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Phase-III, randomized controlled trial of the behavioral intervention for increasing physical activity in multiple sclerosis: Project BIPAMS

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ABSTRACT

Background: We propose a phase-III, randomized controlled trial (RCT) that examines the effectiveness of a behavioral intervention based on social cognitive theory (SCT) and delivered through the Internet using e-learning approaches for increasing physical activity and secondary outcomes (e.g., symptoms) in a large sample of people with multiple sclerosis (MS) residing throughout the United States.

Methods/design: The proposed phase-III trial will use a parallel group, RCT design that examines the effect of a 6-month behavioral intervention for increasing physical activity and secondarily improving mobility, cognition, symptoms, and quality of life (QOL) in persons with MS. The primary outcome is accelerometer-measured moderate-to-vigorous physical activity (MVPA). The secondary outcomes include self-report measures of physical activity, walking impairment, cognition, fatigue, depression, anxiety, pain, sleep quality, and QOL. The tertiary outcomes are mediator variables based on SCT. Participants (N = 280) will be randomized into behavioral intervention (n = 140) or attention and social contact control (n = 140) conditions using computerized random numbers with concealed allocation. The conditions will be administered over 6-months by persons who are uninvolved in screening, recruitment, random assignment, and outcome assessment. There will be a 6-month follow-up without intervention access/content. We will collect primary, secondary, and tertiary outcome data every 6 months over the 12-month period. Data analysis will involve intent-to-treat principles and latent growth modeling (LGM).

Discussion: The proposed research will provide evidence for the effectiveness of a novel, widely scalable approach for increasing lifestyle physical activity and improving secondary outcomes and QOL in persons with MS.

1. Introduction

Physical activity is lower among persons with multiple sclerosis (MS) than the general population [1]. This is problematic considering the exceedingly low rate of physical activity in the general population [2], evidence that physical activity levels decline over time in MS [3, 4], and observation that physical activity benefits might be greater in this population [5].

The standard approach for promoting physical activity in MS has involved structured, supervised exercise training [6]. That approach has resulted in evidence of considerable benefits [5], but it has not altered the rate of physical inactivity within MS over the past 25 years [1]. Researchers have proposed moving away from structured exercise training, and focusing on behavioral interventions for changing lifestyle physical activity (i.e., accumulation of physical activity through planned or unplanned leisure, occupation, or household activities as part of everyday life) in MS [7, 8]. Such behavioral interventions teach people the skills, techniques, and strategies for changing physical activity, typically based on a health behavior theory [7, 8].

Researchers have developed, refined, and tested a behavioral intervention based on Social Cognitive Theory (SCT) [9] and have delivered this through an Internet website for changing physical activity and secondary symptomatic outcomes in MS [10–13]. Although efficacious, the major weakness of that previous approach identified through formative evaluation [10, 11, 13] was the reliance upon content delivered through a text-based medium (i.e., participants read

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online text and passages for learning about principles of behavior change). That medium offered a passive, non-interactive, and non-immersive approach for learning the skills, techniques, and strategies necessary for changing physical activity. Such a weakness may be overcome through the adoption of e-learning software that permits the development of interactive video courses that seemingly provide an engaging user experience through pre-built and customizable interactions; slide layers and triggers; and a more immersive, engaging learner experience (see https://articulate.com/360/storyline). The e-learning approach may increase the interest, processing, and accessibility of information by users for a greater impact of the behavioral intervention.

We recently completed a 6-month, phase-II, randomized controlled trial (RCT) that examined the efficacy of a newly developed Internet website that delivered a SCT-based behavioral intervention using e-learning approaches for increasing physical activity and improving symptoms, walking impairment, and neurological disability [14]. Participants with MS ($N = 47$) were randomly assigned into behavioral intervention ($n = 23$) or waitlist control ($n = 24$) conditions. Outcome assessments were administered before and after the 6-month study period. There were positive intervention effects on self-reported and objectively-measured moderate-to-vigorous physical activity (MVPA), as well as on fatigue, depression and anxiety symptoms, walking mobility, and disability status. Such outcomes provide proof-of-principle evidence for a large, phase-III RCT testing the effectiveness of this approach for improving physical activity and secondary outcomes as well as examining mediators based on SCT (e.g., self-efficacy or goal setting).

The planned phase-III RCT will test the effectiveness of the behavioral intervention [14] for increasing physical activity and improving secondary outcomes among a large sample of people with MS residing throughout the United States. The primary objective examines the immediate and sustained effect of the behavioral intervention on objectively-measured MVPA; MVPA was deemed the primary end-point considering its importance for overall health as well as prevention of chronic disease and premature mortality. The secondary objective examines the immediate and sustained effect of the behavioral intervention on self-reported measures of physical activity, walking mobility, cognition, symptoms, disability status, and quality of life (QOL). The tertiary objective examines SCT variables as mediators of the behavioral intervention effect on change in physical activity.

