Clinical trial

The effect of acupressure therapy on pain, stiffness and physical functioning of knees among older adults diagnosed with osteoarthritis: A pilot randomized control trial

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ABSTRACT

Introduction: Osteoarthritis (OA) is one of the most common and fast-growing chronic diseases among older adults. The aim of this study was to assess the effect of acupressure therapy on pain, stiffness, and physical functioning of a knee affected by osteoarthritis.
Methods: A single-blind pilot randomized control trial was conducted on 51 older adults with OA of the knee living in one of 3 nursing homes. Nursing homes were randomly allocated to one of three study groups; acupressure therapy, placebo, and routine care. The intervention group received acupressure therapy on eight acupoints. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score and the separate WOMAC subscales were used to evaluate pain, stiffness and physical functioning of knees.
Results: A one-way ANOVA revealed that WOMAC index was not significantly different at the baseline between the three groups (P = 0.296). After intervention, ANOVA showed significant differences between groups in regard to total WOMAC index, pain and physical dysfunction (p < 0.001). Post hoc comparisons revealed that participants receiving acupressure showed a significant decrease in total WOMAC index, pain and physical dysfunction (p < 0.001). Indeed ANCOVA detected a difference in means of pain (p ≤ 0.001), stiffness (p = 0.038) and physical dysfunction (p ≤ 0.001) in three groups.
Conclusion: Acupressure may be an effective intervention for reducing the pain, stiffness, and improving the function of knees with osteoarthritis.

1. Introduction

The elderly population of Iran is growing fast, it is estimated that by 2025 and 2050 respectively they will consist of 10.5% and 21.7% of population respectively [1]. The prevalence of osteoarthritis (OA) in this population is increasing and it is one of the most common chronic diseases among older adult patients around the world [2,3]. The prevalence of OA among Iranians has been estimated to be 16.6% for urban inhabitants (Tehran) approximately 20.5% in a rural area (Tuyserkan villages) [4].

The knees are the most vulnerable joints to become affected by the

disease [5]. To manage the disease, OA patients have to face some challenges in preserving their physical functioning, pain management, and preventing any further disabilities leading to incapability in doing their every day life activities [6]. Consequently, impaired physical fuctioning and chronic pain associated with anxiety disorders could lead to avoidance or decrease of strength when doing activities [7].

