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Effect of acupressure on knee osteoarthritis symptoms in the elderly: a double-blind randomized clinical trial

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Abstract

Background: Knee osteoarthritis is known as one of the common causes of disability worldwide. Despite the elderly tendency towards the use of traditional medicine, there is no clear consensus regarding acupressure efficacy to manage symptoms of knee osteoarthritis.

Objective: This study aimed to determine the effect of acupressure on knee osteoarthritis symptoms in the elderly.

Methods: This double-blind randomized clinical trial was performed from February 2017 to July 2018. Ninety-six patients were selected from comprehensive health care centers in Rafsanjan, Iran, according to inclusion criteria and then equally allocated into three groups (acupressure, sham and control) randomly, by the minimization method. The acupressure group received acupressure bilaterally at 6 points in 10 sessions for two minutes for each point in 10-seconds pressure and 2-seconds rest periods. Subjects In the sham group received only touches without any pressure with the same pattern as the acupressure group and the control group received no intervention. The osteoarthritis symptoms were measured before, immediately and one month after intervention on WOMAC scale. Data was analyzed by IBM-SPSS version 22 using Chi-square goodness of fit and repeated measure ANOVA at 0.05 level of significance.

Results: There were no significant differences between-groups regarding demographic characteristics. The mean of WOMAC score were significantly different between the three consecutive measurements (the time effect), ($p=0.001$, effect size = 0.082). But there was no significant difference between-groups (group effect) ($p=0.852$, effect size = 0.003). There was a significant difference in the interaction between time and group ($p=0.001$, effect size = 0.106).

Conclusion: The study showed that acupressure was able to correct the WOMAC and pain scores in long and short term and improve physical function in short term in patients with knee osteoarthritis. Accordingly, acutherapy as an effective approach can be applied in self-care programs for knee osteoarthritis symptom management in the elderly, but in the sham groups, the selection of acupoint positions could be a crucial factor.

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1. Introduction

Knee osteoarthritis is the most common form of arthritis in the elderly, which affects all joint tissues (1). It appears with degeneration of the joint cartilage, pain, stiffness, movement restriction and ultimately, muscle weakness (2, 3). Regardless of age, the incidence of symptomatic osteoarthritis has been reported to be 240 cases per 100,000 people (1). Researchers have estimated that in some Western communities, the proportion of people over 45, with doctor diagnosed knee osteoarthritis, will reach from 13.8% in 2012 to 15.7% by 2032 (4). The prevalence of this disease in Tehran, the capital of Iran, has been reported to be 15.1% (5). Knee osteoarthritis is known as one of the common causes of disability worldwide, which can have a negative impact on physical and psychological well-being (6). The results of studies have shown that in the Eastern Mediterranean region, from 1990 to 2013, the total number of disability-adjusted life years of musculoskeletal disorders had increased to 105.2%, compared to 58% of the rest of the world (7). This disease can affect all aspects of a person's life. It can disturb the sleep pattern through depressed mood and consequently depression (8-10), reduce the quality of life (11, 12) and ultimately lead to exhaustion (13, 14) and increased mortality rates (15, 16).

Today, various methods of surgical, pharmacological and non-pharmacological therapies, or a combination of them, are used to manage symptoms of knee osteoarthritis. Although the role of anti-inflammatory and non-narcotic analgesic drugs are well known in reduction of pain and inflammation, the costs of treatment (17) and the long term side effects of drugs, such as liver toxicity, renal failure, digestive tract toxicity, increased risk of falling, fracture and delirium, (18) and cardiovascular toxicity should not be ignored (19). So that, today, the tendency to use non-pharmacological and complementary therapies to manage the symptoms of diseases is increasing (20), including changes in lifestyle (21, 22), exercise movements (23, 24), acupuncture (25, 26), massage therapy (27), the use of herbal remedies (28), and Ayurveda (29).

