



# Efficacy of Persian Medicine Massage (Qamz) in Nonspecific Shoulder Pain: A Randomized Open-Label Controlled Trial

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## Abstract

**Objectives:** Qamz is a type of massage in Persian medicine (PM). The main goal of this study was to assess the effect of Qamz on shoulder pain and range of motion.

**Materials and Methods:** This controlled clinical trial was conducted on 80 patients with chronic non-specific shoulder pain in 2019; the age range was 18- 60 year. They were randomly assigned to the Qamz (pressing some points around the shoulder with fingers) (A) and control (waiting list) groups (B). The intervention was done one session each week for 4 weeks, and patients were followed for 3 months after the fourth intervention. Qamz was performed, which is generally the pressure of the position with fingers. The visual analogue scale (VAS) was used to measure the shoulder pain at baseline, 1st, 2nd, 3rd, and 4th week of intervention, and 3rd month after the end of interventions. A Goniometer was used to assess the shoulder's range of motion at baseline, 4th week and 3rd month after the end of the interventions. Data were analyzed with repeated measures ANOVA in SPSS software.

**Results:** Thirty-six patients in group A and 34 in group B completed the study. Mean age was 43.92±8.7 years. Twenty-one patients (30%) were male. The shoulder pain decreased as 63.9 ± 30.4% and 11.7± 23.7% in groups A and B, respectively ( $P<0.001$  for comparison between the groups). Flexion [30.69±39.89 vs. 2.64±7.9 degrees,  $P=0.001$ ] and abduction [28.75±37.63 vs 2.2 ± 7.09 degrees,  $P=0.001$ ] of the shoulder were significantly improved in group A more than group B. No adverse effects were reported.

**Conclusions:** Qamz significantly decreased the VAS score of the shoulder pain; it increased the range of flexion and abduction of shoulder in patients with nonspecific shoulder pain more than the control group.

**Keywords:** Massage, Persian medicine, Clinical trial, Complementary medicine, Qamz

## Introduction

Shoulder pain is one of the most common musculoskeletal disorders with a lifetime prevalence of 6.7 to 66.7% (1). About half the population has at least one episode of shoulder pain yearly (2). The number of patients with shoulder pain is increasing at an average rate of 4.6% per year, while the total treatment cost is increasing at a rate of 13.3% per year (2).

Pain and limitation of shoulder's range of motion cause inability to work and social activities, and impose a great burden on individual and society (3). Shoulder complaints are not usually self-limiting; almost 40% of patients with shoulder disorders report persistent or recurrent complaints (3). Most cases of shoulder pain have no definite physical or pathological causes, which are called "non-specific shoulder pain" (4). The prevalence of nonspecific shoulder pain varies from 3% to 50.9% in older adults (5).

The goal of treatment is to reduce pain and increase the shoulder's range of motion, thereby improving shoulder function and ultimately life quality. There is no agreement

on the best way to control pain or disability in non-specific shoulder pain (6); but some measures are usually used, including: painkillers, steroidal and non-steroidal anti-inflammatory agents, ultrasound, electrotherapy, laser, chiropractic manipulation (7), acupuncture, exercise, physiotherapy (6). Although there is evidence for the efficacy of these therapeutic methods, there are also some problems; a number of them are expensive and many of them do not provide a long-term cure (6).

The combination of soft tissue massage and exercise is the most commonly used therapy in shoulder pain (8). Massage is one of the growing treatments of complementary and alternative medicine (CAM), especially in musculoskeletal disorders (9). It has been shown to have a moderate effect on pain (10), and has been mentioned as an uncomplicated treatment for pain control in various studies (11).

Treatments in Persian medicine (PM) vary according to the type of disease such as nutritional modifications and diet therapy, behavioral correction, phlebotomy (wet cupping, bloodletting, leeching), bath therapy, mineral

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## Key Messages

- ▶ Qamz, which is a kind of Persian medicine massage, is an effective therapeutic method for alleviating the shoulder pain and the related disabilities in patients with nonspecific shoulder pain.
- ▶ The shoulder range of motion was also increased after the intervention and continued for at least 3 months in the intervention group.

waters, sand therapy, aromatherapy, Persian Materia Medica, and physical methods (12).