In addition, older adults are more vulnerable to chronic diseases since they are also experiencing physiologic changes exposing them to some problems associated with aging such as polypharmacy, adverse drug reactions, etc. [8,9]. Consequently, treatment of chronic disease is not simple in this population [10–12]. In addition, the Osteoarthritis
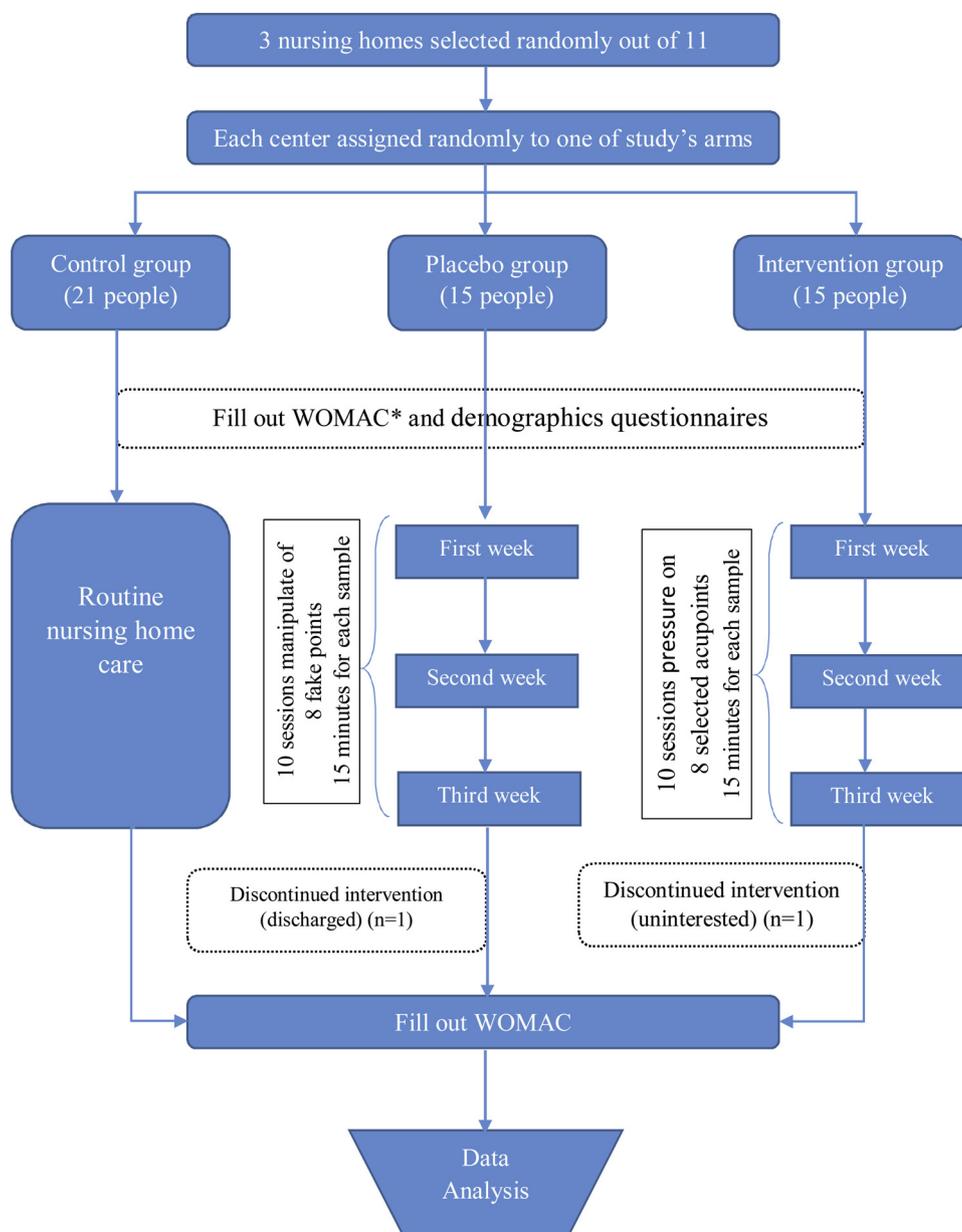
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│          3 nursing homes selected randomly out of 11      │
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┌─────────────────────────────────────────────────────────┐
│         Each center assigned randomly to one of study's arms│
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| Control group (21 people) | Placebo group (15 people) | Intervention group (15 people) |

Fill out WOMAC* and demographics questionnaires

Routine nursing home care

10 sessions manipulate of 8 fake points 15 minutes for each sample

First week
Second week
Third week

10 sessions pressure on 8 selected acupoints 15 minutes for each sample

First week
Second week
Third week

Discontinued intervention (discharged) (n=1)

Discontinued intervention (uninterested) (n=1)

Fill out WOMAC

Data Analysis

Fig. 1. Flow diagram illustrates the progress of patients through the trial.
*Western Ontario and McMaster Universities Osteoarthritis Index.

Research Society International (OARSI) recommends multiple strategies for OA treatment including both pharmacological and non-pharmacological interventions [13].

To avoid the side effects of the medical treatments caused by usual OA pharmacological therapy especially in long term (such as peptic, duodenal ulcers, myocardial infarction and ischemic cerebrovascular events, etc.) many patients prefer the use of complementary and alternative medicine [14].

