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Combined effect of pulsed electromagnetic field and pulsed ultrasound therapy in treating knee osteoarthritis

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***Abstract*---**Background: Osteoarthritis (OA) is a common disease that affects the knee joint in particular. Exercises, pulsed ultrasound therapy, and pulsed electromagnetic fields are all useful in treating patients with knee OA, however there is controversy in the research about which is more effective in treating patients with knee OA. Purpose: to see if adding PEMF to PUST will help reduce pain, improve function, and increase knee (ROM) in those with knee OA. Materials and Methods: Eighty patients, 45–55 years old, from both genders, had moderate unilateral knee OA. The VAS was used to measure pain, the WOMAC Index was used to assess health status and health outcomes for knee OA patients, the Timed Up and Go test and the 10 meter walk test were used to assess patients' functional mobility, and the Electronic Goniometer was used to examine knee joint ROM. They were put into one of four groups: 1, 2, 3, or 4. PUST plus exercise therapy was given to group (1), PEMF plus exercise treatment was given to group (2), PEMF, PUST plus exercise treatment was given to group (3), and sham PEMF, sham PUST plus exercise treatment was given to group (4). Results: The one-way ANOVA test found no significant differences in the general characteristics of all patients in the four groups, including age, weight, height, and BMI ($p>0.05$), and the Chi-squared test revealed no significant changes in gender distribution across groups (p-value > 0.05). There is a highly significant decrease in knee pain and improvement in ROM and functional performance in patients with moderate knee OA in favor to

Group (3) rather than other groups. However, there was a highly significant difference between group 4 & group 2 in favor to group 2 on ROM, VAS, TUG and 10 m walk test. Also, there was significant improvement in group 1 more than group 4 on TUG test. There was a less improvement in group 4 than other groups. Conclusion: PEMF, PUS, and exercise treatment were all found to be effective modalities for treating knee OA when used simultaneously in the current study. Also, PEMF was more effective than PUST and exercise separately, and so PUST with exercise was more effective than an exercise program alone.

***Keywords*---**Knee Osteoarthritis, Pulsed Electromagnetic Field, Pulsed Ultrasound Therapy, Resistance exercise.

Introduction

The most prevalent kind of arthritis is osteoarthritis (OA), which is also a highly frequent condition among the elderly. OA is more prone to develop in joints that have been regularly strained over time. Knee OA accounts for almost 80% of the overall OA burden in the world. Pain, decreased range of motion (ROM), muscular weakness, difficulties with everyday tasks, and a worse quality of life are all common symptoms [1].

It's particularly inconvenient because it's tough to get out of a chair, climb stairs, kneel, stand, and walk. Pain, along with muscular weakness, increased body sway, and poor balance, puts these people at risk of falling and reduced activity [2]. Oral medication, intra-articular drug injections, and physiotherapy rehabilitation programs are some of the conservative therapies for knee OA that reduce pain and improve joint mobility [3]. The strength of the muscles in the lower extremities is vital for knee loading and joint stability when walking. As a result, most exercise regimens for people with knee OA concentrated on quadriceps muscle strengthening [4]. As a conservative therapy, Pulsed Electromagnetic Fields (PEMF) resulted in considerable improvements in symptoms, discomfort, knee function, and activity level. It is a viable option to existing conservative therapies, with the added benefit of being largely devoid of side effects and well tolerated by patients [5].

Pulsed Ultrasound Therapy (PUST) may be indicated for the treatment of persons with knee osteoarthritis since it considerably reduced pain intensity after the fifth session and maintained it until the intervention was completed [6]. Because there is a controversy in the literature regarding which is more helpful in treating patients with knee OA, Ultrasound Therapy or Pulsed Electromagnetic Fields, the goal of this study was to see how adding PEMF to PUST affected pain, function, and knee (ROM) in patients with knee OA.

Materials and Methods

Study design:

This study was a pretest-posttest randomized controlled trial that took place at Horus University's physical therapy outpatient clinic in New Damietta, Egypt, from November 2021 to April 2022. Ethical permission (No: P.T.REC/012/003446) was acquired prior to data collection, and the study protocol was filed on clinical trials.gov with approval number P.T.REC/012/003446 (NCT05151432).

