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Efficacy of a Persian-Based Method of Needling on Clinical Symptoms of Patients with COVID-19: A Pilot Randomized Controlled Clinical Trial

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Abstract

COVID-19 is a pandemic viral infection that has become a challenge for health systems worldwide having no definite antiviral treatment yet. The aim of this study is to evaluate the effect of a Persian-based method of needling (Ghamz with needle) on the clinical symptoms of COVID-19 patients as a pilot study. We conducted a single-blind randomized controlled clinical trial involving hospitalized adult patients with confirmed SARS-CoV-2 infection (COVID-19) by rRT-PCR method using a nasal swab. Nineteen patients who met the inclusion criteria were randomly allocated to receive Ghamz with needle in the intervention group and sham treatment group. The procedure was performed in six points (three bilateral), based on traditional Persian medicine (TPM) texts, compatible with LU5, LU7, and SP6 Chinese points with a duration of 20 minutes, every day, till the patients were discharged from the hospital. The clinical symptoms, laboratory data, and radiological findings were evaluated before and after the interventions in both groups. The results revealed that after comparing the values of the change in the study parameters, despite the significant improvement in the dyspnea (p=0.037) and O2 saturation (p=0.044) of the Ghamz group, no statistically significant difference was observed between Ghamz and sham groups using a visual analog scale (dyspnea: MD: -3.66, 95% CI: -6.49 to 0.84 vs MD: -2.20, 95% CI: -4.60 to 0.20, p= 0.217; O2 saturation: (MD: 2.61, 95% CI: -1.97 to 14.02 vs MD:4.50, 95% CI: -0.49 to 9.49, p=0.163). The radiological findings showed a better improvement in the intervention group than in the sham treatment group. In conclusion, Ghamz with needle in the mentioned points was not effective significantly in relieve the symptoms of the patients with COVID-19. However, further studies with larger samples are recommended.

Keywords: Coronavirus; COVID-19; Needling; Traditional Persian medicine; *Ghamz*; *Kaiy*

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Introduction

An outbreak of a new coronavirus infection, called coronavirus 2019 (COVID-19) by the World Health Organization (WHO), began in December 2019 in Wuhan, China and rapidly spread across China and many other countries [1,2]. The cause of the disease was severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which is a kind of atypical pneumonia [3,4]. COVID-19 had a severe impact globally on several aspects of human life, including environmental, physical, social, psychological, emotional, economic, etc. [5-8].

Some patients develop complications including respiratory distress syndrome, arrhythmia, and shock which are highly associated with the presence of comorbidities such as cardiovascular diseases, hypertension, diabetes mellitus, and respiratory diseases among adult patients [9-11].

Researchers and clinicians all around the world are trying to find a proper treatment or prevention for the disease; however, no definite antiviral therapy has been found yet and all the treatments are limited to supportive care.

Complementary and alternative medicines have been attended by researchers and clinicians recently, and studies have shown their therapeutic effects [12-17]. Persian scholars have mentioned several approaches and treatments in their books for most diseases and the chapter on pneumonia can be found in almost all traditional Persian medicine (TPM) sources due to its high importance. Based on TPM, there are several approaches to pneumonia; however, "*Fasd"* (bloodletting) and "*Ghamz"* were reported by many Persian scholars as the first step in the treatment of pneumonia [18-21]. "*Fasd*" is a stimulating technique by knife or needle used for puncturing specified veins or arteries, and "*Ghamz*" – a kind of massage therapy that is almost equivalent to acupressure– is another specialized term in TPM means pressing of specified points with or without needle which can be used instead of *Fasd* in weak patients [22,23]. In TPM sources, the most important points which have been mentioned to be effective in the treatment of pneumonia are cephalic veins in arms and their branches in the forearms, and great saphenous veins in calves [18-20].

When comparing these points with acupuncture points in traditional Chinese medicine, the mentioned points in TPM can be matched with LU5, LU7, and SP6 Chinese points. These points are among the points which are recommended in "Guidance for acupuncture and moxibustion intervention on COVID-19" which is developed by China Association of Acupuncture-Moxibustion (CAAM) [24].