Complementary and alternative medicine tends to refer to specific unconventional medical approaches to the prevention, diagnosis or treatment of disease, and includes patients' mind and spirit. The individual patient is treated as a whole person and uses a person centred/disease-centered approach [15]. Acupuncture, acupressure, chelation therapy, folk medicine, homeopathy, relaxation therapy Ayurveda, biofeedback, energy healing, hypnosis, naturopathy, Yoga, Tai Chi, Chi Gong, Pilates, meditation, deep breathing or visualization, spiritual activities, chiropractic, massage, and energy therapies are different types of complementary and alternative medicine and are used for

management of OA of the knee [16].

Regarding the pathobiology of the acupuncture Lin et al. [17] stated that acupressure stimulate the triggers in immune system and results in the secretion of β endorphin, which in turn induces vasodilation and decreases the pain [17]. Acupressure follows the same mechanism that acupuncture does, since the pressure is applied to the same body points used in acupuncture. By applying pressure to specific points on the body, improvement in the body systems functioning is stimulated [18]. Shiatsu and acupressure are often used in the literature interchangeably. However, there are several key technical differences between these two terms, including the type of applied pressure, the position of thumb, and the way in which body weight is used [19]. However, a detailed explanation of acupressure mechanism needs further basic science research and is not the focus of this clinical research study.

Robinson et al. [20] in the systematic review study showed a positive effect of shiatsu on chronic stress, schizophrenia, promoting well-being and critical health literacy, angina, low back and shoulder pain,

fibromyalgia, chemotherapy side effects/anxiety and inducing labour. However, most findings were limited on the efficacy of acupressure [20]. Although Sobhani et al. [21] and Kilic Akca et al. [22] have reported some positive effects of acupressure on Multiple Sclerosis (MS), and hemodialysis needling [21,22]. Sorour et al. [23] reported effectiveness of acupressure on pain, stiffness, and physical functioning of the osteoarthritic knee in female patients [23]. On the other hand, there are some studies that have reported the ineffectiveness of acupressure on pain, nausea and vomiting after appendectomy [24] and on pain in the case of osteoarthritis of the knee [25].

Nursing science has a holistic approach to patients, and nurses are in a unique position to empower older adults with chronic conditions [26] and implement the complementary medicine approaches [27]. Given these inconsistent results and existing evidence on the recommendations for using acupressure for pain management in older adults [28,29] the present study aimed to evaluate the effectiveness of acupressure therapy on pain, stiffness and physical functioning of knee osteoarthritis among older adults compared with placebo acupressure and routine care in nursing homes of Tehran, Iran.

2. Methods

2.1. Pilot trial design

This study conducted in 2015 was a single-blind pilot randomized control trial with three arms (acupressure group, placebo acupressure group, and control group). The study populations were older adults, 60 years of age or older [30] with at least one knee with OA and who were residents in nursing homes affiliated to Tehran Social Welfare Organization located in Western Tehran, Iran.

2.1.1. Sample size

This three parallel-group pilot study was designed to investigate the effect of acupressure therapy in older adults with knee OA, and the Persian visual analogue scale adapted form of WOMAC was used to assess the pain, stiffness and physical functioning of knee OA.

Based on the effect size demonstrated in a similar study [31] with a coefficient of 95%, test power of 87%, and accuracy of 2 units variation in the severity of pain due to intervention, the maximum common variance of 4.25, and by 20% estimation for attrition, 51 participants were needed, 21 participants for the control group and 15 participants for each of intervention and placebo groups.

2.2. Participants

51 participants took part in the study between February 21, 2015, and March 17, 2015; one participant withdrew from the intervention group because of showing no interest in continuation, and one participant left the placebo group after being discharged from the nursing home; so, the study continued with 49 participants (Fig. 1).