Acupressure is a traditional Chinese therapeutic approach and a popular treatment method among Asian people, and of increasing interest by Europeans. In traditional Chinese medicine, the physiological function of the human body is the result of the balance between harmony and opposition or the so-called Yin and Yang, and, in fact energy becomes a vital force that flows continuously through meridians or energy channels (30). In this method, non-invasive pressure is used at acupoints to release endorphins in the brain, which results in muscle relaxation and pain relief and hence, a feeling of comfort (31). Researchers have shown that acupressure can be easily used to manage symptoms of osteoarthritis by the elderly (32).

The literature review reveals that there is controversy regarding the role of acupressure in osteoarthritis symptom management. Some researchers pointed out the positive effects of acupressure on pain relief, modification of physical function (32, 33), as well as the improvement of motor ability and quality of life in elderly suffering from knee osteoarthritis (34), while in other studies, acupuncture or acupressure interventions did not show any significant effect on osteoarthritis symptoms (35, 36). In a review article, researchers reported that although complementary therapies are widely used among patients with osteoarthritis, the effectiveness of these treatments in symptom management and reduction of the disease progression still need to be proven (37). Therefore, the aim of this study was to determine the effect of acupressure on knee osteoarthritis symptoms in the elderly.

2. Material and Methods

2.1. Trial design and participants

This double-blinded clinical trial was performed at comprehensive health care centers from February 2017 to July 2018; aimed at determining the effect of acupressure on knee osteoarthritis symptoms in elderly people in Rafsanjan, Iran. All elderly patients with knee osteoarthritis history who had an e-health record in comprehensive health care centers in Rafsanjan were the target population of the study. Selected patients according to inclusion criteria were allocated into three groups (acupressure, sham and control) randomly. The acupressure group received acupressure in six acupoints. In the sham group, acupressure was performed without the pressure with similar patterns of acupressure groups and at points near acupoints. The control group did not receive any intervention during this period. It should be noted that routine treatment continued in all three groups.

2.2. Selection criteria

2.2.1. Inclusion criteria

The inclusion criteria of the study were as follows: over 60 years old, suffering from knee osteoarthritis according to the American College of Rheumatology (ACR) guidelines for at least three months, no history of acupressure for any purpose, lack of any scars, scratches, and abnormality at acupressure points, having cognitive ability, using no anticoagulants or having no history of coagulation disorder, no history of joint surgery relevant to the disease (such as replacement and joint repair), BMI below 35, having phone numbers for follow-up calls, not having advanced neuropathy, not being addicted, lack of using any narcotic analgesics and herbal medicines influencing on osteoarthritis symptoms, no injection of analgesics into the knee joint, and no arthroscopy within 30 days prior to intervention.

2.2.2. Exclusion criteria

Exclusion criteria included: unwilling to continue in the study, feeling no warmth, heaviness, and swelling, or numbness at acupressure points, and receiving invasive therapies or surgical interventions during the course of intervention and missing even one acupressure session.

2.3. Sample size

The sample size was considered to be approximately 96 (32 for each group) according to literature review (38) and the following formula with a standard deviation of 2.75 and 1.27 at the significance level of 0.05 and power of 90%, and the effect size of 2.5 in terms of the minimum difference in means changes in the groups

$n= 2 (Z_{1-\alpha}+ Z_{1-\beta})^2 (S_1^2 + S_2^2) / d^2$

$n=2 (1.96 + 1.28)^2 (1.27^2 + 2.75^2) / 2.5^2=30.78$

2.4. Randomization and blindness

In this randomized control trial, 96 patients were assigned into three groups. The samples were allocated into acupressure, sham and control groups based on the gender categorizes, using the minimization method (39), so that, the first patient entered into the classes of the groups in a simple random way and the rest, based on the total number of samples per class, such that, the total number of samples in each category was equal. Sampling continued until the required sample size was reached. In order to minimize the effect of bias, the study was conducted as a double-blind study; thus, neither the samples nor the individual who completed the questionnaires knew how individuals were assigned to each group.

2.5. Outcome

The main outcome was the standard scale of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, and pain, stiffness and physical function scores of knee joint as the subscales of WOMAC.