Participants:

The study included 80 individuals with knee osteoarthritis, both men and women. The sample size was calculated using an effect size of 0.78 (effect size), a significance threshold of 0.05, and a power of 85 percent for the 10-meter test between the four groups. The sample size was determined to be 20 people each group, with a ratio of 1:1:1:1. Based on a prior study [7], the effect size was estimated. At least 25 patients were required for each group, assuming a 20% loss to follow-up. G*POWER statistical software [version 3.1.9.2; Universität Kiel, Germany] was used to calculate sample size. A random number generator (www.randomization.com) was used to randomly assign the patients to one of the four groups. Randomization was done by a research associate not engaged in the study.

Patients were allowed to participate in the trial if they met the following requirements: 1) The American College of Rheumatology defines moderate unilateral knee OA as morning stiffness, crepitus on knee motion, bone soreness, and no perceptible warmth [8]. 2) Age was ranging from (45–55 years old) from both sexes [9]. 3) Their body mass index (BMI) was < 30kg/ m2 [10]. While patients were excluded from the study if they exhibited one of the subsequent criteria: 1) During the six months leading up to the research, they underwent an intra-articular injection of hyaluronic acid or corticoids. 2) They had a skin problem and had undergone orthopedic knee surgery. 3) They experienced cardiovascular disease, such as acute myocardial infarction, or uncontrolled arterial hypertension, as well as acute-phase respiratory disorders, within the past month [6]. Patients who met inclusion criteria were given a detailed information of the study objectives. Patients who allowed to get involved were requested to sign an informed consent form, then inclusion in either groups was revealed to the patients.

Patients in all study groups were evaluated for 1) pain assessment using Visual analog scale (VAS). (2) health status and health outcomes for knee OA evaluated by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), (3) patients' functional mobility evaluated by Timed Up and Go test and the 10 meter walk test. And (4) knee joint ROM evaluated by Digital Goniometer.

Measurement Procedures

1) Visual Analogue Scale (VAS):
Used to measure the pain intensity of each patient in all groups. The patient was instructed to indicate the intensity of the pain by marking a 10 cm line with two extremes. The patient marked on the line the point that they feel represents their perception of their current state [11].

2) The WOMAC questionnaire Arabic version (Appendix I). It was accurately filled before starting treatment sessions. The patient was asked to fill the printed Arabic questionnaire at a quiet place. The patient was informed with the questionnaire sub scales and was asked to fill the physical function subscale which consists of 17 items, pain which consists of 5 items and stiffness which consists of 2 items. All items were evaluated from 0 which mean nothing, 1 means slight, 2 is moderate, 3 is very, and 4 is extreme. All discussions were in Arabic language [12].

3) Timed up and go test:
Timed Up and Go was used to assess patients' functional mobility. TUG is a reliable test for clinical use in individuals with moderate knee OA. The patient was directed to rise from a standard armchair, walk to a 3-meter mark at a safe and comfortable rate, and then return to a sitting posture in the chair, utilizing gait aids and chair armrests as needed to aid with sit to stand. as shown in the image (1). The metric utilized was the time it took to complete the task. With each passing day, their mobility deteriorates. Then came two recorded trials and a practice trial. The average of the two recorded trials was used in the analysis. Each measurement was followed by a 15-second rest interval [7].

Figure 1: Time up and go test

4) The 10 meter walk test

To account for the patient's acceleration and deceleration, he walked for a total of 10 meters without assistance at his regular walk speed, measuring time for 6 meter. It was permissible to utilize assistive technologies, but it was documented and used consistently during each exam. Time started when the toes crossed the 2-meter mark, and was stopped when the toes reach a distance of 8 meters. The average of the three trials was computed. The order was given "you should keep walking at your regular pace until I tell you to stop, as illustrated in the image" (2) [13].

Figure 2: The 10 Meter walk test

5) Digital Goniometer

In the starting position for measuring knee flexion ROM, the patient was Supine and the stationary arm of goniometer fixed toward greater trochanter of the upper thigh with strap, the movable arm fixed toward lateral malleolus of lower leg and the fulcrum on lateral epicondyle of the knee then the patient was asked to flex his knee active. The number appeared on digital screen was subtracted from extension reading as shown in figure (3) [14].

