cotacio, & Rodríguez-Corredor, 2021; Stensdotter, Hodges, Mellor, Sundelin, & Häger-Ross, 2003). Stensdotter et al. pointed out the effects of open and closed-chain exercises on muscle activity and pain reduction in PFP (Stensdotter et al., 2003). Prieto-García et al. also showed the effects of two types of strength training depending on reducing pain in PFP (Prieto-García et al., 2021). Opposite to our results, Bily et al. showed the effects of 12 weeks of exercise alone and with EMS to reduce pain in PFPs, but no significant effect was found by adding EMS (Bily et al., 2008). This difference could be due to the different devices adopted (e.g., N607 EMS vs Vision Body system), intervention characteristics (e.g., the stimulation protocol was only applied to the knee extensors) and sample involved (e.g., participants with bilateral PFP) (Bily et al., 2008). Thus, we need more studies using the same EMS devices and including larger sample sizes to confirm our results.

Dolak et al. examined the effects of strength exercise on the hip muscles and quadriceps in women with PFP (Dolak et al., 2011). After 8 weeks of training, a significant reduction in pain (VAS) was found regardless of the intervention (the hip group decreased the VAS from 4.6 to 2.4, while the quadriceps group decreased the VAS from 4.2 to 2.6) (Dolak et al., 2011). Khayambashi et al. demonstrated that both hip and quadriceps muscle strengthening exercises on pain and function in women with PFP (Khayambashi, Mohammadkhani, Ghaznavi, Lyle, & Powers, 2012). The training was created by combining hip abduction and the external rotation of the hip with a resistance band on both sides of the body (Khayambashi et al., 2012). After 8 weeks of training, the results showed a pain reduction of 82%, thus suggesting exercises had a greater effect on the external rotator muscles and hip flexors than on the quadriceps muscles alone (Khayambashi et al., 2012). Thus, applying for an exercise program to improve strength and knee alignment generally can contribute to pain reduction (Rixe et al., 2013; Valli et al., 2002). A possible reason for the effectiveness of exercises with EMS could be that electrical stimulation of the vastus medialis oblique muscle improves patellar alignment, reducing knee pain (Bily et al., 2008). Another reason is that EMS could improve body awareness and motor control, thus indirectly influencing patients' symptoms (Rixe et al., 2013).

Effects on the KVA

In our study, EMS may also improve KVA by electrically stimulating the gluteus medius and maximus muscles as well as hip external rotators in the SLH task, which may be due to the use of selected exercises in our study. Since, internal rotation of the femur may be caused due to weakness of the extensor muscles and external rotators of the hip joint, foot inversion or excessive sole flatness (Parikh, Baxi, & Padavan, 2013). The fact that the present study contributed to improvements in KVA for both protocols implies the speculation of improvements in strength, although strength was not assessed. Thus, functional movement pattern improvement and a reduction of the KVA were shown by adding EMS to the exercise training programs. Along the same line, SLL test revealed positive changes after eight training weeks. In addition, group versus interaction analysis supported the efficacy of G1 over G2. Therefore, it seems that adding EMS to exercise training could represent a suitable strategy to control KVA in PFP.

Effect on the performance

Our results agree with previous findings on the field (de Marche Baldon et al., 2014; Talbot, Solomon, Webb, Morrell, & Metter, 2020; Wirtz et al., 2019), which support positive improvements in the strength of lower limbs and jump ability. For instance, Talbot et al. (Talbot et al., 2020) found EMS combined with a home exercise program for the military with PFP groups caused greater improvements in the strength of lower limbs (knee extension and flexion). Furthermore, Wiertz et al. (Wirtz et al., 2019) concluded that EMS training affected performance, speed, and jumping performance in moderately trained athletes. Likewise, Baldon et al. concluded that plyometric training (without EMS) affected female athletes' biomechanics and jumping performance (de Marche Baldon et al., 2014), which was in line with our study. Furthermore, in the present study, the significant

group × interaction analysis of the SLL supports the effectiveness of G1 over G2. Therefore, exercise strength training with EMS represents an option for treatment to increase the SLH test in PFP.

