

The effect of wet-cupping therapy on menopause specific quality of life: A randomized-controlled trial

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Abstract:

Purpose: The purpose of the study was to evaluate the effectiveness of wet-cupping therapy (CT) on menopause specific quality of life (MENQOL).**Methods:** This study was conducted with randomized controlled pretest, and posttest method between July 2015 and July 2016 at a Gynecology Outpatient Clinic of University Hospital in Ankara, Turkey. Intervention group (n=30) received wet CT while control group (n=30) did not receive any therapy. Both groups were measured quality of life using MENQOL scale before and two weeks after wet CT.**Results:** The women's age ranged from 45 to 60 years. Baseline characteristics were similar in the both groups. Women treated with wet CT showed significant improvements in their vasomotor, physical and sexual symptoms (p<0.001). No significant effect was found for psychosocial area (p>0.05). No adverse effects were recorded after treatment.**Conclusion:** Wet CT can be considered as an effective method for reducing of menopausal symptoms. In conclusion, this study provides preliminary data on the effectiveness of various symptoms in postmenopausal period. However, further with larger sample size evidence-based trials are needed in order to confirm these results for improving MENQOL.**Key Words:** wet-cupping therapy; menopause; life quality; post-menopausal women

Introduction

Menopause is a natural biological process, not a disease, but it is a long challenging period of life for many women (about 85%) over the age of 50 due to suffer from various short time or long time physical, psychological, and social symptoms during the menopausal transition, including hot flushes, night sweats, sleep disturbances, sexual dysfunction, mood disorders, vaginal dryness, dyspareunia, back pain, change in skin, weight gain, and cognitive declines, which impacts their quality of life negatively for longer than 10 or 15 years [1,2]. Hormone Replacement Therapy (HRT) is often prescribed to alleviate MS. However, despite the effectiveness of HRT, many women refuse hormonal drugs because of some side effects such as vaginal bleeding, bloating, or other HRT-linked conditions. Eventually, the Women's Health Initiative (WHI) report, it has associated HRT with an increased risk for breast cancer and thromboembolism [3, 4]. Consequently, through menopause non-hormonal several interventions as complementary-alternative medicine (CAM) such as yoga, acupuncture, massage, Tai chi, physical exercise, phyto-therapy, homeopathy, and vitamins are relatively have emerged. The positive results on welfare obtained regarding wide range of CAM have been confirmed by many evidence-based studies and preferred to relieve menopausal complaints (MS) by many women (22%-95%) [5, 16].

Cupping therapy (CT) is not as well-known as other CAM (. In fact, CT has been used since antiquity for health promotion, preventive and

therapeutic purpose in various diseases for millennia through the world, including Turkey such as herpes zoster [17], facial paralysis [18], stroke and fatigue [19], arthritis and osteoporosis [20], anemia and heart disease [21], insomnia, and emotional problems [22], cellulite, acne, psoriasis and other skin problems [23], hypertension [24,25], diabetes mellitus [26], metabolic syndrome [27], fibromyalgia [28], headache, back and neck pains [29,33], carpal tunnel syndrome [34], and even menopausal symptoms (MS) [35]. In spite of its common use by folk healers and practitioners, the evidence for effectiveness of CT is not always well established due to some methodological limitations. However, CT has re-emerged and become a popular formal treatment in the clinical area recently as a cost-effective and simple method and has transformed into a better version over the years [36]. The main purpose of this CT with various mechanisms is; to open meridians so that Qi (invisible life force circulates through the blood vessels and nourishes the body tissue) can flow freely; to increase oxygenation and capillary blood flow, to activate lymphatic system, to regulate the function of organs by assisting in the elimination of waste products/excess heavy metals or toxins/oxidative stress from the body and to promote endothelial cell repair by boosting immunity [37]. CT also provides information on 1) where the problem is, 2) the kind of problem, and 3) the severity of the problem. In this regard, CT is diagnostic as well as therapeutic and its effects are immediate [15, 33]. Similar to acupuncture, CT follows the lines of the meridians at different points on the body. In essence, CT provides one of the best deep tissue massages by creating a vacuum effect within cups (plastic-PVC,