In PM, massage includes “Dalk” (rubbing) and “Qamz” (squeezing with fingers). Massage is one of the most important treatments for joint pain. Qamz means a deep pressure on nerves, tendons and muscle tissue; it is a method to discharge pathogenic substances. It is said to be able to re-establish the neural and blood flow, relieve the muscle cramp and strengthen the joints (13,14).

There is not historical evidence to show the exact history of using Qamz. Some studies explain the history of using massage in different cultures, including Mesopotamia, China, Egypt, Greece, and India (15,16).

These methods have been reflected in PM literature with some modifications during the time (13,14). In the first encyclopedia of Arabic medicine (Firdous al-Hikmat), which was translated into Persian by Ali-Ibn-Rabban Tabari (850 AD), Dalk and Qamz have been considered as the synonyms of massage (17). Ibn-Sina (980-1037 AD) also discussed about types of massage (Dalk and Qamz) in the “Canon of Medicine” (18).

Some clinical evidence supports the effects of Qamz on the neck (19-21), and low back pain (22). In these studies, Qamz decreased the neck pain and increased the motion range of neck and quality of life in patients with non-specific chronic neck pain (16,21); furthermore, Dalk and Qamz reduced pain and improved the performance of patients with low back pain (22).

There is no scientific evidence for the efficacy of Qamz in non-specific shoulder pain. Therefore, the aim of this clinical trial was to investigate the effect of Qamz on non-specific shoulder pain.

## Materials and Methods

This open-label controlled clinical trial was conducted in Tehran (Iran) city from September 2018 to April 2019.

### Inclusion and Exclusion Criteria

Patients were selected among computer user employees during periodic health examinations by a physical medicine specialist. The inclusion criteria were age range of 18-60 years, nonspecific shoulder pain for more than 4 months and written informed consent. When the main source of symptoms was located in the space between the acromion, the junction of the deltoid muscle and the lateral region of the scapula without any physical or pathological

causes or prior diagnosis due to other reasons, it was considered as nonspecific shoulder pain (23).

The exclusion criteria were pregnancy, severe pain that requires other treatments, using other therapeutic interventions (except oral analgesics) in 3 months before the study, complete rupture of the rotator cuff, hemophilia, epilepsy, deep vein thrombosis, anaphylaxis, severe mental illness, insulin-dependent diabetes, neurological symptoms of the upper extremities and symptoms of pressure on the roots of the cervical nerves, history of surgery, trauma, fractures, dislocations in the shoulder area and history of taking anticoagulants such as warfarin. The need for surgery due to shoulder problems, patient’s dissatisfaction with continuing the project, severe underlying disease, taking painkillers or other medications for shoulder problems (except 2g/day acetaminophen) were also considered as attrition criteria.

### Sample Size

The sample size calculation was done using the formula for comparing the mean of shoulder pain between the two groups. Taking into account the first type of error of 0.5 and the power of 80% and considering the results of our pilot study, and 20% drop, the sample size was determined 40 for each group.

### Randomization

After initial evaluation, patients were divided into the intervention and the waiting groups by block randomization method. In this method, all possible forms of blocks containing four interventions (A, A, B, B) were specified, and then were selected randomly using the table of randomized numbers. Finally, a random list consists of participants’ numbers and their assigned intervention was created. For concealment allocation, the sealed envelopes were used; the participants’ numbers had been written on the external part of envelopes, and the group’s name had been written in them.

### Intervention

The control group included 40 individuals on the waiting list, who did not receive any treatments. Patients in both groups could use acetaminophen up to 2 g/d, if there was intolerable pain.

Qamz was performed on 40 individuals once a week for 4 sessions (10-15 minutes each session). The Qamz technique was performed based on the Fateh manual therapy method (14) by Fateh, who has more than 20 years of experience in this field.

While the patient was leaning on the chair and his/her elbow was almost 90 degrees, the patient’s wrist was grabbed, and his/her hand was raised up to the shoulder.