2.6. Intervention and measurements

After the project approval by the Deputy of Research and Technology of Rafsanjan University of Medical Sciences and obtaining a license, one of the researchers attended with a presentation at the comprehensive health centers of Rafsanjan. After studying the health records of elderly patients in an integrated health records system, a preliminary list of elderly patients who had knee osteoarthritis history was prepared, then further information about the patients' history of osteoarthritis was obtained through phone calls. In cases of patients who had history of the disease, the purpose of the study was explained to them, and if they had consented to participate in the research, and met the inclusion criteria, were invited to attend the center. After attending the center, they were referred to a general practitioner, and if the knee osteoarthritis diagnosis was approved, based on the American College of Rheumatology (ACR), they were included in the study. The eligible patients were asked to sign the written informed consent. Demographic data including age, sex, level of education, duration of the disease, type of drugs (oral or injectable) were collected using a researcher-designed questionnaire by face-to-face interview. Before intervention, the WOMAC scale was measured for all study subjects. In all groups, routine treatments continued. In the intervention group, in addition to the usual treatments, the acupressure treatment was performed on even days (Saturday-Monday-Wednesday and Friday) for 10 consecutive sessions by one of the researchers who had received adequate training and valid certification on administration of acupressure intervention from a traditional medicine specialist. The acupressure was applied bilaterally at points of LI4, SP10, SP9, GB34, ST36, ST34 respectively for 2 minutes at intervals of 10 seconds of pressure and 2 seconds of rest (in total ten times at each point per session). The applied pressure was such that the patient felt warmth, pressure and mild pain at the point. For the sham group, along with usual treatments, acupressure was performed without the pressure, but was similar to patterns of the acupressure

group and near to acupoints (2 to 3 cm around the acupressure points) and the control group did not receive any treatment during this period.

The acupressure points' selection was based on the literature review and the common points that were considered in treatment of knee joint problems. The Li4 or Hegu pressure point is located on the back of the hand, in the middle of the angle between bones of the forefinger and thumb. The ST36 point is just under the knee joint and on the shinbone. The GB-34 is located on the lateral aspect of the leg in the space made below the head of the fibula. The St34 pressure point is in front of the thigh and is located between the rectus femoralis and vastus lateralis muscles and above the patella. The Sp9 point is located on the lower border of the medial condyle of the tibia, somewhere between the posterior border of the tibia and the gastrocnemius muscle. When the knee is bent, the Sp9 point can be found in the hollow under the medial condyle at the lower end of the shinbone (tibia). The Sp10 point is located 5 cm proximal to the medial superior border of the patella.

For all participants in this study, WOMAC scale was measured before, immediately, and one month after the intervention through face-to-face interview by someone other than the therapist who was blinded to group allocations. The WOMAC index is used to assess patients with hip and knee joint arthritis, and it consists of 24 questions and three subscales of pain, stiffness, and physical function with 5, 2, and 17 questions, respectively. In this study, a 5-point Likert scale with 0-4 numbering was used. For WOMAC index, the minimum score obtained was 0 and the maximum score was 96. For pain index, the minimum score was 0 and the maximum score was 20; for stiffness index, the minimum score was 0 and the maximum was 8; and finally for the physical function index, the minimum score was 0 and the maximum was 68 (40). The Persian version of WOMAC scale is a valid and reliable patient-reported clinical instrument for knee osteoarthritis, with a Cronbach's alpha of 0.917 and the average measure for Interclass Correlation Coefficient was shown to be 0.964 (41). The global WOMAC score reliability was shown as 0.68 for the Likert version and 0.64 (Kendall's tau c) for the VAS version (40).

2.7. Statistical analysis

Data were analyzed by SPSS software version 22 using descriptive statistic, Chi-Square goodness of fit test (to compare ratios) and repeated measure ANOVA to compare the mean change of WOMAC scores and its subscales at consecutive measurements in the three groups. The statistical modeling was used to test the time-by-time interaction between times and groups at a significance level of 0.05. In order to reduce the effect of gender and time of measurement as confounding factors, at the time of sampling, the groups were matched for gender categories and all of measurements were done at the same time.