silicone, glass or bamboo), which is called as dry-CT. In wet CT with combination of vacuum, the skin is lacerated by superficial incisions so that blood is drawn into the cup using a vacuum, which is also known as "hijama" and it is seen to be more effective than dry-CT. Wet-CT is generally considered safe and painless when performed by trained and competent professionals [9,29]. However, wet CT can cause rarely infections on the cupping region. The cupping point's appearance (red marks due to local suction on blood vessels) generally returns to normal in a few days. Like many CAM, CT includes the potential to improved many different clinical conditions and enhance the quality of life [9, 38, 40]. More studies have been proposed to elucidate the health benefits of CT in clinical situations and to encourage its practice in the clinical setting by World Health Organization [41].

Evaluation of life quality is quite remarkable in terms of measuring well-being, which is one of the health indicators in postmenopausal women. Initiatives to increase postmenopausal women's life quality are also valuable in reducing the burden on public health costs. Indeed, the effectiveness of wet CT to treat MS is well unknown across the world [16]. At present, there is not any study about therapeutic effect of CT for MS in the literature. Therefore, the present study was designed to objectively evaluate the effectiveness of the wet CT on menopause specific quality of life (MENQOL).

Methods:

Sample Size, Study Design, and Participants

We rigorously implemented a randomized controlled pre and post treatment trial to evaluate the effectiveness of wet CT on MENQOL between July 2015 and July 2016 at a Gynecology Outpatient Clinic of University Hospital in Ankara, Turkey. Sample size was calculated on the basis of the assumptions that the minimum clinical improvement, that resulted in 30 women in each group with 80% power and $\alpha=0.05$. In totally, sixty eligible women with menopause at least 3 months (based on the patient record) were selected through purposive sampling during their routine gynecologic visit. Then, they were randomly assigned into control (routine self-care) (n=30) group and interventional (wet CT group) (n=30) group using the table of random numbers. At the end of study; the intervention group received wet CT, whereas the control group received no treatment.

For the both groups, inclusion criteria included: 1) diagnosed with natural menopause (last menstrual ≥ 12 months) at least 3 months, 2) open to communication and cooperation, 3) volunteering women were included in the study, 4) women without an auditory or mental disability, 5) aged between 40-65 years, and 6) not receiving specific treatments for MS such as HRT or other medical therapies (within previous six months and also during study period). Exclusion criteria included: 1) possible spinal pathology, malignancies, 2) being currently surgery and severe or progressive health condition, 3) bleeding disorders, 4) having side effects related to the wet-CT during study period, and 5) having a special drug (anticoagulants or others) or dietary regimen.

The instruments used include 1) Questionnaire Form and 2) MENQOL scale.

Instruments:

1. Questionnaire Form: This form consists of total 24 questions in two sections; related with socio-demographic characteristic (n=9), and general health and menopause specific characteristics (n=15), which was developed by researchers benefiting from the literature [5, 16].

2. MENQOL: The scale was introduced in 1996 as a tool to assess health-related quality-of-life in the menopausal period by Hilditch et al [42]. It was adapted to Turkish society by Kharbouch and Sahin (2007) and its validity and reliability study was carried out. The scale is a self-

administered questionnaire and consists of a total of 29 items in four domains: vasomotor (items 1-3), psychosocial (items 4-10), physical (items 11-26), and sexual (items 27-29). For each item, participants were asked to rate whether or not they had experienced each symptom in the past month from 0 (not all bothered) to 6 (extremely bothered). As the score increases, the severity of the complaint increases and the quality of life decreases. The total scale score is not calculated. The Cronbach's alpha value of the scale is 0.73-0.88 [2].

