Published in final edited form as:

Contemp Clin Trials. 2012 January ; 33(1): 228–236. doi:10.1016/j.cct.2011.10.002.

Physical Activity, Function, and Quality of Life: Design and Methods of the *FlexToBa*^{TM} Trial

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Abstract

The *Flexibility, Toning, and Balance (FlexToBa*^{TM}*) 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*^{TM} 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.

Keywords

Physical activity; older adults; functional limitations; functional performance; quality of life

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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 comorbidities 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 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 discs (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, *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*^{TM} 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*^{TM} 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*^{TM} 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*^{TM} 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 minutes or more ≤ 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 advertise on major radio and television stations that identify older adults as a key element of their market share in central Illinois. Additionally, we will place targeted paid advertisements in all major local newspapers across this area. Finally, we will send a targeted mailing to individuals who have been interested in previous studies but have not met inclusion criteria. All interested participants will be provided with a detailed study

description and screened for eligibility. Basic demographic information will be collected on all interested participants, whether they enter the trial or not, to enhance our estimation of reach. Prior to participation in the program, all participants will be required to read and sign a university Institutional Review Board approved informed consent.

3.4. Randomization

Eligible participants will be randomly assigned to either the intervention or attention control group using a computerized data management system. Randomization will be stratified based on gender, age, and testing location.

3.5. Measures

All measures will be assessed at baseline, following the intervention (6 months) and at 6-month post-intervention follow-up. Measures of functional performance will be conducted at each recruitment site by a team of trained research assistants. A battery of psychosocial measures and an activity monitor will be mailed to all participants 10 days prior to testing. The questionnaires will be completed by the participant at home and they will wear the activity monitor for 7 days (see below for further detail). All materials will be returned by the participant to the study staff at their testing appointments. Table 1 provides details of the range, psychometric properties, and sources of primary self-report measures used in the study.

3.5.1. Physical activity—We will use several methods for monitoring and tracking physical activity behavior. Two self-report measures, the Physical Activity Scale for the Elderly (PASE; [10]) and the Godin Leisure Time Exercise Questionnaire (GLTEQ; [11]), will be completed at each measurement period. Additionally, we will assess physical activity objectively by accelerometry at each time point using an ActiGraph accelerometer (Model GT3X 16MB; *Actigraph, LLC*, Pensacola, FL). Participants will be instructed to wear the activity monitor during all waking hours over a 7-day period (excluding time spent bathing or swimming). During initialization (prior to distribution), the accelerometer will be set to collect activity data in one-minute intervals (i.e., epochs). Once returned, the data will be immediately downloaded and checked for several criteria. Specifically, participants must have at least three days of valid measurement with ten hours of wear time throughout any one day, and 30 minutes of continuous zeros will be considered as non-compliant [12]. In addition, data reflecting activity counts greater than or equal to 20,000 per minute will be designated as unreliable [12]. If all criteria are met, an average number of daily activity counts (i.e., usual activity) will be calculated (i.e., total counts per day summed and divided by days of monitoring). In addition, the average number of minutes of daily sedentary, light, moderate, and vigorous activity will be calculated using established cut points [13].

3.5.2. Physical function—The Short Physical Performance Battery (SPPB; [14]) will be used to assess physical function and will be administered by trained research personnel at each testing site. The SPPB assesses balance, gait speed, and lower extremity strength. Balance is assessed by asking participants to maintain their balance for up to ten seconds per test while standing with their feet in side-by-side, semi-tandem, and tandem positions. Gait speed is assessed by measuring the time it takes a participant to walk four meters at a normal pace. Lower extremity strength is assessed by a chair stand test which instructs participants to sit in and fully rise from a chair five times as quickly as possible, without using their arms for support. The SPPB has been well-validated in older adults [15].

In addition to the SPPB, we will also use components of the Senior Fitness Test [16] to assess additional domains of physical function. These components include an arm curl test to assess upper body strength and endurance, a back scratch test to assess upper body

flexibility, and the sit and reach test to assess lower body flexibility. Finally, we will measure standing balance using the one-leg stand test and grip strength using a hand dynamometer.

3.5.3. Functional limitations—The 15-item abbreviated function component [17] of the Late-Life Function and Disability Instrument (LL-FDI; [18]) will be used to assess functional limitations. This scale assesses basic lower extremity, advanced lower extremity function, and upper extremity function. Participants are asked to indicate how much difficulty they have with each task on a 5-point Likert scale ranging from 1 (*cannot do*) to 5 (*none*). Composite scores are computed by summing subscale items, with higher scores indicating fewer difficulties in performing activities of daily living.