2. Methods

2.1. Study design and overview

The proposed phase-III trial will use a parallel group, RCT design. The primary outcome is accelerometry as an objective measure of minutes/day of MVPA. The secondary outcomes include self-report measures of physical activity, walking mobility, cognition, fatigue, depression, anxiety, pain, sleep quality, and QOL. The tertiary outcomes are mediator variables based on SCT. Participants ($N = 280$) will be randomized into the behavioral intervention condition ($n = 140$) or an attention and social contact control condition ($n = 140$) using a random numbers sequence with concealed allocation. The conditions will be administered over six months by trained behavior coaches who will be uninvolved in screening, recruitment, random assignment, and outcome assessment. There will be a six-month follow-up period wherein participants will not access the study website nor engage in video chats with behavior coaches; this is important for determining if the behavioral intervention results in relatively permanent and stable levels of physical activity based on the logic of teaching the participants skills, strategies, and approaches for initiating and maintaining behavior change over time. We will collect primary, secondary, and tertiary outcome data every six months over the 12-month period(i.e., baseline, immediate follow-up, and 6-month follow-up). The data analyses will involve intent-to-treat principles and latent growth modeling (LGM). This study does not include a data safety monitoring board as it is a low risk, behavioral intervention with minimal side effects conducted in a population that is not identified as vulnerable and has been approved by an Institutional Review Board.

2.2. Participants

We will recruit a sample of 280 persons with MS from across the United States through postal and electronic advertisements delivered using the National MS Society (NMSS), NARCOMS, and iConquerMS. We further will distribute advertisements among the MS Centers identified through the NMSS website(https://www.nationalmssociety.org/Treating-MS/Find-an-MS-Care-Provider), and request that the materials are distributed among persons living with MS who visit the Centers for services. The advertisements will describe the study as comparing two different approaches delivered through the Internet for managing consequences of MS and improving health indicators. Those interested in participation will contact the study project coordinator either by e-mail or telephone; we will establish a toll-free telephone number considering the nationwide recruitment effort. This initial e-mail or telephone call will be followed-up by a phone call from the project coordinator who will describe the study and its procedures, answer all questions, and conduct a screening for inclusion criteria. The inclusion criteria involve (a) diagnosis of MS; (b) relapse free in the past 30 days; (c) Internet and email access; (d) willingness to complete the questionnaires, wear the accelerometer, and undergo randomization; (e) being non-active defined as not engaging in regular physical activity (30 min accumulated per day) on more than two days of the week during the previous six months (i.e., not meeting current physical activity guidelines for MS); (f) ability to ambulate with or without assistance (i.e., walking with or without a cane or walker, but not a wheelchair) as this intervention focuses on walking as a main agent of changing lifestyle physical activity behavior; and (g) age between 18 and 64 years. We will exclude all individuals with moderate or high risk for contraindications of possible injury or death when undertaking strenuous or maximal exercise using the Physical Activity Readiness Questionnaire (PAR-Q; [15]); this is a simple, self-reported screening tool for determining safety and possible risk for starting a physical activity program. During the initial phone contact with the project coordinator, participants will verbally respond to the 7-items on the PAR-Q, and those individuals who report no more than one YES or affirmative on the seven items on the PAR-Q will be considered at low risk and included for participation. All other individuals will be considered at moderate or high risk for starting a physical activity program and excluded from participation, and further advised to seek medical guidance before becoming more physically active.

2.3. Sample size

We conducted a conventional power analysis to estimate the appropriate sample size for detecting a Condition (2 levels of between-subjects factor: Intervention vs. Control) × Time (3 levels of within-subjects factor: 0, 6, & 12 months) interaction on the primary outcome of objectively-measured MVPA. The medium effect size (Cohen's $d = 0.35$) for the power analysis was from our recent pilot RCT [14] of the same behavioral intervention compared with a waitlist control condition for increasing minutes/day of MVPA in persons with MS. The power analysis included assumptions of reliability for the within-subjects factor of ICC = 0.50, two-tailed $\alpha = 0.05$, and $\beta = 0.05$ (i.e., 95% power). The power analysis indicated that the minimal total sample size for testing the Time × Condition interaction on physical activity should be nearly 240 participants. This would support our goal of recruiting 280 participants as yielding adequate power, based on retention of 85% of the participants. We have successfully retained over 90% of participants over six months in our pilot trial of the behavioral intervention

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