Procedures

The data were obtained through face-to-face interview method by the researchers during the routine gynecologic visits at the study hospital. Filling up the Questionnaire form and MENQOL scale lasted about 20 minutes. Five points of the posterior neck, bilateral perispinal areas the neck and thoracic spine were located for wet CT according to the WHO criteria [41]. Same points were used for all women in the intervention group.

All women in the intervention group underwent a physical and neurological examination and, then Wet CT was performed to women by a single physician who was trained in CT and regularly performed CT in the study hospital. For the CT, participants were asked to lay topless on the massage stretcher. This protocol for application of wet CT involved the following steps; first, the selected site was cleaned with antiseptic solutions; sterile disposable plastic cups (5 cm) were placed on selected region bilaterally. Then, negative pressure was applied by cupping pump. After about 5 minutes of wait, cups were gently removed and twelve superficial incisions was made on each chosen area in 2 mm-depth using a sterile auto-lancet; the cups were replaced again over the incision area; suctioning was made by manual pumping and blood was drained; after 10-15 minutes' till filling with blood the valve of cup were opened and removed the cups. Finally, the area was disinfected by betadine and dressed. For the possibility of any negative reaction, a physician and a nurse with emergency response kit were kept ready in the room during the CT procedure.

Women were advised to avoid water contact on the cupping areas within the next 24 hours and limited tobacco/alcohol intake to prevent delays in wounding healing. No advice for stretching or strengthening exercises was given after the intervention. All other medications, CAM therapies, and physical therapies were prohibited for two weeks. After some minutes of rest, patients were free to leave. No adverse events were reported throughout the study and this procedure was very well tolerated (cupping point assessment was made by using the CONSORT criteria [43]. Meanwhile, the control group received routine self-care. After 2 weeks, women in the both groups again filled out the MENQOL scale. At the end of the study, the women in the control group were counseled the CT and then also offered to specialist in case of severe MS. No women were dropped out from study following randomization.

Ethical Approval

The study protocol was approved by the Institutional Review Board of Research Department of Gynecology Outpatient Clinic. (approval number: 06-4358) All women who suffer from menopause syndrome for at least three months signed written informed-consent about study purpose, benefits, the right to refuse and withdraw at any time, as well as obtain confidentiality before the beginning of the study. Rules specified in the Helsinki Declaration were observed in the data collection phase.

Data Analysis

The descriptive statistical analyzes the number of percentage, mean, standard deviation were used. Data were evaluated with the Statistical Package for the Social Sciences (SPSS, version 20.0, Chicago, USA). After the Kolmogorov-Smirnov test was performed to evaluate normality.

Differences between groups were assessed using the Chi-square test or the Fisher exact test (if the expected count was <5) for categorical variables and either the Mann-Whitney test (two groups) or the Kruskal-Wallis test (three or more groups) for ordinal variables. Differences in change between groups were evaluated with Student t test, Paired t-test, and Repeated Measures ANOVA. Two-sided $p < 0.05$ was considered statistically significant.

Results

As shown in Table 1, baseline characteristics were not significantly different for both groups ($p > 0.05$). In the intervention group; it was established that the mean age of women was 54.1 ± 4.9 (min=42,

max=63), the average BMI was 28.2 ± 3.8 . It was found that 90% of the women were married, 70% of women's income level was good, 66.7% graduated from primary school, 63.3% were housewife and the average number of delivery was 3.1 ± 4.6 (all women had social security).

It was investigated that hot flashes (100.0%), sleeping problems (96.6%) and joint and muscle pain (96.6%) were the most frequently experienced MS. Also, it was determined that 93.3% of the women had emotional problems, 90% of the women had sexual problems, 77% of the women had aches in back of neck or head, respectively (Table 1).