Inclusion criteria were people who were older than 60 years old, diagnosed with grade II to III OA according to Kellgren–Lawrence grading system [32] in one or both knees by a rheumatologist and based on X-ray, not having a severe pain in the afflicted knee (less than 90% of maximum pain according to visual analogue scale), no pertinent knee surgery history (replacement, reconstructive), acceptable cognitive health status (score of 7 or higher according to Abbreviated Mental Test (AMT) [33]), no health situation contradicting with acupressure (i.e. open wounds, cancer), no sever symptoms of psychological diseases, no use of narcotics drugs, no other chronic diseases in a critical stage (i.e. insulin-dependent diabetes, lupus), and no injection of analgesics into the afflicted knee in the past 30 days or having plan to inject during the study.

Exclusion criteria: were withdrawing from the study, leaving the nursing home, death or intensification of symptoms so that hospitalization was needed, development of acute diseases or any intervening

conditions, and injecting analgesics medications to the afflicted knee during the study. In this study one person withdrew from the intervention group and one person discharged from the nursing home in the placebo group after the intervention.

2.3. Intervention

Ten questions of Abbreviated Mental Test (AMT) [33] were filled out by an interview with participants and aimed to assess the acceptable cognitive health status of participants. Those who correctly answered approximately 7 out of 10 questions were eligible to take part in the study. An acupressure protocol (includes information about different effective knee acupoints, several strategies of acupuncture, caution notes etc.), was developed by the researcher according to related literature [23,31,34], this protocol was reviewed further by members of research team, the nursing home authorities and Tehran Welfare Organization experts (11 field informants people in total). The executive researcher was trained for a month under the supervision of a physiotherapist who was qualified in the acupuncture and acupressure therapy. Intervention in acupressure group was included one minute of deep pressure on one of eight selected acupoints on knee (ST34, ST35, EX-LE4, EX-LE2, GB34, SP10, SP9, and ST36) (Fig. 2) [25]. Participants had been asked to wear comfortable clothes for sessions and breathe deeply during the intervention.

Intervention for the placebo group was included manipulation of eight fake points that were selected away from the real acupoint and only gentle touching was done instead of required pressure. The intervention lasted for 10 continuous 15-minutes sessions, for 3–4 weeks (acupressure group in the odds and placebo group in even days of the week). The control group received no intervention except the nursing homes routine care.

In this study, 2 cases in acupressure group, 2 cases in placebo group, and 4 cases in control group were diagnosed with grade II to III according to Kellgren–Lawrence grading system OA in both knees. In these cases, each knee was considered as a separate case in assessment, treatment, and analyzing the data. Participants in the placebo group and routine care group received a free course of acupressure session, the acupressure protocol, and study results after study completion, if they were interested.

2.4. Randomization

There were 11 nursing homes in western Tehran. All of them affiliated with Tehran welfare organization and had similar characteristics in terms of physical and care conditions. This organization approved the study at first.

We selected three nursing homes through a table of random numbers. Each nursing home assigned to placebo, or intervention, or routine care group, randomly. It means all eligible subjects in one nursing home were assigned to one group. All people in each center were screened for the eligibility criteria by the researcher. 51 people were eligible to enroll in the study. As a result, all the eligible subjects were enrolled in the study.

The health care providers and participants were not aware of group allocations for blinding purpose. In addition, the data were analyzed by a blinded bio-statistician independently.

2.5. Measures

A demographics questionnaire was developed by the researcher and reviewed further by the research team, nursing home authorities and Tehran Welfare Organization field experts (11 people in total). This questionnaire included some questions about participants' age, gender, education level, height and weight to calculate BMI, former occupational status, duration of disease, history of analgesics injection into a knee, and history of using non-pharmacological pain management

ST 34: on the thigh, on a line drawn between the outside border of the kneecap and the pelvis bone, in a depression 2 cun* above to the kneecap.

ST35: on the knee immediately below the knee cap and outside the tendon below the kneecap.

ST36: below the knee, 3 cun ‡ below ST-35, one finger breadth outside to the front part of the lower leg bone.

SP9: on the inside of the lower leg just below the knee joint line.

SP10: 2 cun* above the kneecap on the inside muscle.

