INTRODUCTION

Menopause is accompanied with the dramatic shift in hormonal balancing, decrease in estrogen and increase in FSH and LH, that ultimately reduces the level of progesterone and causes permanent amenorrhea. Acute menopausal symptoms include vasomotor phenomena (hot flashes and night sweats), and psychosomatic symptoms that is differently experienced in people with mental, social and cultural characteristics. The most common symptom during the menopausal period that women suffering from, is hot flashes. The pathophysiology of hot flashes is unknown, however, the reduction and cessation of estrogen hormone plays an important role in instability of thermoregulatory center in hypothalamus. Various studies express significant tendency of women to complementary therapies, acupuncture and medicinal plants due to low side effects and their optimal effects. Nettle with the scientific name of urticadioica contains phytoestrogen components such as flavonoids, sterols such as beta sitostrol and lignans. Acupuncture is also a healthy and accessible method with minimal side effects that can be effective for the treatment of hot flashes. According to the above-mentioned effectiveness of complementary medicine, we decided to design a clinical trial to evaluate the effect of nettle plant and acupuncture in controlling hot flashes symptom.

ABSTRACT

Acute menopausal symptoms include vasomotor phenomena (eg. hot flashes and night sweats), and psychosomatic symptoms that is differently experienced in people with mental, social and cultural characteristics. The most common symptom during the menopausal period that women suffering from, is hot flashes. The pathophysiology of hot flashes is unknown, however, the reduction and cessation of estrogen hormone plays an important role in instability of thermoregulatory center in hypothalamus. Various studies express significant tendency of women to complementary therapies, acupuncture and medicinal plants due to low side effects and their optimal effects. Nettle with the scientific name of urticadioica contains phytoestrogen components such as flavonoids, sterols such as beta sitostrol and lignans. Acupuncture is also a healthy and accessible method with minimal side effects that can be effective for the treatment of hot flashes. According to the above-mentioned effectiveness of complementary medicine, we decided to design a clinical trial to evaluate the effect of nettle plant and acupuncture in controlling hot flashes symptom.
studies done on nettle in modern medicine indicated its diuretic, anti-hypertensive, anti-diabetic, anti-spasmodic, anti-anemia, anti-inflammatory and regulating lipid profile effects as well as anti-rheumatic and anti-arthritis effects [9]. The effect of nettle root extracton inhibiting 5-alpha reductase enzyme has been reviewed and its administration in the treatment of BPH in various studies has been approved [9, 10].

Various studies showed the effectiveness of acupuncture in improving frequency and severity of hot flashes in premenopausal and postmenopausal women [11]. It is believed that acupuncture relieves hot flashes by affecting neuroendocrines. Increase in endorphins influences the amount of GnRH, followed that ACTH causes the reduction of cortisol, catecholamines and sympathetic tone. On the other hand, LH is decreased and FSH would be modulated. The other mecanisms are affecting thermoregulatory center of the hypothalamus and reducing the activity of vasomotor center in the medulla oblongata. Some other studies also expressed that acupuncture has no effect on reducing vasomotor symptoms in menopausal women [12]. But due to extensive researches carried out on use of complementary and acupuncture therapies and also providing beneficial complementary therapy protocols with fewer side effects in women diseases, including hot flashes, they are used as adjuvant therapy in many diseases [4].

In this study, we guess that the use of herbal medicine accompanied by acupuncture in the treatment of hot flashes seems essential to achieve more complete results.

**Evaluation of Hypothesis**

This study will be designed as randomized double blind clinical trial. Patients will be selected by using random sampling method among the patients referring to gynecological and also acupuncture clinics who passed the inclusion criteria. Inclusion criteria include: 1. Perimenopausal women (patient's own reporting on irregular menses in the last three months or more) and postmenopausal women (patients who experienced amenorrhea for 12 months or more), 2.Age of 45-60 years old, 3.having a relatively a normal life with the husband.

Exclusion criteria include 1.Pregnancy, 2.history of hysterectomy or oophorectomy, 3.Anti-cancer therapies because of Malignansies, 4.history of cancer in the past five years, 5.history of allergies 6.history of chronic physical and mental diseases such as diseases related to kidney and heart, depression, aplastic anemia, hypothyroidism and hyperthyroidism, thromboembolic events, uncontrolled hypertension and diabetes mellitus, 7.vaginal bleeding with unknown reason in the past six months, 8.Taking drug treatments such as HRT and SSRI for hot flashes during the past 8 weeks.

Patients will be randomly divided into four groups after entering the study, which include (1. acupuncture + Nettle, 2. acupuncture + nettle placebo, 3. placebo of acupuncture + Nettle and 4. placebo of acupuncture + placebo of nettle). Intervention will be done on these groups for 7 weeks (two sessions of acupuncture in the first week to the fourth and one session in fifth week to seventh). Nettle root extract will be administered 150 mg three times a day [13].

Data collection tool includes personal characteristics, daily reports, questionnaire of Menopause Rating Scale (MRS) and the Menopause-Specific Quality of Life Questionnaire (MSQoL). The daily reporting is a table that severity of hot flashes is recorded by the patient, one week before intervention, week 7, and week 11 after intervention[14]. Menopause Rating Scale is a scale that deals to examining most important symptoms of menopause. This questionnaire includes 11 questions related to three areas of physical (4 questions), psychological (4 questions) and genitourinary characteristics (3 questions) [15].

Menopause-Specific Quality of Life Questionnaire also examines four dimensions of vasomotor, psychomotor, physical and sexual abilities in patients that answering to these questions has been set as a criterion degreed from 0 to 3; in fact, quality of life is poor whatever score achieved is greater [16].

Data analysis will be done by SPSS statistical software, Version 16. Significant level of p is considered less than 0.05.

**CONCLUSION**

According to the indigenous nettle plant in most parts of Iran, reasonable price, low side effects, containing phytoestrogens, frequent administrations in different diseases of women in the references of Persian medicine and also its properties that have been proven by scientific researches nowadays, it is predicted that this plant could play an important role in treatment of hot flashes. Acupuncture is also a healthy and accessible method with minimal side effects that can be effective in this disorder. It is expected that acupuncture in combination with nettle show dramatic effect on hot flashes symptom in postmenopausal and premenopausal women.

**Conflict of Interest Statement**

The authors have no conflict of interest.

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