3.5.4. Self-efficacy—Four measures of self-efficacy will be administered to assess various aspects of participants' beliefs in their physical capabilities; the exercise self-efficacy scale (EXSE), the lifestyle self-efficacy scale (LSE), the gait efficacy scale (GES), and the function self-efficacy scale (FXNSE). The EXSE [19] is a 6-item scale that assesses individuals' beliefs in their ability to exercise at a moderate intensity three times per week for 40 or more minutes per session in the future (up to 6 months). The LSE [20] is a 6-item measure assessing individual beliefs in capabilities to successfully accumulate 30 minutes of physical activity on 5 or more days of the week for incremental months. The GES [21] is a 6-item scale that assesses individuals' beliefs in their capabilities to successfully negotiate stairs and objects in their path. The FXNSE is a newly developed 15-item scale which measures individuals' confidence to complete specific functional activities without assistance. Participants respond to items in each measure by indicating their confidence to execute the given behavior on a 100-point percentage scale ranging from 0% (*not at all confident*) to 100% (*highly confident*). Total strength for each measure of self-efficacy is calculated by summing the confidence ratings and dividing by the total number of items in the scale, resulting in a maximum possible efficacy score of 100.

3.5.5. Physical and mental health status—The 12-Item Short Form Health Survey (SF-12; [22]), will be used to assess physical and mental health status. Composite scores representing physical and mental health status are computed, with higher scores reflecting a more favorable health status.

3.5.6 Global quality of life—We will assess global quality of life using the Satisfaction with Life Scale (SWLS; [23]). The SWLS is a 5-item scale which measures life satisfaction as a cognitive-judgment. Each scale item uses a 7-point Likert scale ranging from 1 (*Strongly Disagree*) to 7 (*Strongly Agree*), with higher scores indicative of greater life satisfaction.

3.5.7. RE-AIM metrics—*Reach* will be assessed based on the ratio of individuals enrolled to those exposed to recruitment. In addition, we will determine the proportional reach across gender, ethnic, and racial categories to determine the representativeness of study participants in relation to those who declined participation and in relation to the broader audience exposed to our advertising campaign. We will also assess rates of attrition based upon these participant characteristics to determine the characteristics of potential end-users of the program. Finally, we will gather feedback from those who decline participation or drop out during the course of the study related to why they chose not to participate. *Effectiveness* will be assessed by effect sizes across time on the primary outcomes of physical activity, physical function performance, functional limitations, and QOL. *Adoption* reflects the organizational uptake of the intervention and will not be directly assessed. However, to gather information necessary for a potential broader dissemination, participants will provide

feedback on the DVD flow, structure, and attractiveness for older adults as well as their thoughts on the value of the DVD. *Implementation* will be determined by the extent to which the intervention treatments are delivered according to study protocol. This information will be garnered via their logs and the post-intervention and follow-up process analysis. Finally, *Maintenance* will be measured by assessing physical activity rates at follow-up (12 months beyond baseline) and the extent to which gains in functional performance, functional limitations, and QOL are maintained. Participants will also provide feedback on how often they used or will continue to use the DVD program.

Finally, we will use the *RE-AIM* summary measures proposed by Glasgow et al. [24] to assess overall individual impact level. Initially, this will be done by multiplying *Reach* and *Effectiveness*. This will be expanded to create summary measures of effectiveness across outcomes and considering levels of differential impact between sub-groups (e.g., males and females) to determine the robustness of effects.

3.5.8 Additional measures—We propose to assess a number of secondary psychosocial outcomes under the general umbrella term of psychological well-being. These include: the Perceived Stress Scale [25]; the Fatigue Symptom Inventory [26]; the Pittsburgh Sleep Quality Inventory [27]; the Physical Self-Perception Profile [28]; the Rosenberg Self-Esteem Scale [29]; the Hospital Anxiety and Depression Scale [30]; the Positive and Negative Affect Schedule [31]; the Physical Activity Enjoyment Scale [32]; and the Multidimensional Outcome Expectations for Exercise Scale [33].

