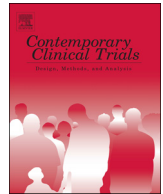




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Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Rationale and design of the tele-exercise and multiple sclerosis (TEAMS) study: A comparative effectiveness trial between a clinic- and home-based telerehabilitation intervention for adults with multiple sclerosis (MS) living in the deep south

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ARTICLE INFO

Keywords:

Multiple sclerosis

Exercise

Telerehabilitation

Teleexercise

Randomized controlled trial

Research design

ABSTRACT

Long-term exercise/rehabilitation is an integral component of the continual care for people with multiple sclerosis (MS). However, access to this care, which includes comprehensive exercise/rehabilitation services to people with MS, remains a significant challenge, especially in rural, low-income areas. Telerehabilitation, or what we refer to as teleexercise, can help fill service gaps for underserved MS populations in this region. This pragmatic, cluster randomized controlled effectiveness trial will compare a 12-week, 20 session complementary and alternative medicine (CAM) intervention composed of neurorehabilitative (functional) exercise, yoga and Pilates delivered at home, using pre-loaded tablets and Interactive Voice Response (IVR) system technology (TeleCAM), to the same intervention delivered in clinic by a therapist (DirectCAM). Eight hundred and twenty people with MS are being recruited across Alabama, Mississippi and Tennessee. Primary self-reported patient-centered health outcomes are: pain, fatigue, quality of life and physical activity. Secondary outcomes include four physical functioning measures: balance, endurance, gait, and strength. Each of these outcomes will be examined by age, race, sex, severity of MS and other demographics to determine if outcomes are beneficial across all groups (i.e., heterogeneity of treatment effect). The project is important to people with MS and/or caregivers because it aims to reduce their barriers to receiving exercise treatment and increases the convenience and appeal of such programs through technology.

Clinical Trials.gov Identifier: [NCT03117881](https://clinicaltrials.gov/ct2/show/study/NCT03117881)

1. Introduction

Multiple Sclerosis (MS) is a neurological disorder with several symptom-based conditions that limit various life activities. Health trajectories in the general population typically impacted by lifestyle behaviors and genetics have a third, less understood dimension in people with MS: the onset and course of secondary conditions and their “weighted” or “additive” effect on changes in health and function [1]. Some of the highest rates of secondary conditions in people with MS are

associated with low rates of physical activity, including fatigue, deconditioning, weakness, falls and depression [2,3]. These health conditions often limit or restrict participation in general life activities including employment, social and community engagement, and performing instrumental activities of daily living [4–7]. Since the symptoms of MS often fluctuate at random, many people report feelings of anxiety and uncertainty, particularly if they are not actively engaged in decision-making about their own care or are unable to obtain the types of exercise and rehabilitation that can improve their health [8].

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<https://doi.org/10.1016/j.cct.2018.05.016>

Received 25 October 2017; Received in revised form 20 May 2018; Accepted 22 May 2018

Available online 30 May 2018

1551-7144/ © 2018 Published by Elsevier Inc.

While there is a substantial volume of literature supporting the benefits of clinic-based exercise and rehabilitation in people with MS [9–14], it remains an underutilized treatment for improving health and function and reducing symptom-based secondary conditions in this population [12,15]. Several studies have reported that rates of exercise utilization among people with MS remain much lower than in the general population [16–19]. What is clear, however, is that lack of exercise is not related to lack of interest. In a survey of health care preferences and priorities among people with MS, information on exercise was the most sought-after information [20]. While many health care providers understand the importance and value of exercise for their patients with MS, they often lack the necessary resources for providing personalized exercise recommendations that have a greater likelihood for meeting the needs of people with MS who have varying levels of health and physical function [21]. In a recent qualitative study, people with MS indicated that they want exercise recommendations from their healthcare providers [22].

To fully address the barriers to accessing exercise, including the need for healthcare providers to have off-the-shelf resources that they can quickly provide to their patients, Telerehabilitation, or what we refer to as teleexercise, is a promising area of technology that could be of great assistance to people with MS. Providing various forms of traditional (i.e., cardiorespiratory and strength exercise) and non-traditional (i.e., complementary and alternative medicine, CAM) exercise [23] in the comfort of a person's home would increase regular and sustainable access to services limited by driving distance, costs, the need for a driver, time away from work, or being a primary caregiver. Likewise, since most MS and primary care clinics are unable to provide comprehensive rehabilitation programs in the clinic, remote training can be a viable alternative to bringing these important services closer to patients who are unable to attend such programs for various reasons. However, the transfer of promising clinic-based exercise programs for people with MS into the home setting through a telerehabilitation platform is limited. This was emphasized in a recent 2015 Cochrane report (*Telerehabilitation for persons with multiple sclerosis*) [24], in which researchers emphasized the importance of using telerehabilitation “to fill the existing service gap in the care of people with MS,” and recommended that “effectiveness trials be conducted in future research.” [p.324].

