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Original Research

The Efficacy of Hot Footbath in Hospitalized COVID-19 Patients: An Open-Label Randomized Controlled Trial

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Abstract

COVID-19 spread rapidly around the world from the end of 2019. Hot footbath is a simple ancient technique, which has been used to alleviate many disorders. We aimed to investigate the effect of hot footbath in hospitalized COVID-19 patients. This open-label randomized controlled trial was conducted in Iran with allocation ratio of 1:1, with final sample size of 35 patients in each group. The intervention group received hot footbath (immersion of feet into the hot water at 42 °C, 10 cm above the ankles for 20 minutes, and then kept warm for 5 minutes) once a day for a week, in addition to the conventional therapy. The control group received only the conventional therapy; the primary outcomes evaluated were fever, respiratory rate, cough, fatigue, and myalgia; whereas admission rate, ICU admission, and mortality were assessed as the secondary outcomes. Except for cough intensity, cough frequency and fatigue (p value < 0.05), no significant differences were observed between the two groups in the primary and secondary outcomes. No adverse events were reported. Hot footbath can be used as a non-invasive, highly acceptable, and complementary technique to alleviate COVID-19 patients without any needs to expensive or special equipment; nevertheless, further studies with larger sample sizes are needed so as to accurately evaluate the effectiveness of hot footbath on clinical symptoms of COVID-19.

Keywords: *C*OVID-19; Hot footbath; Traditional persian medicine; Complementary and alternative medicine; Integrative medicine

Introduction

The first time, novel corona virus was identified in Wuhan, China, at the end of 2019; it rapidly spread around the globe. It caused the COVID-19 infection, with various clinical manifestations ranging from asymptomatic infection to severe pneumonia [1]. Several dimensions of health are affected by COVID-19 pandemic, and COVID-19 infected patients suffer from both physical symptoms and psychological pressure [2]. Fever, fatigue, dry cough, myalgia and dyspnea are reported as the most common symptoms in hospitalized patients. Also, anxiety and depression are the two symptoms with high prevalence in hospitalized COVID-19 patients [3].

Many antiviral and palliative therapies have been reported to be effective on COVID-19. However, none of them have been approved currently as the standard treatment [4-8]. Thus, researchers around the world are working to find out the safe and effective treatment candidate for COVID-19.

The prevalence of complementary and alternative medicine (CAM) therapy for many disorders has steadily

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increased around the world. It is estimated that up to 70% of the lower, and middle-income countries use CAM to treat their health problems [9]. Healthcare professionals with different therapeutic approaches have intended to prescribe dietary supplementations, vitamins, and any other options that can alleviate symptoms and boost the immune system of patients with COVID-19 [10].

Hot footbath is an ancient technique which consists of soaking the feet in a basin of warm water at temperatures ranging from 39 ◦C to 43 ◦C based on the tolerance of the patients. The method has been used for centuries to alleviate several disorders. Hot footbath can initiate skin vasodilatation and induce sweating through increasing peripheral temperature leading to regulation of cardiovascular system. According to principles of Persian medicine, transfer of heat and energy from the depth of body (internal organs) to the skin can justify the effectiveness of hot footbath in relieving such symptoms as fever, cough, dyspnea, and headaches. Meanwhile, adding decoction of medicinal herbs, herbal extract, or salts are recommended in some disorders to enhance the therapeutic effect of this procedure [11,12].

Several studies have reported the effectiveness of hot footbath to treat sleep disorders, improve heart and respiratory functions, and reduce anxiety, fatigue, and pain. Due to application of various drugs in hospitals, a simple method was suggested in this study, with the main aim to evaluate the efficacy and safety of hot footbath in hospitalized COVID-19 patients [13-17].

Materials and Methods

Study design

This open-label randomized controlled clinical trial was conducted to determine the effect of hot footbath on hospitalized COVID-19 patients, in addition to the conventional therapy; the results were compared to the control group with parallel allocation ratio of 1:1. Trial registration: This trial was registered in the Iranian Registry of Clinical Trials, under Reg. No. 20180923041093N5.

