



Experimental protocol of a randomized controlled clinical trial investigating exercise, subclinical atherosclerosis, and walking mobility in persons with multiple sclerosis

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ABSTRACT

Background: This randomized controlled trial (RCT) will investigate the effects of a home-based aerobic exercise training regimen (i.e., cycle ergometry) on subclinical atherosclerosis and walking mobility in persons with multiple sclerosis (MS) and minimal disability.

Methods/design: This RCT will recruit 54 men and women who have an Expanded Disability Status Scale characteristic of the 1st stage of MS (i.e., 0–4.0) to participate in a 3 month exercise or stretching intervention, with assessments of subclinical atherosclerosis and walking mobility conducted at baseline, week 6 (midpoint), and week 12 (conclusion) of the program. The exercise intervention will consist of 3 days/week of cycling, with a gradual increase of duration followed by an increase in intensity across the 3 month period. The attention-control condition will incorporate stretching activities and will require the same contact time commitment as the exercise condition. Both study groups will participate in weekly video chat sessions with study personnel in order to monitor and track program adherence. Primary outcomes will consist of assessments of vascular structure and function, as well as several walking tasks. Additional outcomes will include questionnaires, cardiorespiratory fitness assessment, and a 1-week free-living physical activity assessment.

Discussion: This investigation will increase understanding of the role of aerobic exercise as part of a treatment plan for managing subclinical atherosclerosis and improving walking mobility persons in the 1st stage of MS. Overall, this study design has the potential to lead to effective aerobic exercise intervention strategies for this population and improve program adherence.

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1. Introduction & background

Multiple sclerosis (MS) is a neurological disease of the central nervous system with a prevalence of 1 per 1000 persons in the US [1]. Life expectancy is reduced by ~10 years in populations with MS, but the disease itself is rarely the cause of premature death [2]. Co-morbidities, including cardiovascular

disease (CVD), are a leading cause of mortality in MS and epidemiological studies have demonstrated an increased risk of CVD in persons with MS compared with the general population [2–4]. Vascular co-morbidities have been associated with diagnostic delays and worsening of mobility disability, and mobility disability itself is a hallmark feature of disease progression in MS [5,6]. Such observations underscore the importance of identifying approaches for managing CVD and its associated consequences for mobility disability.

Physical activity, particularly aerobic exercise training, may have beneficial effects on CVD and mobility disability in MS. Physical activity is inversely and independently associated with

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symptoms of CVD [7], markers of subclinical atherosclerosis [8], and mobility disability [9] in persons with MS. There are currently no data examining the effects of aerobic exercise training on subclinical atherosclerosis in persons with MS, although aerobic exercise training has improved mobility disability [10]. Importantly, aerobic exercise training has improved subclinical atherosclerosis in the general population [11,12], and markers of subclinical atherosclerosis are predictive of CVD mortality and morbidity [13–17]. Collectively, aerobic exercise training might improve both subclinical atherosclerosis and mobility disability in persons with MS.

One major limitation of exercise programs delivered among persons with MS involves the degree of supervision of the intervention. For example, supervised exercise training in a center has improved walking mobility in persons with MS, whereas unsupervised exercise programs in the home have not yielded the same effect, perhaps based on poor compliance [10]. This undermines the potential of providing an effective therapy for those with MS who cannot undertake supervised, center-based exercise programs. Accordingly, home-based exercise programs that adopt strategies for maximizing compliance might present a novel and efficacious approach. Such strategies include using exercise equipment with Internet access for monitoring program compliance, along with support from behavioral interventionists using strategies for behavior change based on an established theory, such as social-cognitive theory (SCT) [18].