### Grap

Then the “Grap” maneuver was done. Grap is a word in ancient Iran, meaning catching and grabbing. At this stage,

we take the nerves and ligaments and release them. Grap maneuver was performed with the fingers on the patient's humerus bone between the small and large tubercle, 3 to 4 fingers below the armpit. In the Grap maneuver, the local nerves, tendons, and muscles are grabbed by fingers for a short time (Figure 1). In this condition, the tendons of the biceps, brachialis, and especially the thoracobrachialis, and the radial, medial, and ulnar nerves are affected.

### Pock

The next step was the "Pock" maneuver. Pock in Persian means to go down. The procedure is pressing on the deltoid muscle and both sides of the arm with the fingertips (Figure 2).

### Hack

In the third step, the "hack" maneuver was performed. In Persian, Hack means carving an image on a surface. At this stage, deep rubbing or deep pressure was applied to the nerves and muscles. The back of the elbow joint and the end of the humerus were deeply rubbed with fingers, while the elbow was bent according to Figure 3.

### Outcome Measures

#### Primary Outcome

The primary outcome was shoulder pain, which was measured using a 0-10-point VAS; score zero indicates the absence of pain, and 10 is equivalent to the most severe pain experienced in the shoulder area. Patients were instructed to identify the mean pain over a period between the two visits. The shoulder pain was measured using VAS at the baseline, 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> week of intervention, and 3<sup>rd</sup> month after the end of interventions.

#### Secondary Outcome

Patients' disability and the shoulder's range of motion were the secondary outcomes of the study. SPADI questionnaire (Shoulder Pain and Disability Index) was also used to measure patients' pain and disability at baseline, 4<sup>th</sup> week and 3<sup>rd</sup> month after the end of the interventions.

This 13-item questionnaire was developed by Roach et al. from VA Health Services Research and Development in 1991. It consists of 5 items for measuring pain, and 8 items for measuring disability; each item scores from 0 to 10. Higher scores indicate more pain and disability (24). The Persian version of this questionnaire was assessed for validity and reliability by Ebrahimzadeh et al in Mashhad University of Medical Sciences (Mashhad, Iran) (25).

The shoulder's range of motion was measured using a goniometer at baseline, 4<sup>th</sup> week and 3<sup>rd</sup> month after the end of the interventions.

A plastic goniometer was used to measure the shoulder's range of motion. The reliability of the measurement with a goniometer has been reported as 0.87-0.99 (26). Each measurement was repeated three times, and the mean value was reported.



Figure 1. Grap Maneuver.

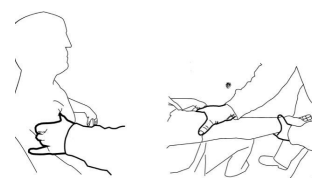


Figure 2. Pock Maneuver.

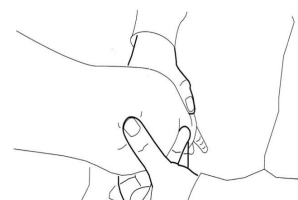


Figure 3. Hack Maneuver.

To measure the shoulder's range of motion, the focal point of the goniometer was placed below the acromion process (bony end/shoulder tip) in the center of the patient's shoulder. One arm of the goniometer was placed on the mid-axillary line, and the other was placed on the midline of the humerus. To measure the degree of shoulder flexion, the patient raised his/her arm forward until it was comfortable, and the angle between the two arms of the goniometer was read. The normal range of motion for shoulder flexion is 180 degrees.

To measure the degree of shoulder extension and abduction, patient was asked to move his/her arm backward and outward, respectively. A normal range of motion for shoulder extension is 45-60 degrees, and for shoulder abduction is 150 degrees. Acetaminophen was also measured at the end of the 1<sup>st</sup> and 4<sup>th</sup> sessions of the study.