Participants

Hospitalized COVID-19 patients with a positive nasopharyngeal RT-PCR test, or a positive chest CT scan findings were entered to the study; those with the following conditions were excluded: intubated or hospitalized patients in ICU, pregnant women, breastfeeding women, presence of immune deficiencies, taking corticosteroid and/or immunosuppressive drugs.

Study setting

This open-label randomized controlled clinical trial was conducted at Shahid Mofatteh hospital of Varamin city, Tehran, Iran from May, 2020 to August, 2020. The patients who met the eligibility criteria were conducted into the study via block randomization method.

Intervention

All patients were randomly enrolled into the intervention (hot footbath plus conventional therapy) and the control (only conventional therapy) groups after confirming a written informed consent by a trained nurse. All patients received the conventional therapy according to *the Protocol for Diagnosis and Treatment of Novel Coronavirus Pneumonia (5th edition)* published by Iranian Ministry of Health and Medical Education. Patients in the intervention group received hot footbath (immersion of feet into the hot water at 42 °C, 10 cm above the ankles for 20 min, and then kept warm for 5 min), in addition to the conventional therapy, once a day for a week. Patients in the control group received only conventional therapy.

Outcomes

Primary and secondary outcomes were determined in different time points including 1-2-3-4-5-6-7 days of the intervention.

Primary outcomes were measured by the following methods, fever via thermometer, respiratory rate by counting the number of breaths per minute, cough (intensity and frequency), fatigue and myalgia by visual analog scale (VAS).

According to the study protocol registered in IRCT, the primary outcomes were as follows: temperature, cough, respiratory rate, fatigue, myalgia, lymphocyte count, C-reactive protein (CRP), O2 saturation, and anxiety. However, accurate evaluation of these outcomes was not possible due to lack of cooperation of patients in completing the standard anxiety questionnaire, daily discharge of some participants, and failure to check some daily parameters such as lymphocyte count, CRP, O2 saturation, and CXR. It is noteworthy that clinical symptoms were assessed daily via telephone after discharge. Based on CONSORT recommendation, changes in the outcomes were reported in the text.

Secondary outcomes included number of hospital discharge, ICU admission and mortality.

Sample size

Initially, the pilot sample size of 20 was estimated in each group, due to lack of similar studies. According to the parameters obtained from this pilot study and regarding the types I and II errors of 0.05 and 0.1, the pilot sample size was calculated 35 in each group using the following equation 1:

Equation 1. $$n = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2 \times (\sigma_1^2 + \sigma_2^2)}{d^2}$$

Randomization

All eligible patients were allocated sequentially by a trained nurse to one of the two study groups via a blocked randomization list (non-stratified, four patients in each block) generated by a biostatistician using Microsoft Excel® 2019 software.

Statistical methods

Demographic information, including age and gender was compared between the two groups, using the Chi-square test. Meanwhile, with the purpose of comparing the primary outcomes in these groups at 7 different time points (1, 2, 3, 4, 5, 6, and 7), the Friedman test was utilized.

The Mann-Whitney U test was applied for comparing the changes between the two groups with using an intention-to-treat approach. The statistical analysis was performed using SPSS V.23; the resultant $p<0.05$ was considered statistically significant.

Ethics

The Medical Research Ethics Committee of Shahid Beheshti University of Medical Sciences approved the present study (code: IR.SBMU.RETECH.REC.1399.029). They were assured of the confidentiality and anonymity of the study (Registration code: IRCT20180923041093N5).

Results

Flowchart of the study

In the present study, 100 hospitalized COVID-19 were evaluated. Of which, 25 patients were excluded duo to lake of inclusion criteria, and 5 patients declined to participate in the study. Finally, 70 patients were equally randomized and allocated in two groups. Two patients in the intervention group and five patients in the control group were lost to follow up, because of ICU admission or death. Eventually, 32 patients in the intervention group and 30 patients in the control group, completed the study and were analyzed (Figure 1).

Demographic characteristics

Among the studied individuals, 51.4% of the patients were male, and 48.6% were female. The most common age group was 31- 45 years. There was no significant difference between the two groups ($p > 0.05$) (Table 1).