GB34: below the outside aspect of the knee, 1 cun† below the head of the fibula.

EX-LE2 (heding): in the middle just above the kneecap.

EX-LE4 (medial xiyan): on the knee, immediately below the kneecap, and inside the tendon below the kneecap.

Notes:

†1 cun: about the breadth of your thumb

*2 cun: about the breadth of your index finger to ring finger close together

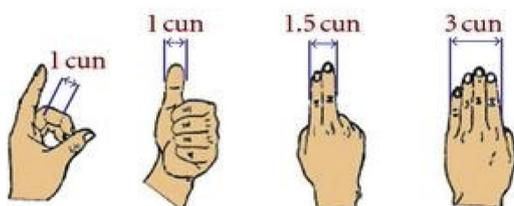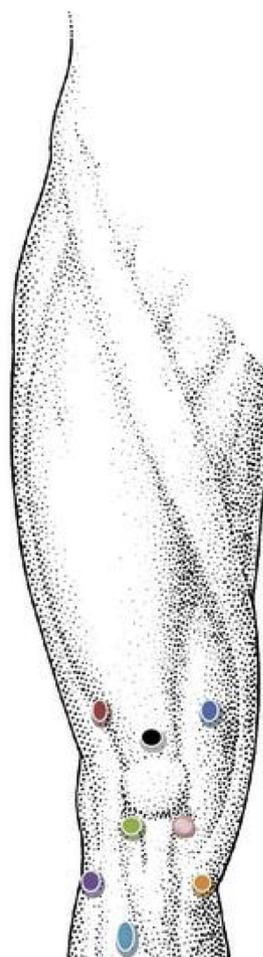‡3 cun: about the breadth of your index finger to pinky finger close together

Fig. 2. Acupoints used in this study [25].
The authorities were contacted by email and the permission to use this figure has received.

strategies. This questionnaire was filled out by all participants in three groups at the baseline before the intervention.

2.6. Outcomes

To assess the pain, stiffness and physical functioning of knees with OA, a Persian visual analogue scale (VAS) adapted form of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [35] was used.

The WOMAC contain 24 questions with 3 subscales about experience of pain, stiffness and physical dysfunction in different situations during the last 48 h. The pain subscale includes 5 questions about the severity of pain during various activities such as sitting, lying, walking, going up or down the stairs, in bed during nights, and standing in upright position. The stiffness subscale includes 2 questions about joint stiffness upon waking up in the mornings and later on during a day. physical dysfunction subscale includes 17 questions aims to measure the amount of difficulty in doing daily activities such as using the stairs, changing position from a sitting or lying to standing up, bending, walking, or getting in or out of a car, shopping, putting on or taking off socks, lying in the bed, getting in or out of a bath, and doing heavy or light house chores. WOMAC has Likert, NRS, and VAS formats, in all of these formats there is a minimum starting point of none or no pain/stiffness/physical dysfunction to a maximum point of extreme pain/stiffness and physical dysfunction. On the Visual Analog version, a ruler is used to measure the distance (in mm) from the left end of line to the point that the patient marks. For each item, the possible range of scores is therefore 0 to 100. Items are summed up for each subscale, resulting in possible ranges as follows: pain = 0–500, stiffness = 0–200, physical dysfunction = 0–1700 [36]. Questionnaire was validated with an intraclass correlation coefficient (ICC = 0.964) and Alfa Cronbach (α = 0.917) for Iranian population [35]. Also several studies have examined and confirmed its reliability and validity [37–39]. Before intervention and two days after the last session, the WOMAC were filled

out for participants in all three groups.

2.7. Ethical considerations

In observance of ethical codes, permission was secured from Iranian Clinical Trial Registration Center under the number of IRCT2015041521758N2 and ethical code number of IR.USWR. REC.1394.9 from Ethics Committee of University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. In addition, ethical requirement of each nursing home was met.