### Statistical Analysis

Data were analyzed using SPSS software (version 17). Descriptions were done by mean ( $\pm$ standard deviation) for quantitative variables and number (%) for qualitative ones. The normal distribution of variables was assessed using Shapiro-Wilk and Kolmogorov-Smirnov tests in each group.

Friedman test was used to investigate the changes of quantitative variables during the study. Paired comparisons

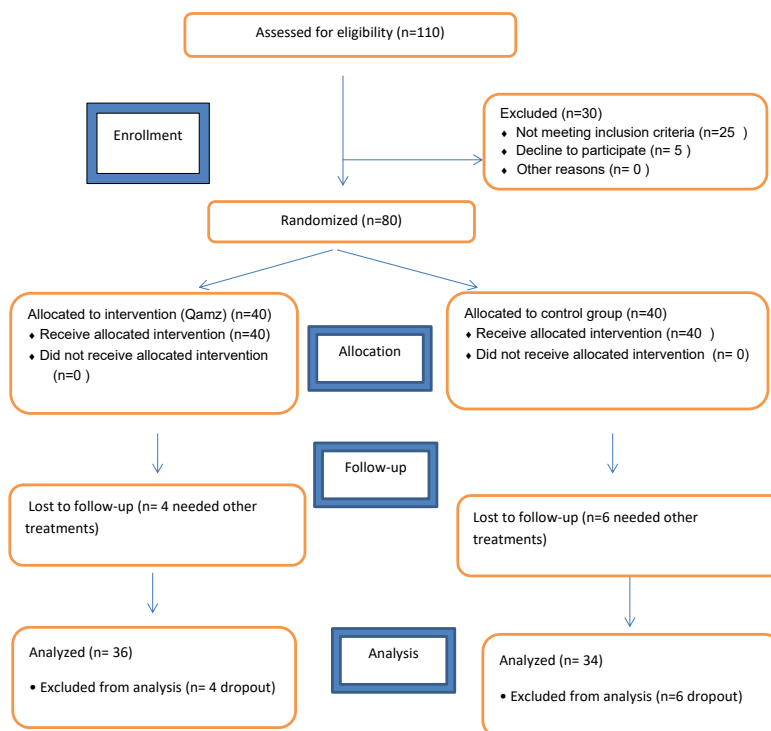


Figure 4. The CONSORT Flow Diagram of the Study.

were performed with Wilcoxon test. Comparison of qualitative variables was performed with chi-square test or Fisher's Exact test between the two groups.  $P$  values less than 0.05 were considered as statistically significant.

## Results

### Demographic and Baseline Characteristics of Participants

From 5500 individuals, who were examined in annual periodic examinations, 110 individuals had some degrees of shoulder pain; of which 85 had the entrance criteria, and 80 subjects entered with their consent. Eighty cases were randomly divided into two groups, but only 36 individuals in the massage group, and 34 in the waiting list completed the study. Figure 4 shows the CONSORT flow diagram of the study. The demographic and baseline characteristics of patients have been shown in Table 1. The baseline characteristics were not significantly different between the two groups. Age, sex, BMI and the duration of disease were not also significantly different ( $P > 0.05$ ).

### Shoulder Pain

The VAS scores for pain severity of the two groups are shown in Table 2. The VAS score at each time point was compared with baseline in both groups.

According to Table 2, the shoulder pain score significantly decreased from  $5.8 \pm 1.5$  to  $2.1 \pm 1.9$  after 4 sessions of Qamz ( $P < 0.001$ ), and to  $2.2 \pm 1.8$  after 3 months follow up without any interventions ( $P < 0.001$ ). VAS score significantly decreased from the first week of Qamz ( $P < 0.001$ ). In the control group, the shoulder pain score decreased from  $5.2 \pm 1.1$  to  $4.6 \pm 1.5$  after 4 sessions

( $P = 0.009$ ), and to  $4.5 \pm 1.7$  after 3 months follow up ( $P = 0.01$ ).

According to Table 2, pain relief (percent of changes in VAS score from baseline to 3 months after the study) was  $63.9 \pm 30.4\%$  in the Qamz group, while it was  $11.7 \pm 23.7\%$  in the control group ( $P < 0.001$ ).