2.8. Research ethics

This trial was approved in the Clinical Trial Registration System of Iran with the code: IRCT20180114038366N1, and the code of ethics was obtained from the ethics committee of Rafsanjan University of Medical Sciences (Ref: IR.RUMS.REC.1396.121). Moreover, as noted, the ethics of research in the study was considered by the researchers, such as: Voluntarily participation of the subjects in the study and freedom to withdraw from the study at any time, providing a written informed consent form to the participate before entering the study and furthermore, in order to ensure that there was no harm in the routine treatment of participants in the study, all the therapies were respected and all conditions that could affect osteoarthritis symptoms were emphasized and monitored. The study did not result in any financial, spiritual or physical harm to the participants.

3. Results

From total of 212 patients with diagnosis of knee osteoarthritis assessed for eligibility, 96 patients who met the inclusion criteria entered the study. About 116 patients excluded because of meeting the exclusion criteria (105 patients) or declining to participate in the study (11 patients). The sampling details were explained in the consort flow diagram (Figure 1). The results of the data analysis indicated that the mean and standard deviation of the sample's age was 70.28±7.690 with a minimum of 60 and a maximum of 90 years. There were no significant difference between the three groups regarding demographic characteristics such as age, gender, occupation, type of drug, body mass index, and duration of the disease. The groups were consistent in these variables (Table 1). To examine the changes of the WOMAC score during consecutive measurement times (time effect) and among the study groups (group effect) over the time and taking into account the effect of the groups considering the time of measurements (interaction between time and group), repeated measure ANOVA was used. The results of Mauchly's Sphericity test showed that the correlation coefficients of the consecutive measurements were not significantly different (p=0.420). Therefore, the assumption for the correlation equation was accepted; consequently, the

Sphericity was used to report p-value. In the examination of the interaction between time and group, the results of Multivariate Bonferroni test showed a statistically significant difference (p=0.001, effect size = 0.106) (Table 2). Moreover, the mean score of WOMAC was statistically different at three consecutive measurements (the time effect) (p=0.001, effect size = 0.082). The between-subject effect test used for the comparison of WOMAC mean scores between the groups (group effect) and the results did not show a significant difference (p=0.852, effect size = 0.003).