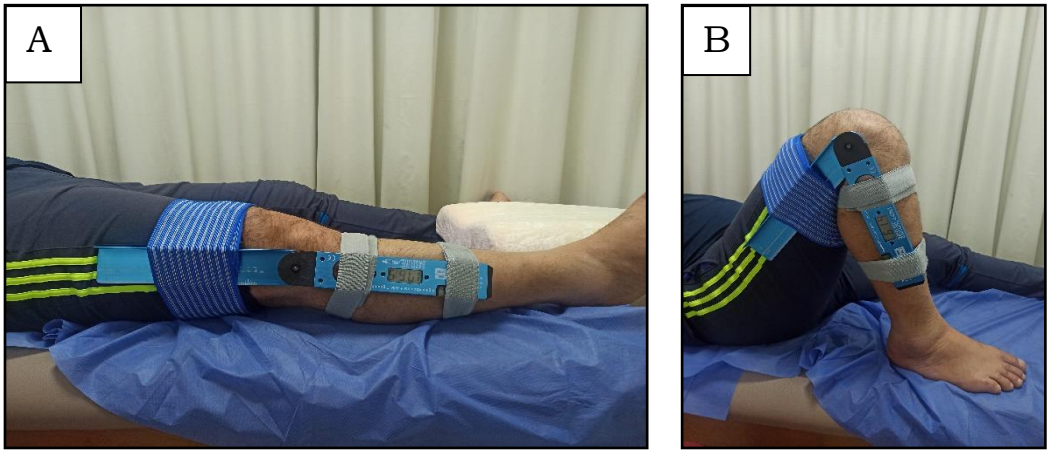

Figure 3: Digital goniometer for measuring knee ROM: (A)starting position, (B) end position

Treatment procedure:
All treatment sessions were done by the same therapist. Group (1): received PUST plus exercise program. Group (2): received PEMF plus exercise program. Group (3): received PUST, PEMF plus exercise program. Group (4): received sham PUST, sham PEMF plus exercise program. Patients in all groups received the treatment program for 3 sessions per week for 4 weeks.

Group (1) and (3) A single physiotherapist administered US treatments to the patients. Active US therapy was delivered with a device 4cm2, 1-MHz US with a sound-head area of effective 4cm, radiating area of 3.5 to a beam non uniformity ratio of cm2. 5:1, and a therapeutic dose of approximately 112.5J/ That is, pulsed US was delivered for 9.5 minutes at a peak intensity of 1W/cm2 at a 20% duty cycle, resulting in a spatial temporal average intensity of 0.2W. These figures are the same as those in the previous report [15]. To increase energy penetration into the joint area, participants were positioned in a supine posture with the afflicted knee bent at 90° and the sound-head held stationary over the tibio-femoral joint medial to the patellar tendon [16].

Figure 4: Ultrasound Therapy application

Group (2) and (3) patients received as illustrated in figure (5), the patient's knee was placed between two plates coil applicators, providing a magnetic field intensity of 1.5 mT and a frequency of 75Hz [17]. Each session lasted 30 minutes. The magnetic field was first generated for 1 second before being interrupted. The first treatment's break was 3 seconds long, and each subsequent treatment's break was 0.5 seconds long. 3 times per week [18].

Figure 5: Electromagnetic Field application

Exercise program for all groups

1. Stretching exercises for the hamstrings and calf muscles while holding the stretching position for 30 seconds with two repetitions for each session as shown in figure (6) [19].

Figure 6: Stretching exercise

2. Isometric quadriceps exercise:
   A rolled up towel was placed beneath the knee of the patient in a supine position. then he/she was told to tense his/her thigh muscles to their maximum strength in order to straighten his/her knee and hold the contraction for 5 seconds as shown in figure (7) [20].

Figure7: Isometric quadriceps exercise

3. Straight leg raising (SLR) exercise:
   The patient was supine, produced maximal quadriceps contraction before the lifting phase of exercise, then started to elevate the leg straight 10 cm above the plinth and hold contraction for ten seconds before returning to place as shown in figure (8) [20].

Figure 8: Straight leg raising (SLR) exercise

4. Isometric hip adduction exercise:
   For five seconds, the patient was asked to execute isometric hip adduction exercises while lying on his back with a small pillow between his legs. He was instructed to hold the position for 5 second as possible, as shown in figure (9) [20].

Figure 9: Isometric hip adduction Exercise

5. Hip abductor strengthening (lateral leg raise):
   The patient lied down on the unaffected side, with ankle weights on the affected limb, then started to raise the upper lower limb upwards for about 30 degrees, hold for 5–10 sec, and slowly lie down as shown in figure (10) [21].