Baseline Characteristics (n=60)	Control	Intervention	P value*
	Mean \pm SD	Mean \pm SD	
Age	53.2 \pm 4.5	54.1 \pm 4.9	0.36
Age of menopause	47.6 \pm 3.1	48.1 \pm 4.6	0.45
Body mass index (BMI)	28.2 \pm 3.8	27.4 \pm 4.2	0.60
Number of delivery	2.9 \pm 5.5	3.1 \pm 4.6	0.33
Marriage	N (%)	N (%)	
Married	26 (86.6)	27 (90.0)	0.73
Single	4 (13.4)	3 (10.0)	
Education			
Primary school	22 (73.3)	18 (66.7)	0.64
High school and above	8 (26.7)	11 (33.3)	
Occupation			
Working	10 (33.4)	12 (36.7)	0.31
Housewife	20 (66.6)	18 (63.3)	
Income level			
Good	24 (80.0)	21 (70.0)	0.16
Poor	6 (20.0)	9 (30.0)	
Menopausal symptoms**			
Having hot flashes-experiencing sweat	30 (100.0)	30 (100.0)	0.10
Joint and muscle pain	30 (100.0)	29 (96.6)	0.10
Having sleeping problems	28 (91.6)	29 (96.6)	0.10
Emotional problems	26 (86.6)	28 (93.3)	0.10
Vaginal dryness / dyspareunia	26 (86.6)	27 (90.0)	0.10
Aches in back of neck or head	22 (73.3)	23 (77.0)	0.10

* χ^2 test, Mann Whitney U test, and student's t test

** Other symptoms in totally; change in the appearance of skin (68.5%), headache (67.1%), feeling memory fading (53.5%), energy decrease feeling (51.6%), weight gain (68%) and hair problems (48.4%).

Table 1; Baseline characteristics of women

The mean pre-test MENQOL subscale of intervention group; vasomotor area was 4.34 ± 1.12 , psychosocial area was 2.77 ± 1.24 , physical area was 3.45 ± 1.06 , and sexual area was 3.90 ± 1.55 . The mean post-test MENQOL subscale; vasomotor area was 3.95 ± 0.92 , psychosocial area was 2.66 ± 1.23 , physical area was 3.16 ± 1.00 , and sexual area was 3.65 ± 1.49 (Table 2).

The mean pre-test MENQOL subscale of control group; vasomotor area was 4.22 ± 0.75 , psychosocial area was 2.00 ± 1.16 , physical area was 2.63 ± 0.82 , and sexual area was 3.36 ± 1.32 . The mean post-test MENQOL subscale; vasomotor area was 4.07 ± 0.70 , psychosocial area was 1.98 ± 1.23 , physical area was 2.60 ± 0.79 , and sexual area was 3.31 ± 1.26 (Table 2).

MENQOL Subscales	Intervention	Analysis ^a	Control	Analysis ^a
	Mean \pm SD		Mean \pm SD	
Vasomotor				
Pre-test	4.34 \pm 1.12	t=5.065	4.22 \pm 0.75	t=1.112
Post-test	3.95 \pm 0.92	p=0.000	4.07 \pm 0.70	p=0.043
Psychosocial				
Pre-test	2.77 \pm 1.24	t=0.441	2.00 \pm 1.16	t=2.096
		p=0.662		

Post-test	2.66±1.23		1.98 ±1.23	p=0.090
Physical				
Pre-test	3.45±1.06	t=8.060	2.63±0.82	t=2.841
Post-test	3.16± 1.00	p=0.000	2.60±0.79	p=0.080
Sexual				
Pre-test	3.90±1.55	t=3.557	3.36±1.32	t=1.720
Post-test	3.65±1.49	p=0.044	3.31±1.26	p=0.096

*Student t test , Paired t test, SD; standart deviation

Table 2: The distribution of the mean pretest posttest MENQOL scores of women for both groups

At the beginning of the study, before the wet CT intervention there was no significant differences between in two groups in terms of scores in MENQOL subscales (p>0.05). In table 2, in the intervention group; there were significant changes of the MENQOL score before and after wet-CT in the vasomotor, physical area and sexual area (p<0.05). There was no statistically significant change in the psychosocial area before and after the intervention (p> 0.05). In the control group; there was no statistically

significant difference between the pretest and posttest in all MENQOL subscales except the vasomotor area (p> 0.05).