Limitations and future directions

The current investigation presents some limitations. Firstly, the study protocol was retrospectively registered which consequently may have been added (Harriman & Patel, 2016). Nonetheless, the present RCT was conducted following the CONSORT (Moher, 2010; Schulz Kenneth & Altman Douglas, 2010), and REPORT-PFP CHECKLIST 2021 (Barton, 2021) guidelines to improve its overall methodological quality. Secondly, even though we adopted a high-intensity strength training protocol following recent evidence on PFP (Beckwée, Bautmans, Scheerlinck, & Vaes, 2015; Emamvirdi et al., 2019; Valli et al., 2002); it was only performed for 8 weeks in a specific population of handball athletes, which avoids generalizations to other sports, non-athletic populations or individuals with longer symptoms duration and larger sample size (Cobos et al., 2010; Hott, Brox, Pripp, Juel, & Liavaag, 2020; Lankhorst et al., 2016). Moreover, other high-intensity strength exercise approaches (e.g. eccentric exercise focus with a tempo of 4 seconds (Suarez et al., 2023) or its combination with EMS) could also provide additional benefits and thus, they should be tested in future research. Thirdly, this study did not assess the intervention effects using a longer follow-up and including other reliable and validated outcome measures (e.g., global rating of change, self-efficacy, pain-related fear, and pain catastrophizing), which should be implemented for future multicentric RCT (Crossley, Bennell, Cowan, & Green, 2004). Fourthly, our study showed a statistical significance for the outcomes analyzed that does not necessarily reflect their clinical relevance in the population of handball players with PFP (Sainani, 2012). Accordingly, future studies should investigate outcomes considering their minimal clinically important differences or minimal clinical detachable changes (Esculier, Roy, & Bouyer, 2013). Fifthly, when compared with a 2-dimensional, a 3-dimensional assessment with a higher frequency rate of the video camera used (Hott et al., 2020; Munro, Herrington, & Carolan, 2012; Shibayama et al., 2013) would deliver a more accurate and reliable kinematic image of the KVA measurement that should be considered in future analysis. Lastly, although EMS intended to produce muscle strength effects, we did not assess the change in muscle strength and neuromuscular activation (e.g., using EMG), thus offering the opportunity for the next investigations. Furthermore, it has been suggested that kinesiophobia is associated with kinematic impairments in people with PFP, while knee strength is not (Oliveira-Silva, 2019). Thus, future studies could consider analyzing if EMS could impact psychological variables in PFP. For example, a recent study supports the effectiveness of Pilates training to reduce pain for people with chronic low back pain who also experienced knee pain or discomfort (López Mesa et al., 2024). But no research was found combining Pilates and EMS which could provide additional benefits.

Conclusion

The high-intensity strength training with EMS showed more improvements than the exercise without EMS in relieving pain and disability while increasing kinematic and lower limb performance in professional handball players. Nonetheless, both groups improved all the outcomes. Although both training programs could be applied and feasible to professional handball players with PFP, future studies are needed to confirm the clinical relevance of the findings.

Abbreviations

EMS: Electrical Muscle Stimulation, E: Exercise, G: Group, G1: Exercise plus EMS training, G2: Exercise without EMS training, PFP: Patella Femoral Pain, KVA: Knee Valgus Angle, VAS: Visual Analog Scale, SLL: Single Leg Landing, SLH: Single Leg Hop, RPE: Ratings of Perceived Exertion.

Conflict of Interest

In this study the authors declare that they have no conflicts of interest**.**

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Consent for publication

All figures in the manuscript got permission and consent to be published by all participants.

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Supplementary files

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3,4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5,6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6,7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5,7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	11
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	5-7
Randomisation:			
Sequence generatn	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealmt mechanim	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5,6
	11b	If relevant, description of the similarity of interventions	7-10
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10,21
	13b	For each group, losses and exclusions after randomisation, together with reasons	21
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	19
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	20
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	20
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	20
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	20
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-14
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	9,10
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA

REPORT-PFP CHECKLIST 2021

Checklist of strongly recommended and recommended items for quantitative patellofemoral pain studies

Section 1 – Items Strongly Recommended (Essential)		Reported on page # or N/A
Demographics		
1	Sex or gender of the participants	Page 5
2	Age of the participants	Page 5
Baseline symptoms		
3	Symptom duration	Table 2
4	Pain Severity	Table 3
5	Unilateral/bilateral symptoms	Page 5
Outcome measures		
6	Condition specific patient-reported outcome	Pages 13 – 16
7	Pain severity	Table 3
Outcome measure description		
8	Describe assessment in adequate detail to allow replication	Pages 10 – 11
Reporting study results		
9	Mean and standard deviation for parametric data	Table 3
10	Median and interquartile range for non-parametric data	N/A
11	Precision of estimate for all inferential statistics (e.g. 95% confidence interval for between group differences)	Table 3
Section 2 – Items Recommended (encouraged but are not required to meet consensus recommendations)		**Reported on page # or N/A**
Demographics		
12	Anthropometrics (including body mass and height or body mass index)	Table 2
13	Physical activity levels	Page 7
14	Source/setting/location of participants	Page 3, Page 12
15	Ethnicity of the participants	Page 3
Baseline symptoms and previous treatment		
16	Previous treatment	Page 6
17	Pain location(s)	Page 6
18	Aggravating factors	N/A
19	History of knee surgery	Page 6
20	Other symptoms, musculoskeletal symptoms, and comorbidities	Page 6
21	Crepitus	Page 6
22	Pain quality	Page 6
Outcome measures		
23	Physical activity	N/A
24	Global rating of change	N/A
25	Health-related quality of life	Page 11
26	Psychological factors (including self-efficacy, pain-related fear and pain catastrophising)	Page 11
Outcome measure description		
27	Provide measurement properties of assessments	Page 10, 11
28	Provide videos and/or images of assessments	Page 7
Clinical trial methodology		
29	Follow recommendations from EQUATOR Network[2]	N/A
30	Use existing checklists for interventions, including TIDiER; CERT for exercise interventions; and Toigo and Boutellier for resistance training interventions	N/A
31	Provide videos and/or images of treatments	Table 1

N/A = not applicable

CERT = Complete Exercise Reporting Template[1]; EQUATOR = Enhancing the QUAlity and Transparency Of health Research[2]; TIDiER = Template of Intervention Description and Replication[3].