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Physical activity, function, and quality of life: Design and methods of the *FlexToBa™* trial ☆

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ABSTRACT

The *Flexibility, Toning, and Balance* (*FlexToBa™*) *Trial* is a two-armed randomized controlled trial which will contrast the effects of a DVD-delivered, home-based, physical activity intervention and a *Healthy Aging* attention control condition on physical activity, functional performance, functional limitations, and quality of life in low active, older adults. This innovative trial will recruit 300 participants across central Illinois who will be randomized into the intervention arm or control arm of the study. The intervention will last 6 months with a 6 month follow-up. Assessments at baseline, post intervention and follow-up will include physical activity (self-report and accelerometry), a battery of functional performance measures, functional limitations, quality of life, and an array of psychological health measures. In addition, measures of external validity will be included to determine public health significance of a successful outcome. Participants will engage in a progressive series of activities focusing on flexibility, strengthening, and balance exercises which are demonstrated by a trained exercise leader and age-appropriate models on a series of DVDs. Delivery of the intervention has its basis in social cognitive theory. The specific aims of the trial are (a) to determine the effects of the DVD-delivered *FlexToBa™* program on physical activity, functional performance, functional limitations, and quality of life, (b) to examine the mediators of the relationships between physical activity and functional limitations and quality of life, (c) to assess external validity indicators relative to the intervention, and (d) to determine differential effects of the intervention on psychosocial health measures.

1. Introduction and background

According to the U.S. Census Bureau [1], the population of adults 65 years and above is expected to grow from approximately 38 million in the year 2008 to nearly 89 million by the year 2050. Increased life expectancy, however, is likely to be associated with multiple co-morbidities resulting in compromised functional performance, increased functional limitations and disability, and reductions in quality of life. Accumulating evidence suggests that engaging in regular physical activity can help enhance physical function and attenuate functional limitations. A systematic review by Paterson and Warburton [2] indicates that, among older adults, a dose–response relationship exists between aerobic physical activity and improved functional performance and reduced functional limitations. Although poor strength and balance have been implicated as important determinants of disability [3], little evidence exists relative to the effects that strength and/or

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balance training may have on functional limitations [4]. Moreover, with aging comes a loss of flexibility which has implications for muscle disuse, declines in functional abilities, and overall health status. As an adjunct to aerobic training, there is some evidence to suggest that these training modalities may counter the age-related loss in muscle size, coordination, and power necessary for daily living [2].

Delivering physical activity interventions to older adults, however, can be expensive, have limited reach, and be difficult to implement. In this paper, we present the methods and design for an innovative physical activity intervention with a unique delivery mode that will maximize reach and overcome a number of barriers to successful engagement in physical activity interventions for older adults. Although there have been numerous physical activity trials conducted that target older adults, they have typically been center-based and conducted within university or clinical settings. Although such interventions have their inherent strengths and are generally internally valid, they sacrifice reach by excluding those individuals who might benefit the most (i.e., sedentary individuals in small town and rural settings and those who are low functioning). As delivering a group-based activity program to participants in a broad geographical area is neither feasible nor fiscally sound, more innovative approaches to program delivery are needed. We propose to deliver the *Flexibility, Toning, and Balance* (*FlexToBa*™) trial via digital video/versatile disks (DVDs). This approach has broad reach, is convenient, does not involve travel, is easy to implement, requires few resources, and has the potential for broad dissemination (e.g., home, community, or senior living facilities; [5]). Another unique element of the *FlexToBa*™ trial is the adoption of the RE-AIM framework [6] in the trial design in an effort to influence public health. This framework addresses the dimensions of **R**each, **E**ffectiveness, **A**doption, **I**mplementation, and **M**aintenance. Careful integration of RE-AIM dimensions will become increasingly important in demonstrating accountability of intervention practices.

Consequently, the *FlexToBa*™ trial was designed as a randomized controlled trial to test the effectiveness of a home-based physical activity intervention targeting flexibility, toning, and balance delivered in DVD format and designed for older adults. The primary outcomes are reductions in functional limitations and improvements in physical activity, functional performance and quality of life (QOL). Secondary outcomes include improvements in psychosocial outcomes and assessment of external validity.

2. Specific aims

The *FlexToBa*™ trial was designed to test the following specific aims. First, we will determine the effectiveness of a 6-month, DVD-delivered physical activity intervention for increasing and maintaining physical activity levels and functional performance, reducing functional limitations, and enhancing quality of life in low active older adults as compared to an attention-control condition. Second, we will examine the mediators of physical activity effects on functional limitations and quality of life at the end of the trial and at 6-month follow-up. In addition, we have two secondary aims. First, we will implement RE-AIM principles into the design and evaluation of the trial in an effort to determine the translational potential and public health impact of delivering physical activity via DVD media. In addition, the effects of the intervention on other elements of psychological well-being (e.g., sleep, fatigue, enjoyment, perceived stress, self-esteem, depression, and anxiety) will be examined.

3. Method

3.1. Overview and study design

The *FlexToBa*™ trial is a randomized clinical exercise trial comparing the effects of a 6-month DVD-delivered physical activity program and an attentional healthy aging control group on physical activity, functional performance, limitations, and well-being. We will randomize 300 low active adults aged 65 and older to each condition. The *FlexToBa*™ condition will receive the DVD delivered physical activity program which incorporates behavior change principles based in social cognitive theory [7]. The control group will receive a commercial DVD (*Healthy Aging*™ by Andrew Weil, MD) delivering educational information related to healthy aging (e.g., healthy eating, social and cognitive health) with no specific emphasis on physical activity. Following baseline testing and randomization, further assessments will occur at the completion of the 6-month intervention and once more after a 6-month follow-up period. Participants in the control condition will receive the *FlexToBa*™ DVDs after all follow-up data have been collected. We will recruit participants from several counties across central Illinois with testing at each time point occurring at local community centers to reduce participant travel burden.

3.2. Eligibility

In an effort to increase the ecological validity of the study, we have very few exclusion criteria for this trial. The minimal criteria for entry into the study are being low active (i.e., physically active for 30 min or more $\leq$2 days per week on average over the past 6 months); aged 65 and older; capable of participation in a program of flexibility, toning, and balance without exacerbating any pre-existing condition(s), as determined by their personal physician; and willingness to be randomized. Participants will be screened for cognitive impairment using the 13-item modified Telephone Interview of Cognitive Status measure (TICS-M; [8]). Individuals who score below 21 (out of 39) on the TICS-M will be excluded from the trial. A score below 21 is equivalent to a score below 25 on the Mini Mental State Exam. Finally, all participants will be required to complete the Physical Activity Readiness Questionnaire (PAR-Q; [9]) and obtain written approval from their personal physician to participate in the trial.

3.3. Recruitment procedures

Inherent in our recruitment efforts are the application of RE-AIM principles [6] to enhance the generalizability of our outcomes. The first step in doing so is to increase reach. Therefore, we will advertise broadly the opportunity to participate in a free, professionally developed, in-home physical activity program designed to enhance those elements of physical activity that have implications for the successful maintenance of independent living in older adults. We will