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Study Protocol

Effects of acupuncture in postmenopausal women with prehypertension or stage 1 hypertension: study protocol for a prospective, comparative, interventional cohort study

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ABSTRACT

Background: Hypertension is a major cause of cardiovascular disease and associated mortality, and postmenopausal women are at a high risk of hypertension. We aim to investigate the hypotensive effect and safety of acupuncture, focusing on postmenopausal women with prehypertension and stage 1 hypertension. In addition, we aim to investigate whether the effect of acupuncture treatment differed, depending on Sasang Constitution and cold–heat pattern.

Methods: This study is designed as an intervention cohort study. Two hundred postmenopausal women aged <65 years with prehypertension or stage 1 hypertension living in Daejeon city in Korea will be recruited, and randomly assigned to either an acupuncture or no-treatment control group. The intervention will consist of four sessions; one session will include acupuncture performed 10 times for 4 weeks. There will be a 20-week observation period after each session, and the total study duration will be 96 weeks. Acupuncture will be applied at the bilateral Fengchi (GB20), Quchi (LI11), Zusanli (ST36),

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and Sameumgyo (SP6) acupoints. The effect of acupuncture will be evaluated by comparing the change in systolic and diastolic blood pressure between the acupuncture and control groups every 4 weeks until the end of the study.

Discussion: To evaluate the success of blood pressure management, long-term observation is required, but no long-term studies have been conducted to evaluate the effect of acupuncture on blood pressure in postmenopausal women. To our knowledge, this study will be the first long-term study to investigate this issue for more than 6–8 weeks.

1. Introduction

Hypertension is the major risk factor for cerebrovascular disease and cardiovascular disease. Hypertension guidelines (The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; JNC7) recommend the management of blood pressure (BP) and the risk factors of hypertension from the prehypertension stage.[1,2] Individuals with prehypertension are twice more likely to progress to hypertension than individuals with normal BP.[3] Moreover, BP increases sharply in postmenopausal women due to imbalances in the cardiovascular system, such as decreased estrogen levels and the activation of the renin–angiotensin system.[4,5] Postmenopausal women are more likely to develop hypertension, obesity, diabetes, and other cardiovascular diseases (CVD) than men.[6] Therefore, in postmenopausal women, BP must be monitored and managed more carefully.

Pharmacotherapy, which is a common method of controlling blood pressure, cannot be used in the prehypertension stage. A recent Cochrane review found that antihypertensive pharmacotherapy does not provide any benefit for mild hypertension.[7] In another study, 9% of the patients discontinued treatment because of the side effects of antihypertensive drugs.[8] To complement or replace pharmacotherapy to manage BP in postmenopausal women, continuous research and development of non-pharmacological interventions, such as lifestyle modification, are required.[9] Long-term use of antihypertensive medication may result in side effects and increase the cost of medical care, thereby lowering the quality of life.[10]

Acupuncture treatment, which is widely used in East Asia, can be used as a non-pharmacological intervention to control hypertension in postmenopausal women. In several studies, acupuncture showed a BP-lowering effect in men and women in the prehypertension and hypertension stages.[9–12] Acupuncture has also been shown to be effective in controlling vasomotor symptoms, such as hot flushes in menopausal women.[13] Recent studies have shown that the use of acupuncture is increasing and it is effective for lowering blood pressure.[12,14] Another study reported that the use of acupuncture in combination with pharmacological therapy is effective in decreasing arterial BP in patients with prehypertension or hypertension.[15] Although several studies have shown that acupuncture is effective in lowering blood pressure,[10–16] the evidence from well-designed studies that is needed to introduce acupuncture treatment for hypertension in postmenopausal women in clinical practice is still lacking.

Sasang Constitution (SC) types and cold–heat patterns categorize individual characteristics that indicate health status and human individuality.[17,18] These classification systems are commonly used in Korean medicine (KM) practice, and they are being standardized for use as an alternative medicine. Previous studies have suggested that the effect of acupuncture differs depending on SC type and cold–heat pattern.[19,20] Symptoms must be assessed according to constitution and pattern identification, and treatment must be prescribed accordingly.[21,22] Recently, Lee et al's study showed that the prevalence of hypertension among the four SC types was the highest in the Taeeum (TE) type, and that the SC type could be a risk factor for hypertension.[23]

Hence, this study has two objectives: first, to establish evidence of the efficacy of acupuncture in lowering BP in postmenopausal women with prehypertension and stage 1 hypertension; second, to analyze the effects of acupuncture according to SC and pattern identification.

2. Methods

2.1. *Study design*

This study is a prospective, comparative, randomized, interventional cohort study. To evaluate the hypertensive effect of acupuncture, we will divide the participants into a treatment group and a no-treatment control group; the cohort model will be used to observe the long-term effects of acupuncture.

This study will consist of four sessions. Each session will include acupuncture treatment administered for 4 weeks, followed by a 20-week follow-up period in the acupuncture group. The participants in the control group will not receive acupuncture treatment; they will simply be observed for 24 weeks (Fig. 1). The no-treatment control group will be educated using a brochure containing information on hypertension while maintaining routine care, without acupuncture treatment. During the study period, lifestyle modifications, such as a low-salt diet, weight control, alcohol restriction, smoking cessation, lipid- and carbohydrate-intake control, dietary fiber intake, and exercise, will be implemented.

The schedule of trial enrollment, interventions, and assessment is presented in the SPIRIT flow diagram (Fig. 1).