3.6. Intervention: FlexToBa™ arm

Figure 1 depicts the involvement of the participants in the intervention arm throughout the trial. The *FlexToBa*™ intervention is composed of DVD-delivered exercise sessions each consisting of two sets of 11–12 different exercises that target balance, strength, and flexibility. This program has been successfully used in several of our center-based exercise trials and is enjoyable and well-tolerated by older adults. In order to effectively adapt and improve this program for delivery by DVD, we conducted focus groups with older adults to maximize the effectiveness of the program in the home environment. For whole-body (i.e., combination moves involving legs, abdominals, and arms) and partial-body (e.g., arms-only) strengthening exercises, 12 repetitions are performed in each set, and for balance (e.g., standing on one foot while holding chair) and flexibility (e.g., hamstring stretch) exercises, poses are held for up to 20 seconds. Each exercise session also includes a brief aerobic warm-up, and a series of stretches for all major muscle groups are performed as part of both the warm-up and cool-down. Participants are instructed to exercise with the *FlexToBa*™ DVDs three times per week on non-consecutive days. The program is modeled and narrated by a trained exercise leader who provides a detailed explanation and demonstration of each movement prior to leading participants through that exercise. Participants have the option to play the DVD without these detailed instructions once they become familiar with the exercises. Throughout the DVDs, the exercise leader is accompanied by three age-appropriate models who completed a similar, onsite exercise training program prior to DVD production.

The DVD set includes six separate exercise sessions, each of which is intended to be used for four weeks. The exercise sessions are designed to be progressive in nature. For example, Session One consists of relatively simple exercises which can be completed from a standing or seated position (e.g., bicep curls with band, one leg stand). Session Two is slightly more challenging than Session One, as it incorporates exercises to be completed on the floor. As participants move into the second half of the program (Sessions 4–6), the difficulty level is increased by utilizing more complex exercises that involve multiple movements (e.g., bicep

curl to shoulder press) and additional balance components (e.g., triceps extension while balancing on one leg). A particularly unique aspect of the program and of particular importance to older adults is a component that allows participants to progress at their own pace by making use of movement modifications. For each exercise, the exercise leader also demonstrates a modified version that is slightly less difficult and a more challenging version that adds difficulty for those who have mastered the exercise. Each of the three exercise models performs a different version of the exercise to allow participants to follow along with ease. These modifications allow the *FlexToBa*^{TM} program to be highly adaptable for older adults with a wide range of capabilities.

All participants are provided with an exercise prescription designed to aid them in progressing through the program gradually and safely. For the first two weeks of each month, participants are instructed to complete 1–2 sets of 8–10 repetitions at a Rating of Perceived Exertion (RPE; [34]) of 10–12 (i.e., fairly light). For the last two weeks of the month, the prescription advises participants to complete two sets of 10–12 repetitions at an RPE of 13–15 (i.e., somewhat hard). All participants are provided with two resistance bands to be used for the strengthening exercises. They are advised to begin all exercises with the thinner, lower resistance band, and encouraged to advance to the thicker band only when/if they are able to successfully complete two full sets of a particular exercise with the thinner band with relative ease.

As adherence to any health behavior is a major concern, the *FlexToBa*^{TM} program incorporates social cognitive principles [7] into its materials to enhance self-efficacy and reduce attrition. Briefly, the exercise leader and models provide advice and discuss strategies throughout the exercise sessions for overcoming barriers, effectively setting goals, self-monitoring one's behavior, forming realistic outcome expectations, and building social support. This content is reinforced in both an introductory DVD and an accompanying *FlexToBa*^{TM} handbook.

3.6.1. Exercise logs—Each participant will be provided with a binder that contains one exercise log for each day of the *FlexToBa*^{TM} program. They are instructed to complete a log every day, regardless of whether they have exercised. If they did not exercise, they simply indicate as such. If they did exercise with the *FlexToBa*^{TM} DVD, they are instructed to document the number of sets and repetitions they completed and the resistance used (if applicable), for each exercise. Additionally, participants check boxes to indicate whether they completed the warm-up and cool-down. Finally, participants indicate the total duration of the exercise session in minutes, their RPE, and a rating of enjoyment of the exercise session.

In addition to information specific to the *FlexToBa*^{TM} exercises, participants will be asked to report any additional activity in which they engage. For this section, they will be asked to include only planned, structured exercise (e.g., walking, swimming, yoga), and to omit lifestyle physical activities that are already part of their daily routine (e.g., gardening, house work). Participants are also asked to indicate the total duration, RPE, and enjoyment rating for each additional activity they report.

At the end of each four week period, participants are asked to mail their completed logs to the *FlexToBa*^{TM} program office using provided self-addressed stamped envelopes. Once received, data from the logs are entered into a computer program and individual monthly feedback forms are generated.