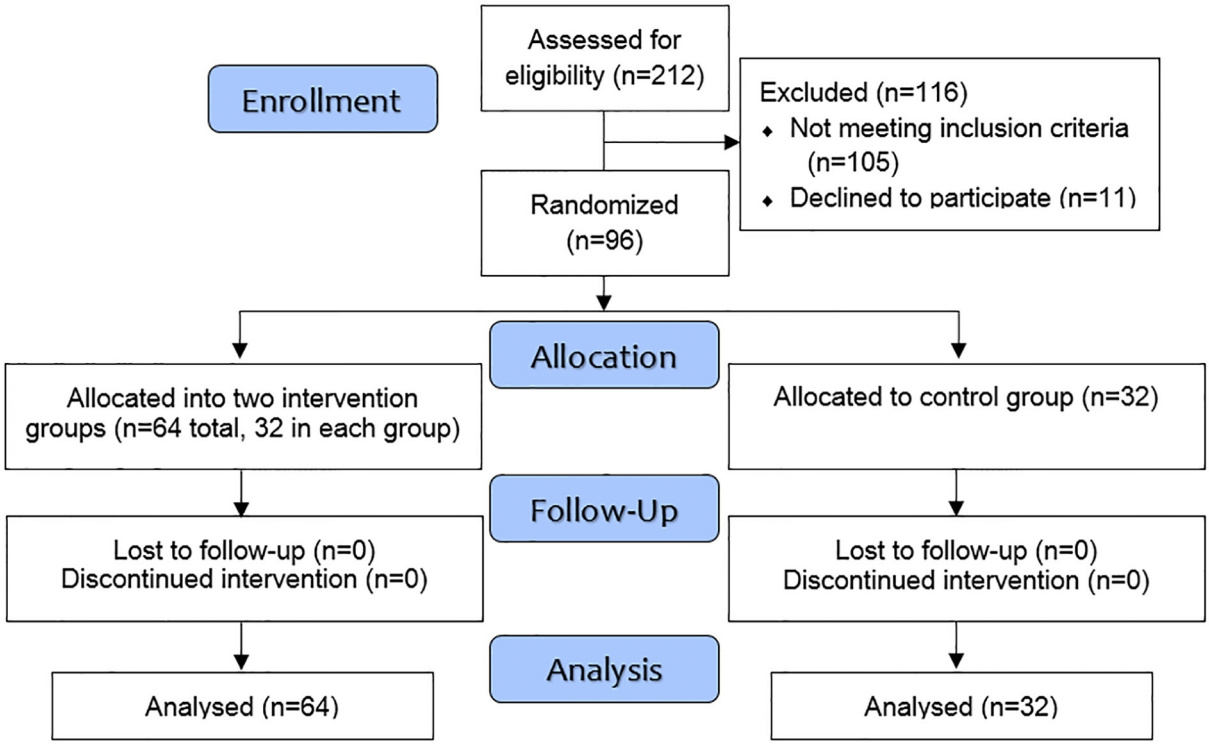

Figure 1. Study flowchart based on CONSORT 2010

Table 1. Comparison of demographic characteristics of the studied groups

Variables		Acupressure	Sham	Control	p-value
Gender, n (%)	Male	8 (8.3)	15 (15.6)	8 (8.3)	0.810*
	Female	24 (25)	22 (22.9)	22 (22.9)	
Job, n (%)	Employed	12 (12.5)	18 (18.8)	13 (13.5)	0.271*
	Unemployed	20 (20.8)	19(19.8)	14 (14.6)	
BMI	Normal	14 (14.6)	22 (22.9)	18 (18.8)	0.069*
	Overweight & Fat	18 (18.8)	18 (18.8)	10 (10.4)	
Drug, n (%)	Oral	19 (19.7)	17 (17.7)	18 (18.7)	0.881*
	Injection	13 (13.8)	15 (15.6)	14 (14.9)	
Age (year), Mean±SD		69.53±7.02	71.22±9.13	70.09±6.84	0.675**
Disease duration (year), Mean±SD		8.97±4.97	9.27±5.21	8.6±5.17	0.871**

* Chi-square test, ** ANOVA

Statistical modeling was used to study the details of interaction between time and group and to study closely the changes in WOMAC score in different groups in different times and their interactions. In within-group pairwise comparison of the changes in WOMAC score at consecutive measurement, the results showed that in the acupressure group, the mean changes of WOMAC score between before and immediately after the intervention (p=0.001, 95% CI: 3.134, 9.554) and between before and one month after the intervention were statistically significance different (p=0.007, 95% CI: 0.860 to 6.890), so that the WOMAC score decreased in immediately and one month after the intervention phase. However, no statistical difference in WOMAC score between one month and immediately after the intervention phase was observed (p=0.239, 95% CI:-5.865 to 0.927). In the control group, the

pairwise comparisons of the mean score of WOMAC showed that, in the one month after intervention phase the WOMAC score increased in comparison with before intervention (p=0.005, 95% CI: -7.047 to -1.016) and immediately after the intervention phase (p=0.049, 95% CI: -6.802 to -0.010), but was not statistically different between before intervention and immediately after intervention phase. In the sham group, no statistical difference was observed in the pairwise comparison of WOMAC mean scores. In between-group pairwise comparison, the mean change in WOMAC scores among the groups did not show any significant difference (p>0.05).