Baseline data

At the time of admission, more than 80% of the participants had no fever; temperature was 38 °C or higher in 5% of both groups. The respiratory rate was normal in more than 90% of all participants. The arterial oxygen saturation showed hypoxia in more than 50% of the participants. 97% of participants in the footbath group, and 94% of participants in the control group reported no myalgia at baseline.

More than 30% of patients in both groups reported fatigue and cough.

In term of laboratory tests, leukocytosis (> 9.5×109 cell/L) was reported in less than 15% of the participants, also leukopenia (< 3.5×109 cell/L) was observed in about 30% of them. CRP increased in more

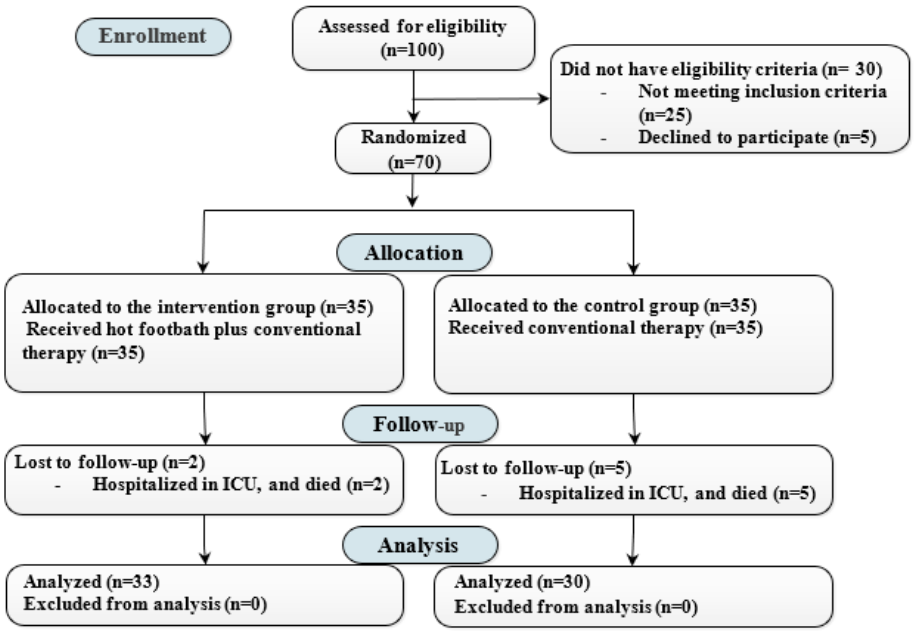

Figure 1. Study flowchart

than 88% of the participants.
There was no significant difference between the two groups in the baseline data ($p > 0.05$) (Table 1).

Comparison of the primary outcomes

Except for cough and fatigue, no significant differences were observed between the two groups in the primary outputs.
The symptoms of cough intensity, cough frequency and fatigue decreased significantly in the two groups between the 1st and 7th days. Cough severity decreased significantly in the footbath group compared to the control group at the first day. The cough frequency improved significantly in the footbath group on the 2nd days compared to the control group.
Fatigue improved significantly at the first day. All symptoms of cough intensity, cough frequency and fatigue remained significant until the end of the intervention (7th day) (Table 2) (Figures 2 and 3).

Comparison of the secondary outcomes

The hospital discharge rate was almost equal in the two groups until the 4th day; this ratio changed from the 5th day, and the discharge rate increased more than three times in the footbath group (20% in footbath group compared to 5.9% in the control group). ICU admission and mortality were lower in the footbath group compared to the control one (5.9% in the footbath group compared to 17.2% in the control group). However, the difference in the secondary outcomes