Figure 10: lateral leg raise Exercise

6. Hip extensor strengthening
   His hips were propped up by pillows while he slept on his stomach. Squeezed the buttocks and raised the leg slightly off the bed while keeping the leg straight. The patient did three sets of ten repetitions each, through each session [22].

7. Hip external rotator strengthening
   he patient was seated on the edge of a treatment table. The knee was bent to 90 degrees, and the thigh was stabilized, preventing sagittal and frontal plane hip mobility. A resistance band was attached around the ankle to the pliable leg. Resistance band length was customised for each patient depending on their thigh measurement (distance from anterior superior iliac spine to medial femoral epicondyle). To eliminate slack in the band, the distance between the exercise limb and the penny leg was shortened. The exercise was performed by externally rotating the hip to approximately 30°, as shown in figure (11) [21].

Figure 11: Hip external rotator strengthening Exercise

Statistical Analysis

SPSS version 28 was used for data administration and statistical analysis (IBM, Armonk, New York, United States). The Shapiro-Wilk test and direct data visualization approaches were used to check for normality in quantitative data. Numerical data were reported as means and standard deviations or medians and ranges based on normality tests. One-way ANOVA was used to compare quantitative data between study groups. In the case of overall significance, post-hoc analysis were performed, and all post-hoc analyses were corrected for multiple comparisons. All statistical tests were conducted on a two-sided basis. Significant P values were defined as those less than 0.05.

Results

Patients' demographic and clinical features:

Comparing the general characteristics of the patients of all groups by one-way ANOVA test revealed that there were no significant differences found between groups in the demographic characteristics, including age, weight, height and BMI ($p>0.05$) as shown in Table (1).

Table (1)
Demographic characteristics of patients in all groups

	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m2)
Group 1	52.35 ± 2.05	168.75 ± 1.44	80.25 ± 2.57	27.99 ± 0.84
Group 2	51.45 ± 2.48	168.20 ± 2.46	79.65 ± 2.49	28.09 ± 0.81
Group 3	51.00 ± 2.73	167.50 ± 4.27	79.25 ± 3.72	28.16 ± 0.91
Group 4	52.00 ± 2.27	168.65 ± 3.61	80.20 ± 3.39	28.02 ± 0.83
F-Value	1.23	0.657	0.475	0.159
P-value	0.303	0.581	0.701	0.924

$\bar{x}$: Mean MD: Mean Difference P-Value: Probability value
SD: Standard Deviation f-value: one-way ANOVA test NS: Non-significant

- One-way ANOVA test Revealed that there was no significant difference between groups pretreatment in all measured variables. However, there was a highly significant difference between groups post treatment.
- There was a highly significant difference between group 1 & group 3 in favor to group 3. Also, there was a highly significant difference between group 3 & group 4 in favor to group 3.
- Also, there was a highly significant difference between group 2 & group 3 in favor to group 3. However, there was a highly significant difference between group 2 & group 4 in favor to group 2.

Discussion

The study's findings indicated that individuals with moderate knee discomfort saw a very significant reduction in pain and improvements in ROM and functional performance when they were assigned to Group (3) rather than the other groups. This outcome is consistent with Abdel-aziem et al., (2018) [10] , assessed the consequences of When PEMF was added to a traditional physical program for addressing knee OA, pain alleviation, range of motion, and functional performance improved significantly more than when the traditional physical programme was used alone.

Furthermore, Wagner et al., (2022) [24] based on a preapproved protocol and the guidelines recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, conducted a systematic review of systematic reviews on patients with OA of one or more joints who underwent PEMF therapy alone or in combination with other therapeutic modalities According to the findings, PEMF treatment appears to be effective in the short term in reducing pain and increasing function in people with OA.