Therefore, due to lack of specific treatment for COVID-19 infection and the urgent need to develop effective therapies for the disease, we aimed to conduct a pilot study to evaluate the effects of *Ghamz* therapy with needle on the clinical symptoms of the patients with COVID-19.

Materials and Methods

Clinical trial design

The present study was a two-arm (parallel group) single-blind randomized controlled clinical trial. There was no change in methods after beginning the trial.

Participants

A total number of 74 patients admitted in *Ali Asghar* Hospital affiliated to Shiraz University of Medical Sciences, Shiraz, Iran between 15th of April and 30th of May 2020 with confirmed diagnosis of COVID-19 infection were eligible to include in the trial. The diagnosis was confirmed by real-time reverse-transcriptase-polymerase chain reaction (rRT-PCR), using nasal swabs to collect the specimen [25]. Eligible patients were the 18- to 75-year-old patients who suffered from dyspnea and cough as the clinical signs and symptoms, blood O_2 saturation level less than 93% measured by pulse oximeter, and the findings in favor of pulmonary infiltration in chest CT scan. The exclusion criteria were pregnancy and lactation, decrease in the level of consciousness, instability in hemodynamic condition, and having underlying diseases including cardiovascular, pulmonary, and endocrine diseases. The patients were enrolled in the study, after filling out the informed written consent form.

Ethical considerations

The procedures followed in the present trial were in accordance with the Declaration of Helsinki (1989 revision) and were approved by the Local Medical Ethics Committee of Shiraz University of Medical Sciences [ethics code: IR.SUMS.REC.1399.043]. Moreover, this study was registered in Iranian Registry of Clinical Trials website by the number of IRCT20150825023753N17 (https://www.irct.ir/trial/51709).

Intervention

The intervention was point stimulation by *Ghamz* therapy - in TPM term- with or without needle. Both of the interventions applied every other day, till the patient was discharged. Each session, the patients received firstly *Ghamz* therapy for 30 seconds and then needling for 20 minutes. The needles were used in size of 0.25X25 mm purchased from Suzhou Acupuncture & Moxibustion Appliance Co., Ltd.

The interventions were performed in six points (three bilateral points); next to the cephalic vein in cubital fossa matched with LU5, below wrist matched with LU7 acupuncture points, and near to saphenous vein

matched with SP6 (Figure 1). Lung 05 (LU5) point is on the transverse cubital crease, on the radial side of the tendon of the muscle biceps brachii. Lung 07 (LU7) is on the anterior, or radial aspect of the forearm, two closed finger proximal to the wrist crease. Spleen 06 (SP6) is located on the inside of the leg, four closed finger above the ankle.

The patients received *Ghamz* therapy with needle in the intervention group. In order to reduce the bias, *Ghamz* without needle was done in the control group as sham therapy to blind the participants (finger pressing of each point for 30 seconds).

All the patients in both groups received their routine medical treatments and supportive care based on the national protocol of COVID-19 treatment.

Outcome measures

The primary outcomes were the severity of dyspnea and cough resolution as the clinical symptoms; which were measured by visual analog scale (VAS). The patients were asked to describe the severity of dyspnea and cough with a score of 0 for no cough or dyspnea (asymptomatic) to 10 (the most serious) before and after receiving the interventions [26].

The second outcome measures were the changes in blood O_2 saturation level, laboratory data, and the radiologic findings in chest CT scan which were recorded by the investigators at the start and the end of the study.

Randomization, blinding, and allocation concealment

The 19 patients who participated in the study were randomly divided into two parallel groups; the intervention and the sham treatment groups. The randomization table was generated by Random allocation software Ink (Version 1.0, May 2004) using a block size of four. The allocation concealment of the patients in each treatment group was guaranteed using sealed opaque envelopes.

Due to the usage of the needles in the intervention group, blinding could not be applied to the physicians who executed the trial, but the patients were blinded by applying sham treatment for the control group. In addition, the statistician was blinded as to the allocation of patients.