Table 1. Baseline demographic and clinical characteristics of included patients

Baseline variables	Subgroup	Hot footbath	Control	P value
Age	18-30	2(5.80%)	2(5.71%)	0.56
	31-45	14(40%)	12(34.28%)	
	46-60	6(17.1%)	6(17.14%)	
	>60	13(37.1)	15(32.85%)	
Sex	Male	18(51.4%)	19(54.28%)	0.99
	Female	17(48.6%)	16(45.71%)	
Temperature	<37.5	30(85.7%)	29(82.85%)	0.48
	37.5-37.9	3(8.6%)	4(11.42%)	
	38-40	2(5.7%)	2(5.71%)	
Respiratory rate	10-20	33(94.3%)	32(91.42%)	0.7
	21-25	2(5.7%)	3(8.57%)	
Leukocytes (cells/L) Normal range: 3500 -10000	WBC>$9.5*10^9$	4 (11.42 %)	5 (14.28 %)	0.69
	$3.5*10^9$<WBC<$9.5*10^9$	21 (60%)	19 (54.28%)	
	WBC<$3.5*10^9$	10 (28.51)	11 (31.42%)	
C-Reactive protein (mg/l) Normal range: 0-3	>3 mg/L	31 (88.57%)	32 (91.42%)	0.88
	normal	4 (11.42%)	3 (8.57%)	
O_2 saturation	<95%	19(54.3%)	21(60%)	0.62
	≥95%	16(45.7%)	14 (40%)	
Cough	No	23(65.7%)	22(62.85%)	0.73
	Mild	3(8.6%)	1(2.85%)	
	Moderate	7(20.0%)	5(14.28%)	
	Severe	0(0.0%)	3(8.57%)	
	Very severe	2(5.7%)	4(11.42%)	
Fatigue	No	23(65.7%)	20(57.14%)	0.14
	VAS 1-3	6(17.1%)	4(11.42%)	
	VAS 4-6	6(17.1%)	8(22.85%)	
	VAS 7-10	0(0.0%)	3(8.57%)	
Myalgia	No	34(97.1%)	33(94.28%)	0.95
	VAS 1-3	1(2.9%)	2(5.71%)	

* Chi-square Test: (P value: significant <0.05), VAS: Visual analogue scale

was not significant between the two groups (p value > 0.05) (Figure 4).