All the participants signed a written letter of consent after being informed carefully about the study's goal and objectives. They were also informed that they do not need to mention their names at all. Also information about participants was stored confidentially and anonymously in a personal computer of researcher. The participants were told that they were free to withdraw at any stage of the study and there was no pressure to participate. The results were sent to participants if they had a desire to receive at the end of study.

2.8. Statistical methods

The data were analyzed using descriptive statistics (Mean, Standard Deviation, Frequency, and Percentage) and inferential statistics (Chi-Square, independent paired-sample *t*-test, variance analysis, Kolmogorov-Smirnov test, Leven test, and covariance) in SPSS V.19 (SPSS Inc., Chicago, Ill., USA).

Mean scores of WOMAC index and the subscales of pain, stiffness and physical dysfunction are continuous variables, so Kolmogorov-Smirnov test was used to determine a normal distribution of WOMAC variables in each measured components both separately and in total for all the three groups in both time points of before and after the intervention. Levene's test was used to test the homogeneity of variances. When there was a significant relationship in investigation group, for more accurate measurement variable among groups Dunnett T3 test and Scheffe's post hoc test was used. Paired *t*-test was used to examine variables changes before and after the intervention. Finally, the covariance test was used for multiple comparisons of mean differences. All tests of this study were measured at a significance level of 0.05.

3. Results

At baseline, comparisons between the three study groups showed no significant differences in their demographic information (p > 0.05) and therefore appeared to be were homogenous (Table 1).

The Kolmogorov-Smirnov test showed a normal distribution of WOMAC variables in each measured components (pain, stiffness and physical dysfunction) both separately and in total for all three groups before and after the intervention (p > 0.05).

The analysis of variance (ANOVA) showed that the WOMAC index was not significantly different at baseline between the three groups (p = 0.296). However, a significant difference was observed after the intervention, when comparing WOMAC index in three groups (p < 0.001) (Table 2). To be more specific, Fig. 3 illustrates a notable decrease in mean scores of WOMAC index after the intervention in acupressure group compared to placebo group (p = 0.006) and control group (p < 0.001).

To determine if the differences in mean scores of WOMAC index and the subscales of pain and physical dysfunction after the intervention among three groups is significant, Scheffler post-hoc test was used. The results showed a significant difference respectively for mean scores of WOMAC index and the subscales of pain and physical dysfunction between the intervention group (group 1) and placebo group (group 2) (p = 0.006), (p < 0.001), (p = 0.026) and between the intervention group (1) and control group (3) (p < 0.001), (p < 0.001), (p < 0.001) (Table 2).

To examine the effect of pretest of WOMAC on the intervention,

Table 1
Demographic characteristics of participants based on the study groups.

Variable	Acupressure (n)	Placebo (n)	Control (n)	p-value
Gender				
M	6	5	8	0.924
F	8	9	13	
Age (year)				
60-70	4	4	6	0.637
71-80	8	6	8	
81-90	2	4	5	
91-95	0	0	2	
Educational level				
Illiterate	2	4	6	0.169
Elementary level	4	6	2	
under high school diploma	4	2	9	
Diploma	4	2	2	
College	0	0	2	
Former occupational status				
Worker	0	2	2	0.089
Office staff	4	1	11	
Housewife	8	10	6	
Other	2	1	2	
Afflicted side				
Right	7	7	11	0.986
Left	7	7	10	
Duration of the disease (year)				
1–5	6	3	8	0.367
5–10	2	6	8	
10–15	4	3	1	
15 <	2	2	4	
Knee injection history				
Positive	3	4	3	0.586
Negative	11	10	18	
Past history in drug pain control interventions				
Positive	6	4	13	0.144
Negative	8	10	8	
Past history in Non-drug pain control interventions				
Positive	4	9	12	0.127
Negative	10	5	9	
Past history in supplementary intake (Ca, vit.D3 and B1)				
Positive	6	6	13	0.418
Negative	8	8	8	

covariance test was used. The results of the test indicated a significant effect of the pretest value of the variables (p ≤ 0.001). The data listed in Table 3 indicate that after controlling the effect of pretest of variables, the effect of intervention on all variables was still significant (p ≤ 0.05). Adjusted coefficient of determination showed 65.6% change in total score of WOMAC, 68.2% in pain, 47.6% stiffness, and 65.7% physical dysfunction of knees.