3.6.2. Monthly feedback—Each month, participants will receive a 1-page individualized feedback form that summarizes the data from their exercise logs and includes 3–4 specific

comments regarding their performance during the previous 4 weeks. The feedback forms utilize graphs to display the data in a manner that is visually appealing and easy to interpret. Specifically, the graphs reflect the number of days of exercise with the *FlexToBa*^{TM} DVD, total number of minutes of exercise, and the average RPE and enjoyment ratings for the exercise sessions for each week. Additionally, the graphs reflect the number of days and number of minutes of additional exercises. Feedback forms are generated and mailed to participants within two weeks of receipt of the logs.

3.6.3. Support calls—In a further effort to enhance adherence to the program, participants will be called by members of the research team on a regular basis. The purpose of these telephone calls is to address any difficulties individuals may be having with the DVDs or the exercise program, to enhance motivation by providing a *FlexToBa*^{TM} exercise tip, and ultimately, to ensure fidelity to the intervention. Phone calls generally will be brief in duration (i.e., 2–3 minutes), but may be longer if an individual has specific concerns to be addressed.

During the first two months of the intervention, participants will be called on a bi-weekly basis. Thereafter, they will be called monthly. The monthly phone calls are scheduled to take place during the third week of each month so that feedback from the previous month can be discussed during the call. For each call, the research team will make three separate attempts to reach the individual. On the third attempt, if the individual does not answer, the researcher will leave a message with the exercise tip.

3.7 Attention-Control: Healthy aging arm

The healthy aging condition represents the comparison group and as such will not receive any specific instructions, materials, or recommendations relative to physical activity. Rather, they will be instructed to go about their lives as they normally would. Individuals in this group will also receive an 85-minute DVD by Dr. Andrew Weil titled “*Healthy Aging*,” which focuses on a range of topics relative to successful aging. Participants will be asked to watch the DVD in its entirety, as information from the video will be discussed during the scheduled telephone calls. Calls to the healthy aging group will be completed on the same schedule as telephone calls to the intervention group, in order to provide equal contact to both groups. Participants in this group will be provided with a healthy aging tip and also reminded that they will receive the exercise program at the conclusion of the 12-month testing period.

3.8. Adverse Events and Data Safety and Monitoring Board

All adverse events for all participants, and their possible relation to the *FlexToBa*^{TM} program will be closely monitored and reported to the study Data Safety Monitoring Board (DSMB), the local Institutional Review Board, and the National Institute on Aging. In addition, a blinded research assistant will make non-spontaneous adverse event telephone calls to all participants at 3 and 9 months. The DSMB will be composed of three external members with doctoral degrees (i.e., MD/Ph.D.), and include a physician, a behavioral scientist with expertise in aging, physical activity, and disability, and a behavioral scientist with expertise in physical activity interventions. The DSMB will be charged with approving the study manual of procedures, assessments of data quality and timeliness, participant recruitment, accrual and retention, risk versus benefit, and other factors affecting study outcomes. The DSMB and the investigative team will meet by conference call on a biannual basis.

3.9 Data Analytic Plan

3.9.1 Analysis of Treatment Effects—Initial analyses will employ multivariate repeated measures analysis of variance using an intent-to-treat approach to examine the

immediate effects of the intervention on the primary study outcomes (i.e., quality of life, functional performance, and functional limitations). In order to examine the rate of change across the three time points (i.e., baseline, end of trial, and 6 month follow-up), we will use latent growth curve modeling (LGM) conducted within a covariance framework, using *Mplus* version 6.1 [35]. LGM is a very useful approach to determine individual level growth trajectories on measures of the same construct over time. Moreover, it can also be used to examine determinants or consequences of longitudinal growth trajectories at both the individual and group level [36]. Thus, LGM will be used to test the effects of the *FlexToBa*^{TM} intervention on primary and secondary (e.g., psychosocial factors) outcomes.

The LGM approach allows for the simultaneous examination of group (between) differences and intra-individual (within) change, and provides a direct test of specific aim one and two, which hypothesize overall *FlexToBa*^{TM} effects on primary outcomes. As we have multiple measures of all of the primary constructs in our models, these constructs will be modeled as latent variables. The primary analyses involve testing for differential rates of change across time for the *FlexToBa*^{TM} and the control conditions. In addition, we will test our theoretically-based models that hypothesize the effects of physical activity on functional limitations operating indirectly through pathways involving self-efficacy and functional performance [37] and the effects of physical activity on global quality of life operating indirectly through self-efficacy and health status [38].