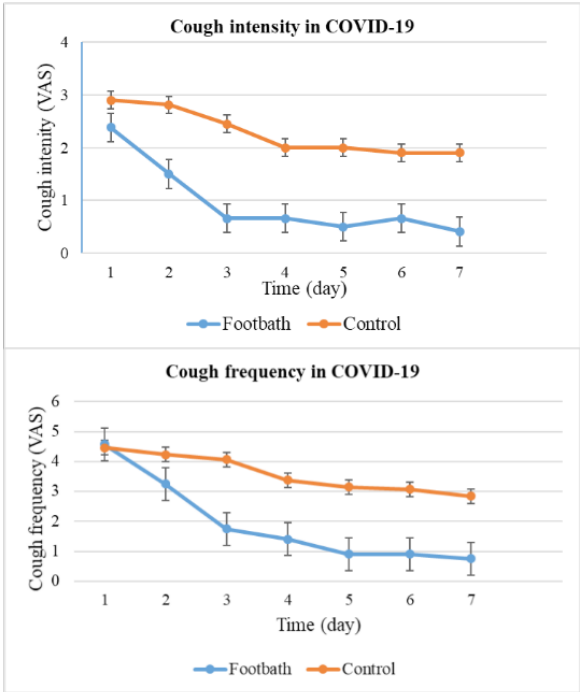

Figure 2. Comparison of cough intensity, and cough frequency

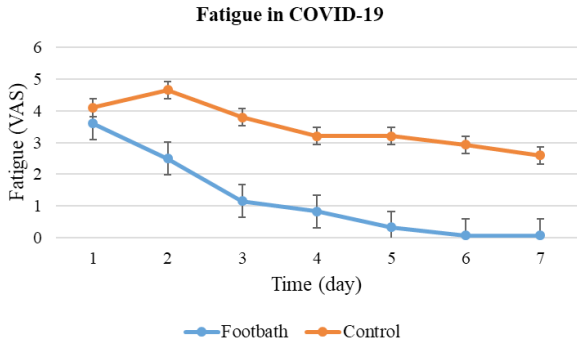

Figure 3. Comparison of fatigue

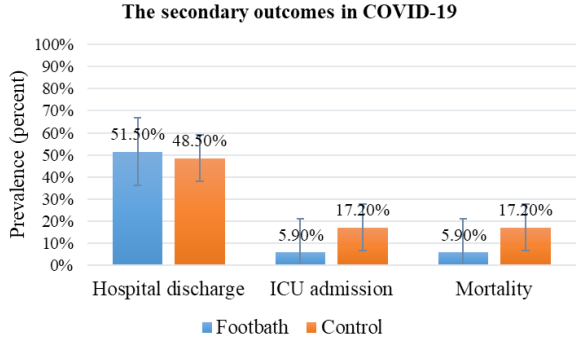

Figure 4. Prevalence of the secondary outcomes

Table 2. Comparison of the primary outcomes

Variables	Hot footbath (Mean ± SE)	Control (Mean ± SE)	P value*
Temperature 1	36.86 ± 0.081	36.99 ± 0.85	0.55
Temperature 2	36.91 ± 0.087	36.89 ± 0.72	0.91
Temperature 3	36.88 ± 0.051	37.04 ± 0.53	0.13
Temperature 4	37.08 ± 0.11	37.04 ± 0.54	0.67
Temperature 5	36.96 ± 0.10	36.99 ± 0.55	0.48
Temperature 6	36.88 ± 0.04	36.90 ± 0.49	0.78
Temperature 7	36.88 ± 0.06	36.91 ± 0.42	0.77
P value*	0.81	0.35	
Respiratory rate 1	17.20 ± 3.22	17.36 ± 3.28	0.94
Respiratory rate 2	17.54 ± 3.31	17.60 ± 3.55	0.89
Respiratory rate 3	16.97 ± 3.07	17.62 ± 4.02	0.86
Respiratory rate 4	16.80 ± 3.15	16.96 ± 3.85	0.90
Respiratory rate 5	16.97 ± 3.62	17.56 ± 4.58	0.90
Respiratory rate 6	16.77 ± 3.58	17.96 ± 4.59	0.29
Respiratory rate 7	16.64 ± 3.85	17.48 ± 4.63	0.76
P value*	0.34	0.67	
Cough intensity 1	2.38 ± 0.99	2.90 ± 1.03	0.080
Cough intensity 2	1.50 ± 1.16	2.81 ± 1.07	0.014
Cough intensity 3	0.66 ± 0.88	2.45 ± 1.21	0.002
Cough intensity 4	0.66 ± 0.77	2.00 ± 1.41	0.018
Cough intensity 5	0.50 ± 0.67	2.00 ± 1.41	0.008
Cough intensity 6	0.66 ± 1.23	1.90 ± 1.37	0.020
Cough intensity 7	0.41 ± 0.79	1.90 ± 1.37	0.006
P value*	0.001>	0.001>	
Cough frequency 1	4.58 ± 1.72	4.46 ± 1.45	0.350
Cough frequency 2	3.25 ± 2.22	4.23 ± 1.96	0.006
Cough frequency 3	1.75 ± 1.96	4.07 ± 1.93	0.033
Cough frequency 4	1.41 ± 1.44	3.38 ± 2.26	0.014
Cough frequency 5	0.91 ± 1.16	3.15 ± 2.50	0.020
Cough frequency 6	0.91 ± 1.56	3.07 ± 2.46	0.020
Cough frequency 7	0.75 ± 1.50	2.84 ± 2.42	0.013
P value*	0.001>	0.001>	
Fatigue 1	3.60 ± 1.31	4.10 ± 1.56	0.130
Fatigue 2	2.50 ± 1.50	4.66 ± 1.75	0.003
Fatigue 3	1.16 ± 1.46	3.80 ± 2.54	0.011
Fatigue 4	0.83 ± 1.33	3.20 ± 2.88	0.027
Fatigue 5	0.33 ± 0.88	3.20 ± 2.88	0.005
Fatigue 6	0.08 ± 0.28	2.93 ± 2.86	0.002
Fatigue 7	0.08 ± 0.28	2.60 ± 2.92	0.010
P value*	0.001>	0.001>	

* Mann- Whitney U test (P value: significant <0.05), * Friedman test (P value: significant <0.05)

Adverse effects
No adverse effects were observed in this study.