Statistical analysis

SPSS software version 18 (Armonk, NY: IBM Corp.) was performed for statistical analysis of data. To check the normality of the data, the Kolmogorov–Smirnov test was applied. Frequency and percent were used to describe the qualitative data of the patients. Moreover, independent t-test and paired t-test were used to compare the quantitative data of the patients in both groups. Moreover, non-parametric tests were applied for analyzing the non-normally distributed data. Moreover, we used Stata software version 14.2 to calculate the effect size of the study results. A p value less than 0.05 was considered significant.

Results

Of 74 patients who were admitted from the 15th of April to the 30th of May 2020, 19 patients were eligible to participate in the present study. These patients were randomly divided into the intervention group (nine patients) and the sham treatment group (ten patients) with no loss to follow-up patients in the groups (Figure 2).

The primary and secondary outcomes were measured before the interventions. The baseline demographic data of the patients in both groups are presented in table 1.

Moreover, table 2 shows that there were no significant differences between the two arms of the study except for a difference in dyspnea score. Subjective dyspnea score which was measured by VAS score, a score between zero to 10, showed a significant decrease in the intervention group compared with the baseline (p value= 0.037). Although the dyspnea score decreased in the sham treatment group compared with baseline, too, the change was not significant (p value= 0.588).

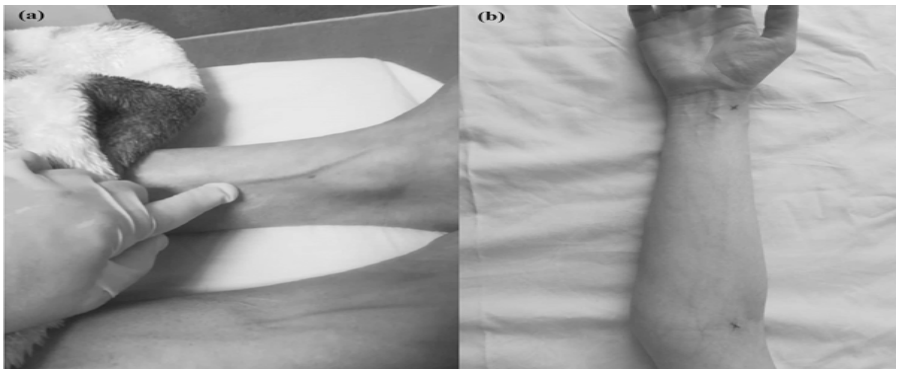

Figure 1. Three points of ghamz therapy with or without needle, (a): four closed finger above the ankle near to saphenous vein matched with SP6 and (b): next to the cephalic vein in cubital fossa and below wrist matched with LU5 and LU7 Chinese points

The cough score was decreased in both groups, but it showed no statistically significant change in both intervention or sham treatment groups (p value= 0.068 and p= 0.078, respectively).

Also, a significant increase, compared to the baseline, was observed in the blood O_2 saturation level in the intervention group (p value=0.044); however, it was not significant in the sham treatment group (p value= 0.075).

There were no significant differences between the intervention and the sham treatment groups in laboratory data (containing; WBC, lymphocyte, neutrophil, hemoglobin, and platelet) obtained from the patients.

Table 2 shows the efficacy of the Persian-based method of needling (*Ghamz* with needle) in the treatment of patients with COVID-19 in comparison to sham treatment.

Table 3 presents the changes in values and the effect sizes of the variables in the survey of the efficacy of the Persian-based method of needling (*Ghamz* with needle) in comparison with sham treatment in patients with COVID-19. Accordingly, no statistically significant difference was observed between the study parameters in patients who received *Ghamz* with needle and those who received a sham intervention.

A computed tomography scan (CT scan) was done for all the patients before and after the study and they were evaluated by a radiologist. As mentioned in previous studies, the most common finding from chest CT scan of the patients was a ground-glass opacity (GGO) pattern with bilateral pulmonary infiltration and consolidation [27]. At the end of the study, an improvement was observed in the imaging of all the patients; however, it showed more improvement in the intervention group. Figure 3 shows the CT scans of the two patients of the intervention group before and after receiving the interventions. GGO, consolidations, and patchy shadows can be detected on computed tomography of the infected patients which have been improved after receiving the interventions.

There were no reports of any topical or systemic adverse events in both groups after receiving the interventions.