This randomized controlled trial (RCT) will examine the effect of a 12-week, home-based aerobic exercise training intervention (i.e., cycle ergometer) versus a minimal exercise, attention-control condition (i.e., stretching) on markers of subclinical atherosclerosis and mobility disability among persons with MS who have minimal disability. The exercise training program will be delivered using Expresso Nuvo cycle ergometers (Sunnyvale, CA) that allow for monitoring of compliance based on Internet access along with weekly support from a behavior interventionist and strategies from previous research in MS [19,20]. Such a study will address gaps in knowledge by implementing a home-based exercise program with provisions for maximizing and monitoring compliance with the exercise training. This study will further establish the scientific basis of aerobic exercise training for improving markers of subclinical atherosclerosis and mobility disability. The protocol utilizes an innovative design, by applying the use of cycle ergometry while evaluating potential improvements in gait and mobility. Therefore, the study may help to isolate potential independent effects of aerobic exercise conditioning and general lower body conditioning, not specific to gait, on mobility parameters. Data from this study should advance our understanding of home-based exercise as a behavioral approach for managing vascular co-morbidities and worsening of mobility disability in MS.

2. Methods

2.1. Study design, overview, & hypotheses

The proposed study and data collection will take place in the Integrative Physiology Laboratory at the University of Illinois at Chicago. The study will use a two-arm RCT design to examine the effect of a home-based exercise training program versus a

minimal exercise, attention-control condition on measures of subclinical atherosclerosis and mobility disability in individuals with MS who have Expanded Disability Status Scale (EDSS) scores characteristic of the 1st stage of MS (i.e., scores of 0–4.0). Fig. 1 illustrates the study sequence. Randomization will take place upon completion of the first study visit, and subjects will have an equal chance to draw each of the two possible study arms. Subjects will draw from a pool containing an equal number of “exercise” or “stretching” cards. This method of randomization was chosen in order to eliminate potential selection bias. The home-based exercise regimen includes cycle ergometry as an aerobic mode of training, and is performed three days per week with a gradual progression of duration and intensity across a 12-week period. The attention-control involves stretching using the same frequency and duration across a 12-week period. Participants in both conditions will further take part in weekly one-on-one behavioral coaching sessions via Skype. These sessions will be based on SCT and will focus on self-efficacy, goal setting, self-monitoring, and strategies and facilitators of behavioral change [20]. We will collect subclinical atherosclerosis and mobility disability data before, during (i.e., midpoint), and immediately after the 12-week intervention. We will use a 2 (condition) by 3 (time) mixed-factor, analysis of variance with intent-to-treat principles for testing the effect of the intervention on outcomes. Our central hypothesis is that a 12-week aerobic exercise training program will reduce both subclinical atherosclerosis and mobility disability. The primary outcomes for subclinical atherosclerosis will be carotid intima-media thickness (IMT), aortic pulse wave velocity (PWV), endothelial function, and arterial stiffness. The primary outcomes for mobility disability will be timed 25-foot walk (T25FW), 6-minute walk (6 MW), gait kinematics, and free-living accelerometry. Additional secondary outcomes include a fasting blood lipid profile and inflammatory biomarkers. We further hope to explore the possible association between changes in subclinical atherosclerosis and walking mobility following exercise training. We hypothesize that improvements in subclinical atherosclerosis will be associated with improvements in walking mobility.

2.2. Participants

We plan to enroll a sample of 54 men and women with MS in the Chicago, IL area who have EDSS scores between 0–4.0. We selected this EDSS range to ensure that our participants are still capable of engaging in sufficient physical activity that is necessary for accruing physiological adaptations. Recruitment will occur through the MS Center at the University of Illinois Hospital and Health Sciences System and presentations at MS support groups. Additional recruitment strategies will be to advertise in local newspapers, television, and radio outlets as needed. We will further contact participants from our previous research who reside within the proximity. Participants will be asked to contact the Integrative Physiology Laboratory for further information about the study and screening for inclusion.

Inclusion criteria are: being physically inactive (defined as less than 2 days of aerobic exercise per week), body mass index < 40 kg/m², EDSS score of 0–4.0 and being independently ambulatory (walking without an assistive device, such as a cane or orthotic), relapse free in the past 30 days, confirmed

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