Discussion
In our study, except for fatigue and cough, no significant difference was observed between the two groups after intervention.

In term of cough, we noticed both intensity and frequency: intensity was related to how deep, hard, or harsh the coughing was; while frequency included the urge or tickle that preceded coughing [18]. The results of our study showed the significant impression of hot footbath on the alleviating of both cough intensity and frequency. Besides, hot footbath may justify the greater improvement of cough frequency, compared to the cough intensity, through mechanisms which are not fully understood. It seems that hot footbath can reduce bronchoconstriction and delay the initial phase of cough reflex. In an emergency center, immediate improvement of bronchial asthma and pulmonary function tests was reported with hot footbath and arm bath [19].

According to the results of our study, hot footbath had the greatest effect on the relief from fatigue. Fatigue is one of the most common symptoms reported by COVID-19 patients, which lasts a long time and is significantly associated with insomnia and pain [20]. Many potential factors in COVID-19 contribute to increase in fatigue such as psychological factors (e.g. anxiety, depression, and sleep disorders), central factors (e.g. neurotransmitter level and inflammation) and peripheral factors (e.g. skeletal muscle viral susceptibility and myopathy) can negatively affect physical and psychological well-being [21,22]. Cytokines including Interferon-γ, transforming growth factor-β (TGF-β) and Interleukin II are important inflammatory factors associated with infectious-related fatigue [23]. Footbath, as a common relaxation technique, has been used for a long time to relieve the fatigue. This method acts via the following mechanisms: balancing the autonomic nervous system, increasing the cardiac output, activating the systematic and cerebral circulation, increasing the hemoglobin concentration in the brain and muscles tissues, increasing the cortisol level, and improving the immune function [24-26]. Several studies have reported the significant efficacy of hot footbath for treatment of insomnia and improving the sleep quality [27-29]. Also, many studies have reported the effect of hot footbath on reducing the patients' anxiety [30,31].

According to the previous studies, hot footbath can relieve the symptom of pain. For instance, the efficacy of hot footbath on alleviating the osteoarthritis joint pain and post-operation pain was reported. Removing toxins from the body, increasing blood flow in the feet and entire skin surface, and reducing the congestion of core organs have been reported as effective causes of hot footbath in pain relief [17,32,33]. It has been reported that acute local thermal therapy can immediately reduce the arterial, venous, and capillary vascular resistances, due to direct effect of increasing the local temperature on the stiffness of vessel walls, which leads to improving the cardiovascular function, and organ blood flow [15,34]. In our study, however, only three patients (one patient in footbath group and two patients in the control group) reported mild myalgia at the baseline, which was completely eliminated on the second day of the intervention upon receiving Naproxen. Therefore, it was not possible to evaluate the effect of hot footbath on myalgia; similarly, fever could not be evaluated for the same reason.

Also, hot footbath changes the autonomic responses via increasing the parasympathetic and decreasing the sympathetic activities, which leads to significant increase in white blood cell (WBC) count and activity, as well as an increase in natural killer cell cytotoxicity, suggesting an improvement in immune system [35].

Unfortunately, in the present study, leukocyte count was not measured daily for all participants; therefore, no acceptable data were available to evaluate the efficacy of hot footbath on this parameter.

No similar studies related to the efficacy of hot footbath and/or other manual therapies in patient with COVID-19 (e.g. massage, cupping, etc.) have been reported so as to compare with our results. Therefore, we focused on the mechanisms of hot footbath in improving COVID-19 symptoms in discussion section.

Our study had some limitations, such as the impossibility of blinding the study, the small number of participants (which led to the inability to evaluate the efficacy of hot footbath for the less prevalence symptoms such as fever and myalgia), and the changes in the primary outcomes such as leukocyte count, CRP, O_2 saturation, and anxiety.

Conclusion
Hot footbath as a non-invasive, highly acceptable, complementary technique can be used to alleviate COVID-19 patients without any need to expensive or special equipment; nonetheless, further studies with larger sample sizes are needed so as to accurately evaluate the effectiveness of hot footbath on clinical symptoms of COVID-19. It should be mentioned that the results of the present study are not generalizable to all COVID-19 patients.

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