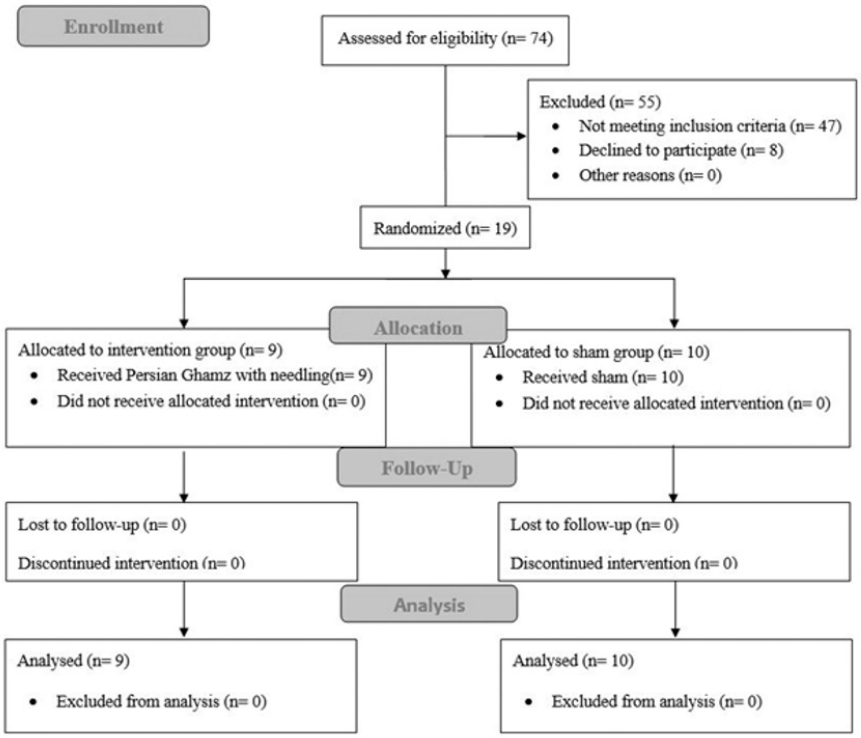

Figure 2. CONSORT flow diagram of the study; the effect of ghamz therapy with needle on the clinical symptoms of patients with COVID-19; a pilot randomized controlled clinical trial

Table 1. Baseline characteristics of the patients in the intervention and the sham treatment group

Outcome measures	Intervention group (*Ghamz* therapy with needle) N= 9	sham treatment group N= 10	p-value
Sex n (%)			
Male	2 (22.2%)	6 (60%)	0.096
Female	9 (77.8%)	4 (40%)	
Age (years), mean ±SD	50.67±13.64	56.90±17.79	0.447