### Shoulder Pain and Disability

Reduction of the SPADI score has been shown in Table 3.

The score of the SPADI questionnaire in the Qamz group significantly decreased from  $35.8 \pm 15.9$  to  $5.5 \pm 15.4$  ( $P < 0.001$ ). It also decreased from  $24.9 \pm 10.5$  to  $22.7 \pm 11.5$  in the control group ( $P = 0.07$ ). SPADI score decrement was  $59.2 \pm 28\%$  in the Qamz group, and it was  $7.9 \pm 19.2\%$  in the control group; the amount of decrement was significantly higher in the Qamz group than the control group ( $P < 0.001$ ). Reducing SPADI score means less pain and patients disability.

### Shoulder's Range of Motion

The shoulder's range of motion has been shown in Table 4.

The flexion range increased from  $142.9 \pm 40.9$  to  $171.3 \pm 20.3$  degrees after 4 sessions of Qamz ( $P = 0.001$ ); it also increased to  $173.6 \pm 18.2$  degrees after 3 months ( $P < 0.001$ ). The range of abduction increased from  $145.1 \pm 41.6$  to  $164.1 \pm 21.5$  degrees ( $P = 0.001$ ) after 4 sessions of Qamz; it also increased to  $173.8 \pm 14.5$  degrees ( $P < 0.001$ ) after 3 months. Changes in range of motion were not significant in the control group.

In the Qamz group, increase in the shoulder range

**Table 1.** Demographic and Baseline Characteristics

Variables	Group		P Value
	Qamz	Control	
Age (y), (mean ± SD)	45.11 ± 7.75	42.67 ± 9.55	0.24 <sup>a</sup>
Gender, No. (%)			
Female	26 (72.2)	23(67.6)	0.79 <sup>b</sup>
Male	10 (27.8)	11(32.4)	
Marital status, No. (%)			
Single	5(13.9)	8(23.5)	0.36 <sup>b</sup>
Married	31(86.1)	26(76.5)	
Education, No. (%)			
Under diploma	0 (0)	5 (14.7)	0.07 <sup>c</sup>
Diploma	10(27.8)	5 (14.7)	
Upper	26(72.2)	24 (70.6)	
BMI, (mean ± SD)	26.33 ± 3.92	26.13 ± 3.31	0.81 <sup>a</sup>
Duration of disease, No. (%)			
4-11 months	10 (27.8)	5 (14.7)	0.06 <sup>c</sup>
1-2 years	7 (19.4)	9 (26.5)	
2-3 years	0 (0)	5 (14.7)	
>3 years	19 (52.8)	15 (44.1)	

SD, standard deviation; BMI, body mass index.

<sup>a</sup> t test, <sup>b</sup> Fisher exact test, <sup>c</sup> Chi-square test.

of flexion and abduction was greater than the control group ( $P=0.001$ ). In the case of extension, there was no significant difference between the two groups ( $P=0.63$ ). The amounts of acetaminophen decreased from  $0.94 \pm 0.72$  to  $0.2 \pm 0.4$  ( $P<0.001$ ) in the Qamz group; it changed from  $0.71 \pm 0.7$  to  $0.68 \pm 0.63$  in the control group ( $P=0.32$ ). No complications were observed in both groups.

## Discussion

The results of this study showed a significant reduction in the shoulder pain, and a significant increase in the shoulder's function and motion range in the Qamz group compared to the controls.

Khoramizadeh et al showed that Qamz increased the

motion range of neck and life quality of patients with non-specific chronic neck pain (16). Qamz also decreased the pain of these patients (21).

Another study in Iran showed the effect of Dalk and Qamz on pain reduction and improving the performance of patients with low back pain and chronic radiculopathy. In this study, forty male patients with the history of radicular low back pain were randomly allocated into Persian massage group ( $n=20$ ) and control group ( $n=20$ ). Intervention was conducted three times a week along with acetaminophen (1300 mg/d) for four weeks, while the control group was asked to use acetaminophen. The VAS, Morris-Roland disability questionnaire and World Health Organization brief questionnaire for quality of life were used to assess the pain, disability and quality of life. Dalk and Qamz led to statistically significant relief in pain after one month ( $P=0.03$ ), as well as improvement in disability ( $P<0.05$ ) and psychological quality of life after 3 months (22).