In different time, the vasomotor (p=0.002) and physical area (p<0.001) scores were statistically significant (p = 0.000) in both groups (Figures 1-2). It was found that the change in the psychosocial between the two groups was not different (p>0.05) (Table 3).

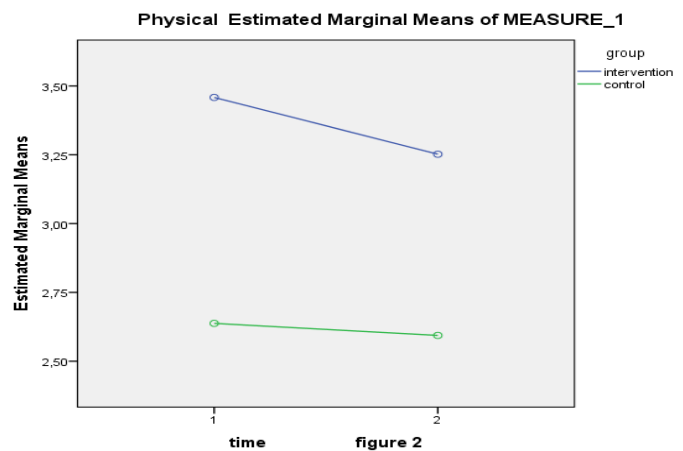
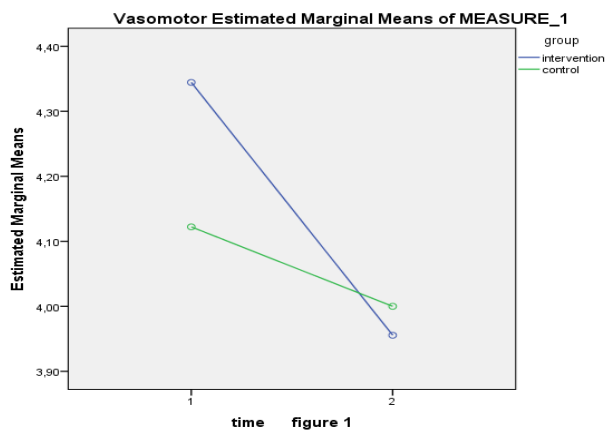
MENQOL Subscales	Pre-test (Time I)		Post-test (Time II)		*Analysis	
	Mean ± SD		Mean ± SD		Time	X
Vasomotor						
Intervention	4.34±1.12		3.95±0.92		F=37.100 ^b p=0.000	F= 10.099 p=0.002
Control	4.22±0.75		4.07±0.70			
Psychosocial						
Intervention	2.77±1.24		2.66±1.23		F=4.545 ^b p=0.037	F =2.909 p = 0.93
Control	2.00±1.16		1.96±1.09			
Physical						
Intervention	3.45±1.06		3.16± 1.00		F=93.674 ^b p=0.000	F =39.557 p= 0.000
Control	2.63±0.82		2.60±0.78			
Sexual						
Intervention	3.90±1.52		3.65±1.49		F=3.615 ^b p=0.011	F=0.213 p=0.646
Control	3.36±1.32		3.31±1.26			