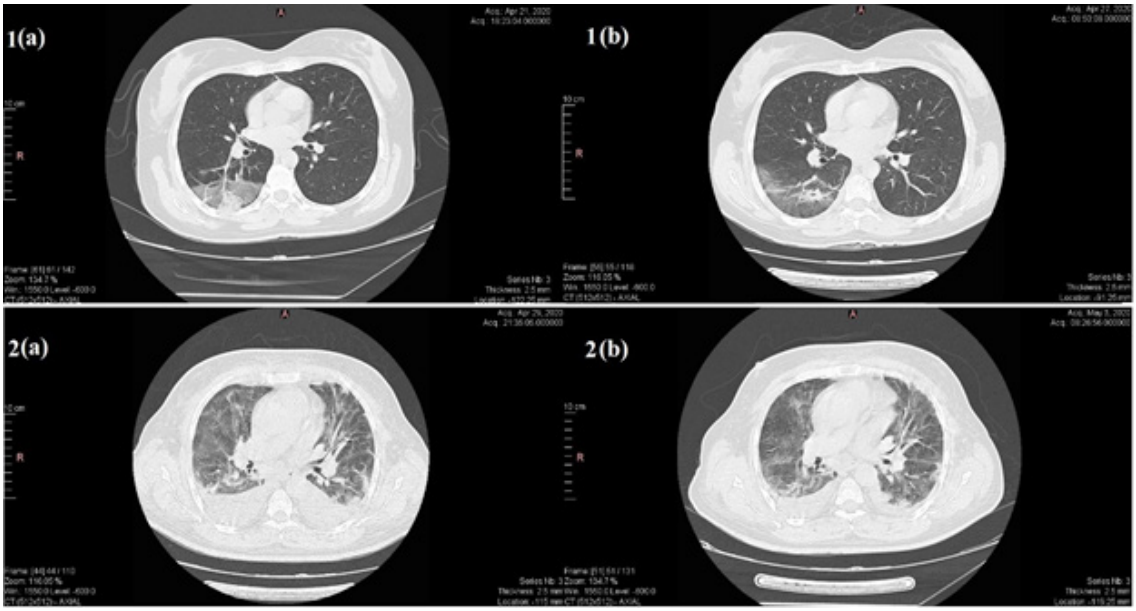

Figure 3. Computed Tomography scans of two patients with COVID_19 of the intervention group before and after receiving the ghamz therapy with needle; (a): before the interventions and (b): after the interventions

Table 2. The laboratory data and subjective VAS scores of cough and dyspnea, before and after the treatment with *Ghamz* therapy with or without needle (intervention and sham treatment group, respectively)

Outcome measures	Study group (n)	Before (mean±SD)	After (mean±SD)	p-value
White Blood Cell (1000/uL)	Intervention (9)	6.80±2.68	9.30±3.46	0.101
	sham treatment (10)	6.88±2.64	7.70±2.42	0.554
	p-value	0.949	0.272	
Lymphocyte (%)	Intervention (8)	25.51±12.77	19.11±9.73	0.359
	sham treatment (10)	23.54±12.46	23.03±11.96	0.817
	p-value	0.761	0.474	
Neutrophil (%)	Intervention (8)	68.76±11.88	75.99±11.22	0.526
	sham treatment (10)	67.95±16.13	66.04±16.93	0.573
	p-value	0.924	0.188	
Hemoglobin (g/dL)	Intervention (9)	12.65±1.58	12.14±1.88	0.719
	sham treatment (10)	12.84±1.91	13.58±2.80	0.628
	p-value	0.863[b]	0.220	
Platelet (1000/uL)	Intervention (9)	171.33±84.83	221.50±71.87	0.607
	sham treatment (10)	203.67±69.23	211.00±89.02	0.771
	p-value	0.519	0.794	
O_2 saturation[a] (%)	Intervention (9)	83.89±7.41	91.89±9.36	0.044[a]
	sham treatment (10)	87.90±5.74	92.40±6.77	0.075[a]
	p-value	0.202	0.647[a]	
Dyspnea[a] (VAS score)	Intervention (9)	7.11±0.60	3.44±3.74	0.037[a]
	sham treatment (10)	5.50±1.43	3.30±3.20	0.084
	p-value	0.017[a]	0.588[a]	
Cough[a] (VAS score)	Intervention (9)	4.44±1.94	1.89±2.20	0.068[a]
	sham treatment (10)	4.10±1.79	2.80±2.53	0.078[a]
	p-value	0.693	0.356[a]	

a. Non-parametric tests were used for these variables.

Table 3. Changes of the variables values and the effect size in the study of the efficacy of Persian-based method of needling (*Ghamz* with needle) in comparison with sham treatment in patients with COVID-19

Variable	Mean difference (95% confidence interval)		p- value	Cohen's d
	Intervention group (*Ghamz* therapy with needle) N= 9	sham treatment group N= 10		
White Blood Cell (1000/uL)	2.500 (-6.07 to 5.60)	0.477 (-1.30 to 2.26)	0.200	0.762
Lymphocyte (%)	-4.60 (-16.31 to 7.11)	-0.51 (-5.43 to 4.41)	0.516	0.98
Neutrophil (%)	4.50 (-15.51 to 24.51)	1.96 (-9.81 to 5.88)	0.336	0.618
Hemoglobin (g/dL)	0.3 (-2.11 to 2.71)	0.26 (-0.96 to 1.48)	1.000	1.29
Platelet (1000/uL)	11.33 (-69.40 to 92.07)	5.750 (-39.195 to 50.695)	0.838	1.65
O_2 saturation (%)	2.61 (-1.97 to 14.02)	4.50 (-0.49 to 9.49)	0.163	0.67
Dyspnea (VAS score)	-3.66 (-6.49 to 0.84)	-2.20 (-4.60 to 0.20)	0.217	0.58
Cough (VAS score)	-2.55 (-5.10 to 0.00)	-1.30 (2.80 to 0.20)	0.334	-0.46