Table 2. Result of Multivariate Bonferroni test for group and time interaction effect in the three study groups at three stages of measurement

Variables		Acupressure	Sham	Control	p-value*
WOMAC score	Before intervention	55.84±11.16	51.65±12.11	51.21±12.36	0.001
	Immediately after intervention	49.50±10.58	49.90±10.54	51.84±10.46	
	One month after intervention	51.96±10.59	52.59±11.89	55.25±9.69	
Pain score	Before intervention	12.00±3.100	10.65±3.46	10.68±2.86	0.001
	Immediately after intervention	9.00±2.82	9.59±3.35	10.75±2.81	
	One month after intervention	9.96±2.87	10.43±3.23	11.37±2.62	
Stiffness score	Before intervention	4.81±1.46	4.03±1.55	3.56±1.47	0.007
	Immediately after intervention	4.59±1.38	3.90±1.61	3.78±1.23	
	One month after intervention	4.71±1.39	4.87±1.51	4.03±1.40	
Physical function score	Before intervention	39.03±7.69	36.97±8.40	36.97±9.39	0.029
	Immediately after intervention	35.91±7.42	36.41±6.95	37.31±7.52	
	One month after intervention	37.28±7.23	37.28±7.96	39.84 ±6.92	

Data are presented as Mean±SD * Adjustment for multiple comparisons: Bonferroni

Data relevant to the subscales of WOMAC index were analyzed. Results regarding the pain subscale showed that there is a significant difference between the time effect (p=0.001, effect size = 0.208) and the interaction between time and group (p=0.001, effect size = 0.219) (Table 2). The group effect was not statistically significant (p=0.555, effect size = 0.013). The results of statistical modeling showed that, in within-group pairwise comparison, in the acupressure group, the pain score at immediately and one month after intervention was significantly decreased in comparison with the before intervention phase (p=0.001, 95% CI: 2.206 to 3.794) and at one month after the intervention significantly increased in comparison with the immediately after intervention (p=0.032, 95% CI: 1.306 to 2.756). No significant results were observed in the control group. In the sham group, the pain score decreased in immediately after intervention in comparison with the before the intervention (p=0.005, 95% CI: 0.268 to 1.857). There were no significant differences between one month after the intervention with before intervention and immediately after intervention phase. In between-group pairwise comparison, the mean change in pain scores among the groups did not show any significant changes (p>0.05).

The results obtained from analysis of stiffness subscale showed that the effect of time (p=0.001, effect size = 0.86), group (p=021, effect size = 0.080) and the interaction between time and group was statistically significant (p=0.006, effect size = 0.076) (Table 2). In statistical modeling, the results of within-group pairwise comparison showed that, in intervention and control groups, the mean changes of stiffness score in three time measurements were not statistically different. In the sham group, the stiffness score one month after intervention increased significantly in comparison with before (p=0.001,95% CI: 0.369,0.675) and immediately after the intervention phase (p=0.001, 95% CI: 0.406 to 1.531). In within-group pairwise comparison, in before intervention phase, the mean scores of stiffness in the acupressure group were significantly higher than that of the control group (p=0.004, 95% CI: 0.335 to 2.165) but it had no significant changes in immediately and one month after intervention among the groups (p> 0.05).

The results of data analysis in the physical function subscale showed that the effect of time was statistically significant (p=0.023, effect size = 0.040). The group effect was not significant (p=0.804, effect size = 0.005) and for the interaction between time and group, the results of Multivariate Bonferroni test showed a statistically significant difference (p=0.021, effect size = 0.060) (Table 2). The statistical modeling results showed that in within-group pairwise comparison, the physical function scores in the acupressure group, decreased significantly at immediately after intervention phase (p=0.009, 95% CI: 0.618 to 5.632), So that the physical function was better on the immediately after the intervention than before intervention phase. In the control group, there was a significant difference between before and one month after intervention (p=0.016, 95% CI: -5.333 to -0.417) and immediately

after the intervention (p=0.049, 95% CI: -5.054 to -0.008). So that in one month after the intervention, physical function deteriorated. In the sham group, the pairwise comparison showed no significant difference (p>0.05). Also, no significant difference was observed in between-group comparison (p>0.05).