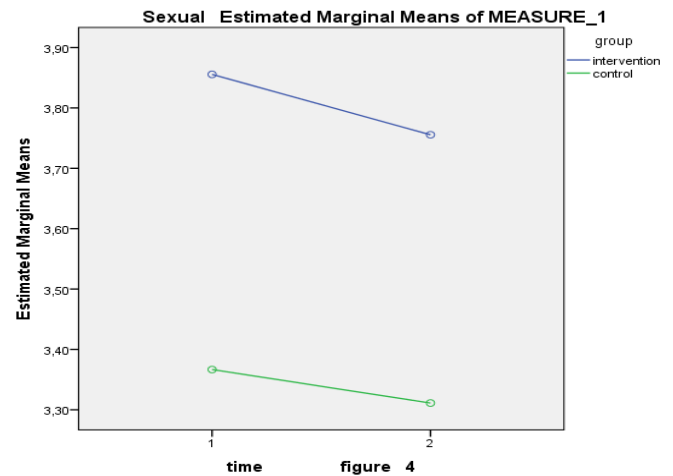
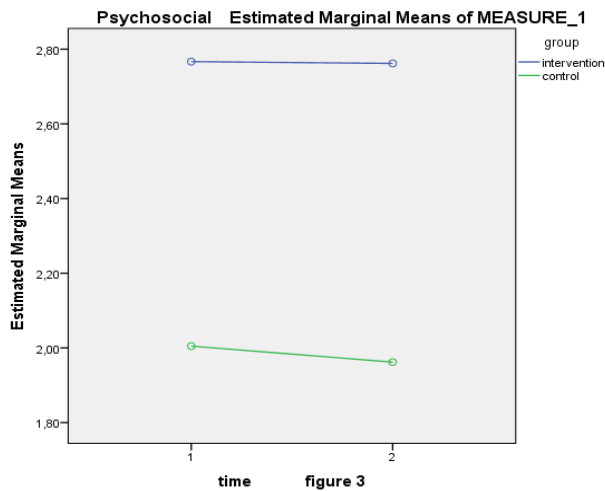
^bRepeated Measure ANOVA

Table 3: Comparison of the mean pretest-posttest MENQOL scores of women in both groups

It was determined that the change between the two groups was different from each other for sexual area. The increase in this area was found to be significant in favor of the intervention group (p<0.05), (Figure 3).

In the intervention group showed a significant improve after the wet CT within two weeks compared to the control group in all MENQOL subscales area (p<0.05), (Figure 4).





Discussion

In the present study, it was determined that the most common symptoms in women with menopause experiencing hot flashes, night sweats, difficulty sleeping, sexual problems and back or neck pain (Table 1). Many women seek solutions for their problems and they show interest in non-pharmacological methods. As a matter of fact, there are also many good news from previous studies regarding the clinical effect of CAM methods on MS such as acupuncture, aromatherapy, hypnosis, biofeedback, homeopathy, herbal medicine, reflexology, yoga, natural products (herbal, dietary, vitamin and mineral supplements), reiki, and cognitive behavioral therapies 5-16). However, the lack of evidence-based studies about applicability or effectiveness of CT as a part of CAM in order to reduce MS in the literature limits the discussion of our study.

Our study confirmed that wet CT has apparently beneficial effect on MS-related life quality only within two weeks ($p < 0.001$), (Table 2). Most of the previous randomized controlled trials's results were consistent with our positive results and they were promising on therapeutic effect of CT in other clinical conditions (I to IV evidence level) [19,21-24,26,27, 32,33,35,38].

Michalsen et al (2009) concluded that CT was effective therapy in reducing the pain of carpal tunnel syndrome [34]. In different study Al-Bedah et al (2016) it has been showed that CT is highly effective for reduction in low back pain in women [29]. According to the Yuefeng et al (2010), dry CT was more effective than analgesic drug treatment in women with painful condition and strain [22]. In a randomized controlled studies conducted by Refaat et al (2014), it was found a significant reduction in serum lipid profile as well as increasing HDL-C serum level as a preventive effect against atherosclerosis in the cupping group. In the same study, it was found that Wet CT has positive effect to blood glucose level by enhancing insulin sensitivity on subject who has diabetes mellitus [44].

Furthermore, CT is also reported to be effective in cellulitis, asthma, and headache, and migraine, genital or oral ulceration [30]. CT appears to be positive effective for infection control by filtering out pathogen, increasing the white blood cell counts, producing disease-fighting lymphocytes and enhancing the body's resistance [26]. A different study examined the benefit effects of CT on cardiac problems [21]. It has been also stated that dry CT is effective in more than half of the women (56%) on MS in particular emotional problems, insomnia, poor memory, and pain in the low back or knee [35].