4. Discussion

This study showed that 10 sessions of acupressure; each session 15 min (3 days in a week for 3–4 weeks) result in a notable decrease in WOMAC index among older adults with a knee OA. OA disease is one of the most common health problems in older adults with the symptoms of pain, stiffness, and physical disability, and it is highly influential on decreasing their quality of life [2].

The results indicated that acupressure was effective in decreasing the pain, stiffness, and improving the functioning of knee in older adults with OA. Covariance analysis also showed that despite all the controls on pretest value of the variables (WOMAC total and subscales values before the intervention), acupressure intervention led to improvement

Table 2
Mean scores of WOMAC index and the subscales in the three groups.

	n	Before intervention Mean	S.D	F	P[*]	After intervention Mean	S.D	F	P[*]	Before & after[***] P
WOMAC										
AG (1)	14	48.07	13.26	1.251	0.296	21.43	10.35	14.564	0.000	0.000
PG (2)	14	49.43	12.81			37.00	12.84		(1-2,1-3)[**]	0.001
CG (3)	21	42.90	12.95			44.14	12.98			0.573
Pain										
AG (1)	14	9.14	2.31	1.430	0.250	2.71	1.27	24.150	0.000	0.000
PG (2)	14	9.86	2.71			7.64	3.52		(1-2,1-3)[**]	0.008
CG (3)	21	2.78	2.78			9.05	2.75			0.143
Stiffness										
AG (1)	14	2.86	1.70	0.675	0.514	1.93	1.33	1.100	0.342	0.000
PG (2)	14	3.14	1.10			2.43	1.55			0.096
CG (3)	21	2.57	1.43			2.62	1.24			0.833
Dysfunction										
AG (1)	14	36.07	10.55	1.082	0.348	16.79	9.18	11.380	0.000	0.000
PG (2)	14	36.43	9.44			26.93	9.06		(1-2,1-3)[**]	0.000
CG (3)	21	32.00	10.06			32.48	10.07			0.770

Acupressure group (AG).
Placebo group (PG).
Control group (CG).
* The result of difference between three groups.
** Exist of post hoc significant difference between groups.
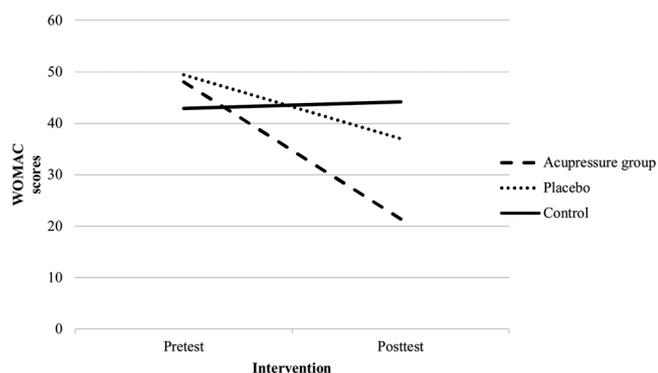*** The result of difference between before & after groups.

Fig. 3. Change trend of mean of WOMAC index between pretest and posttest.

Table 3
Covariance of WOMAC and the subscales based on the study groups.

Variable	Cause of change	F	P	η^2	R^2
WOMAC	Pretest total score	40.52	≤ 0.001	0.474	0.656
	Groups	34.36	≤ 0.001	0.604	
Pain	Pretest pain	28.599	≤ 0.001	0.389	0.682
	Groups	43.098	≤ 0.001	0.657	
Stiffness	Pretest stiffness	42.427	≤ 0.001	0.4685	0.476
	Groups	3.520	0.038	0.135	
Dysfunction	Pretest dysfunction	48.49	≤ 0.001	0.519	0.657
	Groups	31.14	≤ 0.001	0.581	

in symptoms of pain, stiffness and physical functioning of knee with OA among older adults.