4. Discussion

Although there was no significant difference between the three groups in terms of WOMAC and its subscales score, evaluation of within-group WOMAC scores and its subscales changes trend at consecutive measurement times showed that in the acupressure group, the WOMAC and pain scores improved significantly in the short and long term. Moreover, in this group, the physical function improved in short term. This effect is likely to be due to pain relief. It is important that in the sham group, the pain scores significantly improved in short term. However, in this group decreasing the pain score did not lead to improving the physical function, and in contrast, in this group, the stiffness score increased significantly in long term. Correction of pain score in the sham group can be attributed to the effect of psychological factors such as induction, researcher's presence, or placebo effect. In the control group, the physical function worsened in long term. It seems that in the control group, following-up many times, has led to exaggerating the symptoms.

The review of the literature shows a limited number of studies has investigated the effect of acupressure intervention on symptoms management of knee osteoarthritis in the elderly and various results have been reported by researchers in this area (33, 42-45). Some studies similar to ours, indicated the correction of osteoarthritis symptoms in both acupressure and sham groups. Such as the study of Sorour et al., in which the effect of acupressure intervention was compared with isometric exercises and a control group in women with knee osteoarthritis and the results showed that the total score of WOMAC significantly decreased in the two intervention groups with respect to the control group, but there was no difference between the two methods. In the study of subscales, acupressure had a better effect on reducing the pain score than isometric exercises and control group; however, isometric exercises were able to correct the stiffness score and physical function of the joint with respect to two other groups (33). In another study by Chang et al., the administration of the Auriculotherapy or ear acupressure in patients after knee replacement surgery was able to significantly reduce the need for narcotic analgesics and improve joint function compared to the control group (43). Moreover, in the study by He BJ et al., the use of acupressure at the stage before knee joint surgery could reduce pain intensity by the third day and reduce the rate of narcotic analgesic intake (46). Also, the results of a study by Li et al. showed the use of acupressure relieves pain and improves joint physical function in the elderly measured by WOMAC and numerical rating scale (NRS). But in this study, there was no difference between the acupressure and sham group (42). In another study, the therapists did not confirm the therapeutic effects of acupressure on the osteoarthritis symptoms (45). In a systematic review, researchers discussed the controversial results of the sham group and posed that acutherapy significantly affected knee pain and stiffness compared to the control condition without intervention of any acutherapy. Moreover, acutherapy was more effective in sham intervention, which was applied to non acupoints, however; no significant differences were reported on treatment effects between acutherapy and sham acutherapy at the same acupoints (47). In our study, the reduction in pain score in sham group could be attributed to using points near the acupoint areas.

Our study had some strength, such as matching the subjects into three groups in terms of major confounding factors, using standard and specific measurement tools, applying blindness and randomization, and using statistical modeling in repeated measurement ANOVA for more accurate data analysis, which can led to reaching reliable and valid findings. This study also had some limitations, including the impossibility of completing the questionnaire during the 30 minutes after waking up and adjusting the stage of disease. Also, the events of everyday life that could affect the symptoms of osteoarthritis were beyond our precise control.

5. Conclusions

In summary, the study showed that, acupressure was able to correct the within-group WOMAC and pain scores in long and short term and improve physical function in short term in patients with knee osteoarthritis. So that acutherapy as an effective approach can be applied in self-care programs for knee osteoarthritis symptom management in the elderly, but in the sham groups, the selection of acupoint positions could be a crucial factor. Further studies are needed in this area, considering two kinds of sham interventions (at the same acupoints and non acupoints) in terms of its effectiveness. Further studies to examine the therapeutic effects of this method on different stages of the disease are recommended.

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Conflict of Interest:
There is no conflict of interest to be declared.

Authors' contributions:
AAJ, TN, SH and TNB conceptualized and designed the research project. AAJ, TN, and TNB performed the acquisition and analysis or interpretation of data. AAJ, TN, and TNB drafted the manuscript. AAJ, SH and TNB revised the manuscript. TNB performed the statistical analysis and finalized the manuscript. All authors provided significant input in the manuscript, and read and approved the final version of it. All authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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