Table (2)
Each group's pre-and post-treatment comparison

	Group I (n = 20)	Group II (n = 20)	Group III (n = 20)	Group IV (n = 20)	P-value
Knee flexion ROM					
Pre	115.40 ± 10.28	107.85 ±10.75	113.50 ±11.48	110.95±9.58	0.133
Post	125.10 ± 9.49	122.85 ±12.36	133.10 ±5.80	118.95±11.23	0.00001

% of change	↑8.40 %	↑13.90 %	↑17.26 %	↑7.21 %	
p-value	0.001[3]	0.001[3,4]	0.0001[1,2,4]	0.01[2,3]	
VAS (score)					
Pre	7.10 ±1.28	7.75 ±1.37	7.07 ± 1.51	6.70 ± 1.08	0.325
Post	4.17 ± 1.04	3.72 ± 0.54	2.80 ± 1.28	5.05 ± 1.19	0.00001
% of change	↓41.26 %	↓52 %	↓60.4 %	↓24.6 %	
p-value	0.001[3]	0.001[3,4]	0.0001[1,2,4]	0.01[2,3]	
WOMAC (score)					
Pre	54.25 ±6.65	49.75 ± 5.20	51.25 ±6.75	48.90 ± 9.45	0.192
Post	38.80 ± 11.19	34.95 ± 7.77	27.90 ±4.24	41.15± 16.07	0.00001
% of change	↓28.5 %	↓29.74 %	↓45.56 %	↓15.84 %	
p-value	0.001[3]	0.001[3]	0.0001[1,2,4]	0.01[3]	
TUG (sec)					
Pre	11.51 ±1.29	11.92 ±1.42	11.07 ±1.58	11.58 ±0.84	0.745
Post	7.91 ±0.60	6.86 ±1.60	5.13 ±2.22	9.71 ±1.15	0.00001
% of change	↓31.27 %	↓42.44 %	↓53.65 %	↓16.15 %	
p-value	0.001[3,4]	0.001[3,4]	0.0001[1,2,4]	0.01[1,2,3]	
10 m walk test (m/sec)					
Pre	0.55 ± 0.18	0.56 ± 0.17	0.56 ± 0.17	0.58 ± 0.17	0.745
Post	0.85 ±0.18	0.96 ±0.17	1.30 ±0.18	0.78 ±0.16	0.0001
% of change	↑ 54.54 %	↑ 71.42 %	↑ 132.1 %	↑ 34.48 %	
p-value	0.001[3]	0.001[4]	0.0001[1,4]	0.01[2,3]	

Data were presented mean and SD; * Significant; 1: significantly different from group I; 2: significantly different from group II; 3: significantly different from group III, 4: significantly different from group IV

The findings of this study corroborate the findings of Fischer et al., (2005) [25], who found that PEMF has favorable effects on joint blood flow, resulting in reduced inflammation, improved bone and cartilage healing, and increased joint mobility when used for 8-12 weeks. Nicolakis et al., (2002) [25] also found that PEMF stimulation was safe, reduced impairment in daily activities, and improved knee function in individuals with OA knee discomfort.

In contrast, Vigan et al., (2021) [26] found that pulsed electromagnetic field therapy is no better than other conservative therapies like physiotherapy. Adjuvant PEMF therapy does not improve pain in individuals with knee OA, according to Dündar et al., (2016) [27]. The broad variations in the applied protocols in terms of treatment duration and biophysical parameters are responsible for the unsatisfactory results with PEMF application.

Analysis of research that looked at the results of pulsed ultrasound therapy in treating patients with knee OA and found that they agreed with the findings of their own investigations. Therapeutic ultrasonography, according to Rutjes et al., 2010 [28], may help patients with knee OA with pain reduction and functional rehabilitation.

When compared to the control group, pulsed ultrasound therapy (PUST) is more successful at relieving pain and improving function. Even yet, there is only a

statistically significant difference in pain reduction between the continuous US (CUS) group and the control group for continuous US (CUS). Furthermore, PUST was always more likely to be the chosen mode, regardless of pain level or function at the last follow-up time point. However, indications of heterogeneity and sample size limitations in some research may pose a risk to the results' validity DL et al., (2012) [29]

In group 4, there was a decrease in discomfort, as well as an improvement in knee ROM and functional activity. Improved quadriceps strength is linked to less knee discomfort and impairment, according to O'Reilly et al, 1999[30]. The current study has some limitations, including the fact that it only looked at the short-term impacts of the combined effect of PEMF and PUST and did not look at the long-term consequences.

Conclusion

In the current study it could be concluded that combined effect of PEMF and PUST may be a major strategy and more effective than tradition treatment in reducing pain, improving function and increasing knee range of motion (ROM) in dealing with knee OA patients. Also, PEMF was more effective than PUST and exercise separately, and so PUST with exercise was more effective than an exercise program alone.

Conflict of interest

The authors state that there is no conflict of interest concerning the publication of this paper.

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