Discussion

The present study was a pilot two-arm single-blind randomized controlled clinical trial which showed the effect of *Ghamz* therapy with needle in six points (three bilateral points) on the clinical symptoms and radiological findings of the 18 patients who were admitted with the diagnosis of COVID-19. The results of the trial showed that needling in the mentioned points can be effective in decreasing cough and dyspnea, increasing blood O_2 saturation level, and improving the radiological findings of the COVID-19 patients.

Previous studies have shown that acupressure and acupuncture can be effective on the treatment of pneumonia and respiratory diseases and also can improve the pulmonary function and quality of life of these patients [28-33]. The anti-inflammatory effect of acupuncture has been discussed by many researchers and studies have suggested that one of the mechanisms of the effect of the acupuncture on treatment of asthma can be reducing the lung inflammation [34,35].

The probable efficacy of acupuncture on reducing the symptoms of COVID-19 patients and improving their radiological findings has been reported by Chinese researchers. The acupuncture points which were reported to be effective are different and the points that we used in the present trial, based on the TPM texts, were among the points which were mentioned as effective points in the reports of Chinese researchers [24]. However, no report of any clinical trial was found yet to show the definite effect of the acupuncture on treatment of patients with COVID-19.

Point stimulation is one of the most important methods of treatment in TPM, which is categorized under the title of "manual interventions". In TPM, point stimulation is recommended in approach to the many diseases. It is used to achieve different goals according to the condition of patients, stage of the disease, the cause of the disease, etc. One of these goals is to take the pressure off an organ by the mechanism of cleaning the organ from excretory material. In the present study, this aim was achieved by stimulating the points which are located on the distal parts of the extremities. It relates to a concept in TPM that there are connective paths between the body organs, named "*Mohazat* channels", which transport the material in the body. When the function of an organ is disrupted, a pathologic flow moves toward it via these paths. Stimulations, like needling, can divert this flow and remove disease from the impaired organ via these paths [36]. The findings of the present trial confirm this concept; as it was observed that the clinical symptoms and the radiological findings of the patients were improved after receiving the intervention.

The precise points to be stimulated for the treatment of each disease are mentioned in the TPM sources. As mentioned above, the most important points, which are recommended for relieving the respiratory symptoms in cases of pneumonia, are the points which are matched with LU5, LU7, and SP6 Chinese points. To stimulate these points, different methods are mentioned such as phlebotomy (*Fasd*) and point pressure massage (*Ghamz*) [18,20,21]. As it is expressed in the TPM sources, *Ghamz* therapy is a safe method for weak patients [22]. The results of our study were in line with this claim, such a way that no adverse event was observed in the patients of the present trial, which

affirms the safety of *Ghamz therapy* with needle in the patients with COVID-19.

Due to the global prevalence of COVID-19 and its great burden on societies, and the importance of finding a way to treat or relieve the symptoms of the patients as soon as possible, we decided to carry out a pilot study. Of course, it is essential to perform studies with larger samples in future and the results of this study can provide a proper insight for the designing of upcoming studies. We had some other limitations carrying out this study. Due to the fact that the COVID-19 is highly contagious, the experiments had to be done under severe restrictions. Moreover, due to ethical considerations, it was impossible to stop the medications received by participants based on the protocols of COVID-19 treatment, which can affect the results of the study. Finally, the sample size of this pilot study was small, further studies including more patients is necessary.

The strength of the study is the presentation of an inexpensive, easy, safe, and minimal-invasive intervention which relieve the respiratory symptoms of COVID-19 patients in a short time.

Conclusion

This pilot clinical trial showed that despite the significant improvement in the dyspnea and O_2 saturation in *Ghamz* group, no statistically significant difference was observed between *Ghamz* and sham groups. However, more studies with larger samples are needed to confirm the data obtained from the present study

Conflict of Interests

Nothing to declare.

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