In line with these results, Sorour et al. [23] carried out a study in Egypt to determine the effectiveness of acupressure with a same tool on pain, stiffness, and physical functioning of knee with OA among women. Results showed a significant decrease in all three variables comparing with the control group [23]. Moreover, Chan et al. [40] in their study indicated that the acupressure protocol improves the general quality of life in older people with knee OA [40]. It was reported in a systematic review study that all of the included 10 studies showed some positive effects of self-acupressure therapy for primary outcomes

in symptom management, including significant improvements in symptom scores of allergic disease, nausea and vomiting in cancer, symptom scores in respiratory disease, pain symptoms in dysmenorrhea, and stress/fatigue scores and sleep disturbances in healthy people [41].

While Li et al. [41] showed that self-administered acupressure is better than routine care in reducing the pain, due to improved physical functioning in older people with knee OA, but they mentioned that it might be because of placebo effect of touch since they had not controlled for that [42]. There are also some studies about the ineffectiveness of acupressure, Zhang et al. [25] showed no effectiveness of acupressure therapy compared to routine care on knee OA clinical outcomes (e.g., pain, stiffness, and physical functioning) among postmenopausal women measured by WOMAC index [25]. The reason for these inconsistent results could be the training nature of researchers in applying the intervention or failure in implementing the intervention procedure correctly. According to the finding of a study by Torkzahrani et al. [42], acupressure was ineffectiveness in initiating labor as compared with the placebo acupressure and the routine care [43]. Another study by Sharif Nia et al. [43] in evaluating the effect of acupressure on the experienced pain in leukemia patients showed no significant differences between groups who received the acupressure in addition to the routine care, compared with the group who received only routine treatment. However, each group reported significant changes in the level of pain before and after each intervention [44].

Rising costs of health care services around the world has highlighted the role of nurses in providing more home-based health care services (i.e. self-care education, medications administration education, and wound care) [45]. This study showed that through complementary medicine interventions such as acupressure, nurses empower older adults in their self-care abilities of doing ADL. This leads to more independent older adults with a higher quality of life, results in a higher social participation in a society and less mental health related illnesses in this vulnerable population [46–49].

Based on the results of this study, acupressure is suggested as a safe and available complementary medicine for pain management, stiffness and physical functioning of knees with OA in nursing homes. Also, more emphasize on promoting the use of this strategy through complementary and alternative medicine education in nursing school

curriculum in universities or in work training for nurses is recommended.

This study provides primary support for the feasibility of the acupressure intervention in older adult patients especially with knee OA, for future full scaled larger trials. This pilot RCT also has some limitations. All the participants were homogenous and recruited from long term care institutions located in Western Tehran. In addition, this study was performed for a short time (3–4 weeks), given the chronic nature of OA disease, implementing the intervention for a longer period is highly recommended for a future full trial. The subjectivity of pain perception and lack of control on some other factors such as patients' mood swings, having visitors, communication with nursing homes crews, nutrition status may also affect results. These factors may increase or decrease pain tolerance and the expression of pain severity. These factors were out of control of the researchers. Future studies should consider trying to control these co-variables, and include a longer follow-up time period.

5. Conclusion

Acupressure therapy may provide a significant non-pharmacological complementary strategy to alleviate pain, stiffness and improve physical functioning of knee in older adult patients with OA. Acupressure is a non-invasive, low risk, and easy to implement method with limited side-effects, which is suggested to be implemented as a part of nursing cares in nursing homes of countries such as Iran with increasing costs of health care services and fast growing of older population.

Conflict of interest statement

The authors declare no conflict of interests.

Acknowledgements

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