In a study by Van den Dolder et al, the effect of six sessions soft tissue massage on the shoulder pain was compared with the waiting list control group. Massage reduced pain by 26.5 mm on the VAS score and improved the motion range to 22.6 degrees in flexion, and 42.2 degrees in abduction (8). Our study was conducted in 4 sessions in 4 weeks, and the time of each session was less than 15 minutes. Due to the average reduction of 35.6 mm on the VAS score, we had a better result to reduce pain. Our patients also experienced an increase of 30.69 degrees in the flexion and 28.75 degrees in the abduction of the shoulder.

In a clinical trial conducted in 2016 by Saatchian et al, patients with shoulder pain were divided into three groups: short-term massage, neuromuscular facilitation exercises (NFE) and a control group. In the short-term massage group, a 20-minute trapezoidal muscle massage session was performed. In the short-term massage and NFE groups, there was a significant reduction in pain compared to the beginning of the study; no significant difference was found between the two groups (27).

In PM, Qamz is known as a way to drain the materials,

**Table 2.** Pain Score (VAS) During the Study

Time	Pain Score (VAS) (Mean ± SD)			P Value <sup>a</sup>
	Total	Group		
		Qamz	Control	
Baseline	5.55±1.38	5.86± 1.51	5.23±1.18	
The 1 <sup>st</sup> week	3.92±1.87	2.86± 1.74	5.05±1.25	<0.001
The 2 <sup>nd</sup> week	3.9±2.02	2.83±1.9	5.02±1.46	<0.001
The 3 <sup>th</sup> week	3.4±2.05	2.25±1.69	4.61±1.66	<0.001
The 4 <sup>th</sup> week	3.35±2.13	2.16±1.9	4.61±1.57	<0.001
3 months after intervention	3.35±2.09	2.27±1.81	4.5±1.78	<0.001
P value <sup>b</sup>	<0.001	<0.001	0.014	
Pain score decrement	37.72±38.8%	63.9± 30.4%	11.7±23.7%	<0.001

SD, standard deviation.

<sup>a</sup> Mann-Whitney U test, <sup>b</sup> Friedman test.

**Table 3.** SPADI Score During the Study

Time	SPADI Score (Mean ± SD)			P Value <sup>a</sup>
	Total	Group		
		Qamz	Control	
Baseline	30.51±14.53	35.81± 15.9	24.91± 10.51	
The 4 <sup>th</sup> week	18.89±12.59	14.23± 11.33	23.72±12.14	0.001
3 months after intervention	19.04±14.09	15.54±15.45	22.75±11.59	0.003
P value <sup>b</sup>	<0.001	<0.001	0.07	
Decrease of SPADI score	34.33±35.25	59.2± 28%	7.9±19.2%	<0.001

SD, standard deviation.

<sup>a</sup> Mann-Whitney U test, <sup>b</sup> Friedman test.**Table 4.** The shoulder's Range of Motion During the Study

Time		Range of Motion (Degree) (Mean ± SD)			P Value <sup>a</sup>
		Total	Group		
			Qamz	Control	
Flexion	Baseline	155.64±36.09	142.91±40.99	169.311± 24.04	
	The 4 <sup>th</sup> week	170.42±21.56	171.38±20.3	169.41±23.08	0.98
	3 months after intervention	172.71±18.72	173.61±18.22	171.76±19.45	0.83
	P value <sup>b</sup>	<0.001	<0.001	0.1	
	Range of motion increment	17.07±32.19	30.69±39.89	2.64±7.9	0.001
Extension	Baseline	58.51±6.21	57.63±7.97	59.41±3.42	
	The 4 <sup>th</sup> week	59.28±3.1	59.16±2.8	59.41±3.42	0.35
	3 months after intervention	58.94±6.63	58.22±9.1	59.7±1.71	0.58
	P value <sup>b</sup>	0.161	0.25	0.36	
	Range of motion increment	0.44±8.45	0.58±11.7	0.29±1.71	0.63
Abduction	Baseline	156.71±36.82	145.13± 41.6	168.97±26.45	
	The 4 <sup>th</sup> week	166.78±23.91	164.16±21.53	169.55±26.23	0.07
	3 months after intervention	172.57±18.85	173.88±14.59	171.17±22.6	0.83
	P value <sup>b</sup>	<0.001	<0.001	0.24	
	Range of motion increment	15.85±30.34	28.75±37.63	2.2±7.09	0.001

