Brief Title: Walking Exercise on Memory, Subjective Cognitive Complaint, and Brain-derived Neurotrophic Factor for Hypertension

Official title: A Study of the Individualized Walking Exercise Program on Memory, Subjective Cognitive Complaint, and Brain-derived Neurotrophic Factor Among Postmenopausal Hypertensive Women

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Study Protocol

Background

In Taiwan, the adult prevalence of hypertension increased from 20.8% in 2016 to 25% in 2018. More than half of women over age 60 have hypertension, and the hypertension control rate among Taiwanese women remains low, at 28.5% to 50% . These consequences suggest the presence of barriers to hypertension care, including cognitive impairment with memory decline. Memory is one of the most common and most frequently impaired cognitive functions in women with hypertension, and 25% to 55.1% of older women with hypertension reported memory impairments. One non-pharmacological strategy that has demonstrated beneficial effects on cognitive function, specifically improved memory, through positively regulating plasma brain-derived neurotrophic factor, is physical exercise.

Objective

The purpose of this study was to examine the effects of an aerobic walking program on memory, subjective cognitive complaints, and brain-derived neurotrophic factor among older women with hypertension.

Methods

1. Study design:

This study employed a single-blind, randomized controlled trial. Two parallel groups with two assessment periods was adopted to evaluate the effects of the intervention. The inclusion criteria were as follows: (1) age 60 to 80 years, (2) diagnosed with hypertension for at least 6 months, (3) self-reported indications of problems with memory or thinking skills**.** The exclusion criteria were as follows: (1) probable cognitive impairment as assessed by the Montreal Cognitive Assessment (< 24 points); T(sai et al., 2012), (2) significant conditions limiting walking ability (e.g., musculoskeletal problems, visual impairment), (3) already participating in 30 minutes or more of moderate-intensity exercise five times a week, (4) a history of severe cardiovascular disease, and (5) a history of neurologic or psychiatric disorders such as stroke, head injury dementia, Parkinson's disease, and depression.

2. Research tools:

Data collected for this study also included demographic, health-related, and disease-related information in pretest and posttest data collection. The primary outcome was memory performance, which was measured with the Hopkins Verbal Learning Test; the secondary outcomes were subjective cognitive complaints and brain-derived neurotrophic factor. Subjective cognitive complaints were measured with the Cognitive Failures Questionnaire, and brain-derived neurotrophic factor was measured through laboratory analysis of blood samples.

3. Intervention approaches:

Participants in the intervention group received a 24-week aerobic walking program with five 30-mimute sessions per week. The aerobic walking program was delivered by a registered nurse with

training as an instructor in aerobic walking exercise. The instruction given to participants consisted of a 60-minute face-to-face individualized education session on how to perform 30 minutes of walking exercise five times a week, an intervention booklet, and follow-up counseling by telephone and social media every two weeks.

Statistical Analysis Plan

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 25 for Windows (Chicago, IL, USA). Descriptive statistical methods were implemented to characterize the characteristics of the participants and study variables. Independent *t*-tests, chi-square tests, and Fisher's exact test were used to examine the homogeneity between the two groups. Paired *t*-tests were employed to examine the changes in each group between the pretest and 24 weeks in memory, subjective cognitive complaints, and brain-derived neurotrophic factor. The generalized estimating equation was used to evaluate whether memory, subjective cognitive complaints, and brain-derived neurotrophic factor were different between groups at pretest and after 24 weeks. A significance level of 5% was used for between-group comparisons and interaction terms.