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Stakeholder involvement in the design of a patient-centered comparative effectiveness trial of the "*On the Move*" group exercise program in community-dwelling older adults☆

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ABSTRACT

Background: Group exercise programs for older adults often exclude the timing and coordination of movement. Stakeholder involvement in the research process is strongly encouraged and improves the relevance and adoption of findings. We describe stakeholder involvement in the design of a clinical trial of a group-based exercise program that incorporates timing and coordination of movement into the exercises.
Methods: The study was a cluster randomized, single-blind intervention trial to compare the effects on function, disability and mobility of a standard group exercise program and the "*On the Move*" group exercise program in older adults residing in independent living facilities and senior apartment buildings, and attending community centers. Exercise classes were twice weekly for 12 weeks delivered by study exercise leaders and facility activity staff personnel.
Outcomes: The primary outcomes function, disability and mobility were assessed at baseline and post-intervention. Function and disability were assessed using the Late Life Function and Disability Instrument, and mobility using the Six-Minute Walk Test and gait speed.
Stakeholders: Patient and provider stakeholders had significant input into the study aims, design, sample, intervention, outcomes and operational considerations.
Summary: A community-based exercise program to improve walking can be developed to address both investigator identified missing components in current exercise to improve walking and stakeholder defined needs and interest for the activity program. Involvement of stakeholders substantially improves the relevance of research questions, increases the transparency of research activities and may accelerate the adoption of research into practice.

1. Introduction

Disability is a common, costly condition in older adults. Walking difficulty in older adults contributes to loss of independence, higher rates of morbidity and increased mortality [1–5]. Mobility loss is also an early predictor of other disabilities that restrict independent living [6,7]. Compared to older adults without self-reported walking difficulty, those who developed mild walking difficulty over one year had higher healthcare costs (mean $1128 per person). Extrapolated to the estimated 22% of older adults who develop walking difficulty annually, the cost to society is an additional 3.6 billion dollars per year [8]. Therefore, preventing or delaying the onset of walking difficulty will have a substantial impact on older adults' independence and their healthcare costs.

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Exercise is beneficial to physical and mental health, and may prevent mobility disability [9,10]. There are many types of community-based group exercise programs available for older adults. In our experience, many of these group exercise programs are seated programs that focus on improving range of motion, strength, and endurance. Fewer group exercise programs include standing strength and balance exercises or walking for fitness [11–13]. Though most programs include some type of strength and endurance exercise, many of the programs exclude an important component of exercise that is critical to walking, the timing and coordination of movement [14–16]. Therefore, a program designed to address the timing and coordination of movement that is critical for walking may promote independence in older adults.

Based on previous research and with critical input from older adults, a novel exercise program that includes timing and coordination and focuses on improving walking was developed [17]. The program, entitled "*On the Move*", differs from current group exercise programs in that 1) it contains timing and coordination exercises based on the biomechanics and motor control of walking, 2) the majority of the program consists of challenging standing and walking exercises, and 3) the exercises progress in difficulty over the course of the program. Pilot testing of "*On the Move*" established the initial feasibility of the program [17].

Stakeholder involvement in research has been strongly encouraged by some and mandated by other research funding agencies such as the Patient Centered Outcomes Research Institute (PCORI). Stakeholders are "individuals or groups who are responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence" [18]. The 7Ps Framework for Stakeholder Engagement suggests stakeholders can be organized into seven types: patients and the public, providers, purchasers, payers, policy makers, product makers, and principal investigators [19]. Stakeholder involvement should occur throughout the research process (i.e. in the preparation, execution and translation phases). It is thought that involvement of stakeholders may improve the relevance of research questions, increase the transparency of research activities and may accelerate the adoption of research into practice [18]. In general, reports of stakeholder engagement in the literature are minimal and vary in content and quality [18]. Therefore, as we describe the design and methods of our single-blind cluster randomized trial to establish the effectiveness and sustainability of the "*On the Move*" exercise program in community-dwelling older adults, we will also describe the key aspects of input and the participation of our stakeholders in the preparation and conduct of the study.

