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Modifications in response to the COVID-19 pandemic in a multimodal intervention trial to prevent cognitive impairment in older women with cardiovascular disease

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Abstract

Background: Cognitive impairment disproportionately affects women compared to men, and cardiovascular disease (CVD) increases risk. Physical activity and cognitive training may have synergistic effects on cognition when delivered together. However, no multimodal intervention has targeted older women (≥65) with CVD or has utilized a scalable lifestyle approach. Our study seeks to evaluate the efficacy of *MindMoves*, a 24-week multimodal intervention, on cognition and serum biomarkers in 254 older women with CVD. However, effects of the COVID-19 pandemic complicated implementation of our original in-person trial protocol. The purpose of this paper is to describe protocol modifications made by our interdisciplinary team in response to COVID-19,

Method: We employ a 2x2 factorial randomized controlled trial design to determine independent and combined efficacies of *Mind* (cognitive training with BrainHQ) and *Move* (lifestyle physical activity with goal self-monitoring and nurse-led group meetings) interventions. Outcome measures of cognition and serum biomarkers (brain-derived neurotrophic factor, vascular endothelial growth factor, insulin-like growth factor 1) are collected at baseline, 24, 48, and 72 weeks. Nurse scientists oversee interventions, cardiologists refer women ≥65 years with CVD and no cognitive impairment from clinics, and a cognitive neurologist and neuropsychologist oversee outcome measures. Pandemic-related protocol changes were implemented to maximize study integrity and participant/staff safety. Targeted mailings were added to in-person recruitment strategies. Screening activities shifted to phone. In-person data collection was modified for phone/virtual settings, including accelerometer mailing (device measure of physical activity), neurocognitive tests validated for phone use, and home-based participant-administered dried blood spot collection for serum biomarkers. Women are now provided and trained to use iPad tablets to complete intervention activities virtually (e.g., *Move* group meetings).

Result: The anticipated number of participants (19) in the first cohort was recruited without disruption, in the original timeline. Participants completed all phone-based

questionnaires and mailed devices were returned. Randomization occurred as planned. Intervention activities are ongoing, including phone-based orientations and ≥90% attendance at virtual meetings.

Conclusion: The modified trial protocol is being successfully implemented during the COVID-19 pandemic. Results will demonstrate efficacy of pivoting from in-person to virtual delivery of a lifestyle-focused multimodal intervention in at-risk older women with CVD.