In the light of all this information, it is thought that all these positive changes are impressive. The women's experiences with wet CT support the assumption that wet CT might be a prophylactic or protective effect for MS. Several ways of action; might explain the significant effects of wet CT on MS such as anti-nociceptive (analgesic), immune, neural, haematological, and physiological effects [26]. Wet CT leads to improve the blood flow tissue perfusion, and oxygen supply, removal of toxins and other degenerative conditions from the body, regulated neuroendocrine and immune system balance, and provided relaxation of muscle with vasodilation, relaxation thus allowing a deep relaxation to move through the entire body and contributing to increased rate of healing disease [36].

As a matter of fact, CT can be also applied in combination with other treatment methods to increase the effectiveness of treatment creating synergetic effect [18, 22]. It is thought that the positive change in the women's quality of life may be also due to the functioning of wet CT similar to the effect of acupuncture. In the studies of Dodin et al (2013), Jonhson et al (2019), and MacPherson et al (2010) it has been proposed that acupuncture may have potential to relieve vasomotor symptoms frequency and severity by increasing the activity of hypothalamic beta-endorphin and improve quality of life of postmenopausal women. Even if acupuncture therapy is offered as an alternative to HRT, acupuncture appeared to be less effective than HRT [11, 14, 43]. Although it has some negative health effects many studies reported that HRT is the most effective therapy for MS. There are many studies in the literature regarding the effect of acupuncture on vasomotor symptoms. For instance, a randomized controlled study was determined that integrating CT with acupuncture decreased the severity and intensity pain or psychological changes [7, 10, 22]. Thus, they proved CT to be a good analgesic and anti-inflammatory with efficacy better than acetaminophen for treatment of various conditions.

CT may also reduce anxiety through a process called homeostatic regulation, buffering hormonal disturbance and stimulating feel good endorphins. Researchers also believe that CT can reduce pain and inflammation throughout the body and it can promote mental and physical relaxation. There was moderate evidence for the short-term effects of yoga, mindfulness and meditation on psychological symptoms in menopause [8, 13, 14]. Interestingly, Gartoulla et al (2015) tested CT for emotional problems that compared to medications alone, CT combined with plus medications was significantly better on tension and depression remission [12]. Significant reduced on anxiety and sleeping difficulties complaints was found in the CT group only [28, 38]. In the present study, we tested

wet CT on psychosocial symptoms to postmenopausal women who were not receiving any treatment. On the contrary, results of the wet CT showed a little improvement in the women's quality of psychosocial area, therefore, it is not considered truly effective within two weeks ($p>0.05$) (Table 3).

Conclusion

In conclusion, wet CT directly decreased women's vasomotor, physical and sexual problems and increased their quality of life within two weeks. In this regard, relatively evidence emerged only a single intervention that wet CT might be effective in the treatment of MS. These results important source of variation to other trials to improve postmenopausal women's quality of life as it is the first time in the literature. Further comprehensive randomized controlled trials aiming at the mechanism of repeated interventions in different intervals and body points with a broader sample size are required to clarify the effect of wet-CT and better understand to expand the therapeutic spectrum of wet CT on MENOQL in long term following.

Limitation

This study is limited by its short duration. These results of this study may not be generalized due to the small sample size. Although we had positive affect in relieving MS after wet CT, further studies with larger sample size may planned to determine the long-term results of wet CT in different symptoms related to menopause. The other limitation of the study was that the research could not be blinded due to the nature of intervention and the women aware of the mechanism and reason of the CT. On the other hand, there are no suitable sham devices for placebo effect. Because there is lack of clinical trials on this topic, we tried to run a randomized controlled trials with the best possible methodological approach, even though we are aware of its some limitations.

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Conflicts of interest

There is no conflict of interest to declare.

Authors' Contributions

GP and NG participated in the design of this clinical trial. They drafted this manuscript, conducted the clinical trial and participated the statistical analyses. All authors read and approved the final manuscript.

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