2. Methods

2.1. Stakeholders

We included two main types of traditionally non-investigator stakeholders in our research: participants and providers. Stakeholders were identified through personal and professional networks, and our pilot work in the community. We identified two main provider stakeholders who are co-investigators on the project. The two provider stakeholders included 1) a representative of Senior Management from University of Pittsburgh Medical Center health system (UPMC) Senior Communities department and 2) a Lead Geriatric Outreach Nurse also from UPMC Senior Communities. We selected these two providers as they represent different levels of the provider: senior management which has influence over the staff and facilities, and also a more hands-on provider which has close connections to the community and daily interactions with various facilities and residents.

Our participant stakeholders are community-dwelling older adults who reside in Independent Living Facilities or senior housing buildings, or who live in private residences of the community and regularly attend senior community centers. Participant stakeholders were involved in the preparation phase of the study by participating in our pilot studies and focus groups to help develop the intervention. They are also involved in the execution and translation phases as members of our Community Advisory Boards (CABs) which are described below.

Community Advisory Boards (CABs). The purpose of the CABs was to provide ongoing engagement of our participant and provider stakeholders. We created two CABs, one representing the Independent Living Facilities, and another representing the senior housing buildings and senior community centers. Two separate CABs were created for logistical purposes. Our provider stakeholder co-investigators were instrumental in identifying and suggesting members of the CABs. We attempted to have a diverse representation on the CABs with the goal of including individuals representative of a variety of genders, races, types of facilities and both participants and providers (Table 1). The CABs meet twice a year throughout the study. The meetings are a two-way engagement between investigators and stakeholders to provide ongoing input into the execution and translation phases as well as to be briefed on present progress and challenges.

2.2. Study design

The study is a cluster randomized, single-blind intervention trial to compare the effects of a standard group exercise program and a novel "*On the Move*" group exercise program on function, disability and mobility in community-dwelling older adults who reside in independent living facilities (ILFs) and senior apartment buildings, and who live in private residences but regularly attend senior community centers (Fig. 1). Randomization to interventions was at the facility level, stratified by facility type (ILFs, senior apartment buildings or senior community centers). Group exercise classes were twice weekly for 12 weeks, and were delivered by study exercise leaders (i.e. research staff) and facility staff activity personnel (i.e. staff employed by the facilities). Function, disability and mobility were assessed pre- and post-intervention.

The sustainability of the program was examined by randomly assigning participants within each site to either class 1, taught by a study exercise leader, or class 2, taught by staff activity personnel. Study exercise leaders were research staff with training and experience in administering the exercise programs, and were exercise physiologists, physical therapists, physical therapy assistants or from a similar background. Facility staff activity personnel were employees of the facilities themselves who were involved in providing services to the residents. They could have been fitness staff, activity directors, social workers, outreach coordinators, care coordinators or other employees with a similar role. At sites that did not have staff activity personnel willing or with the availability to be trained, we identified (an) older adult(s) from the facility to be trained as a "peer" leader. Individuals randomized to class 1 exercised for the first 12 weeks at the site with the exercise leader. During class 1, the exercise leader trained the staff activity personnel or peer leader who then taught class 2 at the facility.

2.2.1. Rationale for cluster randomized trial

We carefully considered the advantages and disadvantages of randomizing at the level of the facility and the resident. To avoid cross-contamination, it was imperative that we conduct a cluster randomize trial, and randomized facilities to exercise programs. If randomized at the resident level, participants would discuss details of their intervention and cause cross-contamination between the intervention arms. Unlike a traditional randomized clinical trial in which participants are randomized as they are being recruited, a cluster randomized trial also affords the additional benefit of examining the facility characteristics such as type (independent living/senior high rise/community center), and ensuring a balance in those characteristics is achieved by design via stratification rather than chance. Once the facilities were randomized to exercise program, we then randomized participants within each facility to delivery mode (study exercise leader/facility staff activity person or peer leader). We used the pseudo-random deviate generator in SAS® (SAS Institute, Inc., Cary, North Carolina) to randomize facilities to the