SD, standard deviation.

<sup>a</sup> Mann-Whitney U test, <sup>b</sup> Friedman test.

which cause disease; its purpose is to restore nerve flow, blood flow and relieve muscle cramps (12,13,19). Gentle and light massage could stimulate A-beta nerve fibers, which reduce transmission of pain impulses in the lamina of posterior branch of spinal nerve (28,29).

In moderate pressure massage, parasympathetic activity and serotonin increase and substance P decreases; these processes are effective for pain controlling (30). If the massage be more intense, it is possible to activate high-threshold mechanical receptors, which activates the A-gamma fibers (gamma moto neuron, fusimotor neuron); it is a type of lower motor neuron that takes part in the process of muscle contraction (30). This is in accordance with the theory of PM, that using pressure in massage could strengthen the muscles (31).

Manual therapies release endogenous opioids and increase the pain threshold in peripheral receptors (32). They alter plasma cytokine levels, modulate neuro-inflammatory pathways and correct inflammatory responses (33,34). Massage is beneficial to increase blood flow, and has an obvious recovery effect on muscle spasm (35). Cognitive and psychological factors can also be

effective, such as patient satisfaction following immediate pain relief or significant improvement in body flexibility; they may affect patient's understanding of pain, and consequently the results of studies (36).

It was the first study, which evaluates the effect of Qamz on shoulder pain. Further studies should be done to evaluate the efficacy of Qamz on other types of shoulder pain (for example frozen shoulder). In addition, studies with longer following periods are suggested to evaluate the durability of the effects of Persian massage.

#### Limitations of the Study

One of the limitations of this study was the placebo effect, because the control group did not receive any treatments and were on the waiting list. Another limitation was impossibility to use the sham processors in manipulation therapies.

#### Conclusions

This randomized controlled trial showed, that Qamz in patients with nonspecific shoulder pain significantly relieved pain. It also improved motion range over a 4-week

period. Further researches are needed to determine the long-term effects of Qamz. There is no similar study, and the results were compared with other types of massage studies.

#### Authors' Contribution

**Conceptualization:** Fatemeh Behdad, Fataneh Dabaghian.

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**Validation:** Fatemeh Behdad, Fataneh Dabaghian.

**Data curation:** Fataneh Dabaghian.

**Investigation:** Fatemeh Behdad, Fataneh Dabaghian, Hoorieh Mohammadi-Kenari, Korosh Mansouri.

**Resources:** Fataneh Dabaghian, Hoorieh Mohammadi-Kenari, Korosh Mansouri.

**Writing—original draft preparation:** Fatemeh Behdad, Fataneh Dabaghian.

**Writing—review and editing:** Fataneh Dabaghian, Hoorieh Mohammadi-Kenari, Korosh Mansouri.

**Project administration:** Fataneh Dabaghian.

**Supervision:** Fataneh Dabaghian.

#### Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### Conflict of Interests

The authors declare that they have no competing interests.

#### Ethical Issues

The protocol was approved by the Ethics Committee of Iran University of Medical Sciences on November 18th 2017 with the code of "IR.IUMS.REC 1396.9321309009". It was also registered in the Iranian Registry for Clinical Trials (identifier: IRCT20171218037941N1, <https://www.irct.ir/trial/33636>). Prior to the study, all participants were informed about the aim of the study and signed the consent form. In addition, the confidentiality of the personal and research data was ensured.

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