2. Methods

2.1. Study aims

The primary aim will compare the effectiveness of a CAM exercise intervention between people with MS receiving the same treatment on-site at a clinic by a therapist (DirectCAM) versus at home through the use of a tablet (TeleCAM). Effectiveness will be defined as improvement in 4 key self-reported, patient-centered primary health outcomes recommended by our MS stakeholder panel (people with MS, health professionals working with patients with MS, and directors of MS organizations), which include fatigue, pain, quality of life and physical activity. An additional 4 functional secondary outcomes (balance, gait, endurance and strength) are associated with changes in physical health and function. We hypothesize that both active intervention arms will result in improvements, with the TeleCAM arm producing greater improvements than the DirectCAM arm. The CAM exercise intervention is composed of neurorehabilitation training, yoga and Pilates.

Our secondary aim is to examine the heterogeneity of treatment effect (HTE) and is composed of 2 parts: a) performing pre-specified confirmatory HTE analyses across the four key patient-centered health outcomes, and b) developing an exploratory predictive model to explain HTE. The purpose of this aim is to understand for whom the intervention is effective.

Our tertiary aim will examine potential psychosocial mediators, the key social cognitive theory (SCT) constructs, targeted by the

intervention, including social support (friend and family support for exercise participation), self-efficacy (confidence in one's ability to be physically active in various situations), outcome expectancies for exercise, and self-regulation (exercise goal setting) to understand how the intervention is effective.

2.2. Study design

The Tele-Exercise and Multiple Sclerosis (TEAMS) study is a multi-center cluster randomized controlled effectiveness trial that is being conducted across 38 rehabilitation clinics in Alabama, Mississippi and Tennessee between 2016 and 2021. A target sample of 820 participants with MS who meet study eligibility criteria will be enrolled and randomized into DirectCAM ($n = 410$) and TeleCAM ($n = 410$). TEAMS study aims were formulated around what our MS stakeholder panel expressed as three critical gaps: 1) a need to overcome transportation barriers to get to clinics and facilities; 2) developing interventions that are customized for a range of MS symptoms and functional mobility (*one size does not fit all*); and 3) targeting key outcomes related to MS symptoms.

2.3. Participant eligibility

Our target sample represents a broad range of people with MS with varying levels of functional mobility (mild/moderate to severe) and sociodemographic factors (e.g., educational level, caregiver support, and driving distance to the clinic). Based on the feedback we received from our stakeholders, we were advised to keep the eligibility criteria as broad as possible since there is a strong need for rehabilitation across the functional spectrum of MS. Inclusion criteria are: i) mild to moderate disability (Patient Determined Disease Steps [PDDS] 0–7); ii) able to use both arms/legs for exercise while standing or seated (this would include people with hemiparesis); iii) 18 to 70 years old; iv) physician permission to participate in the study. Exclusion criteria are: i) significant visual acuity that prevents seeing a tablet screen in order to follow home exercise program; ii) cardiovascular disease event within the past six months, severe pulmonary disease, renal failure; iii) active pressure ulcer; iv) currently pregnant; v) within 30 days of receiving a rehabilitation session; and vi) already meeting physical activity guidelines (Godin Leisure-Time Exercise Questionnaire [GLTEQ] ≥ 24).

2.4. Randomization

We will implement a cluster-randomized trial with clinics as the units of randomization. Our choice of cluster randomization versus individual randomization was based on the MS stakeholder panel feedback that some study participants from a clinic will likely be part of the same MS support group. Therefore, we decided that to avoid non-trivial risk of contamination (e.g., potential sharing of the tablet videos at the support groups and/or discussing exercise routine), it would be best to randomize at the clinic level. We also recognize that our 38 clinics are spread across different regions of Alabama, Mississippi, and Tennessee and may be different in terms of their geographic location. Hence, we will implement a stratified randomization at the clinic level based on urban versus non-urban location [25].

2.5. Recruitment

We worked with our MS stakeholders for several months to identify a multi-pronged recruitment strategy. First, MS clinics and MS specialists will query their electronic medical records (EMRs) to identify MS patients. Second, project staff well connected to the MS community will share study information through their extensive, three-state network (Alabama/Mississippi/Tennessee), including to neurologists via email, at National Multiple Sclerosis Society (NMSS) Walk/Bike events (these social events occur regularly across the study states in cities and smaller

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