3.9.2. Determining model fit—Multiple criteria will be used to evaluate the extent to which our models fit the data, including the chi-square statistic (χ^2), root mean square error of approximation (RMSEA), and the comparative fit index (CFI). Larger values for χ^2 ($p \geq .05$), RMSEA at or below .06, and CFI at or above .95 will be considered as evidence of good-fitting models [39]. We will also use robust full information maximum likelihood estimation procedures.

3.9.3. RE-AIM analyses—Treatment of the RE-AIM data to determine the public health impact of the intervention will be conducted as described previously.

3.9.4 Power and Sample Size—We conducted a conventional power analysis for detecting a Condition (2 levels between-subjects: Intervention vs. Control) $\times$ Time (3 levels within-subjects: 0, 6, and 12 months) interaction on the primary outcomes of functional limitations and functional performance. The sample size required for detecting a small effect ($f = .10$) with power of .80 and an alpha of .05 was 246. Our goal is to recruit 300 participants (150 per condition). This will allow for attrition of approximately 24% which we believe to be realistic based on other trials conducted by our research team. We also note LGM, which has the distinct advantage of accounting for measurement error, thereby resulting in disattenuation of the relationships among variables and an increase in reliability and reduction of sample size requirements. Indeed, evidence from simulation studies indicates that LGM has 150–200% more efficiency for detecting group differences in the growth trajectory slope than traditional mixed-model ANOVA [40]. This efficiency translates into a greater statistical power for LGM compared with ANOVA across any given sample size. Therefore, we are confident that our proposed sample size will yield appropriate statistical power for testing the primary aims of the proposed project.

3.9.4. Process Analysis—At the conclusion of the trial, participants in the *FlexToBa*^{TM} condition will complete an evaluation of the program in which they will rate their degree of satisfaction with the overall program, professionalism of the staff, quality of DVD and written materials, progression and modification of exercises, testing appointments and the research team. In addition, they will be given the opportunity to respond to open-ended

questions relative to any impact the program has had on their lives and those aspects of the program which they found most beneficial.

4. Limitations

One potential limitation that might be leveled at the *FlexToBa*^{TM} trial is the potential difficulty of delivering the intervention by DVD to older adults, given the often reported difficulties with technology experienced by older adults. However, data released by the Neilson Media Group's third quarter home technology report in December 2006 [41] indicated that more US households (81.2%) own a DVD player than a VCR (79%). Additionally DVD penetration continues to grow whereas VCR penetration declines. Older adults' use of technology in general has risen dramatically in the last several years personified by a doubling of adults 50 years and older using social media in the last year [42]. Moreover, the menu-driven nature of DVDs is easy to follow thereby reducing potential confusion. To further offset this concern in the present study, we will dedicate a research assistant to addressing issues of set-up, DVD usage and operation, technical difficulties, and equipment malfunction. Additionally, we provide clearly presented typed information about correct usage, common problems and their solutions, plus a toll-free number to call our laboratory for rapid assistance.

A further concern might be that our design should include a true, no-contact control condition. We counter this position by noting that the accumulated evidence is overwhelmingly in favor of the conclusion that doing nothing, i.e., remaining sedentary, is unlikely to have any positive effects on functional performance or functional limitations in older, already low active adults. Rather, our design is such that we can effectively compare the intervention condition with a control group which receives similar resources and attention as an effective vehicle for promoting health and well-being in older Americans. It may be argued that participants in the attention control condition may become active having watched the *Healthy Aging* DVD with which they are provided. However, they will not have a systematic, well-developed, progressive activity program that can be conducted in their own homes and has the potential to reduce functional limitations, enhance functional performance and independent living, and improve quality of life. We believe this approach holds the greatest potential for reaching large numbers of older adults.

5. Conclusions

Biomedical advances and the practice of preventive health behaviors have resulted in an unprecedented growth in the older population of the United States, a trend projected to continue over the next several decades [1]. However, the addition of years to life is no guarantee that those years will be quality years and there is considerable evidence to suggest that increasing the lifespan is also associated with decrements in function and increases in disability. Physical activity interventions and the incorporation of physical activity into one's lifestyle represent at least one behavioral modality for possibly attenuating the effects of the aging process on functional limitations and disability and the attendant declines in quality of life. Although flexibility, strength and balance have been identified as important determinants of disability [3], few physical activity interventions are designed to emphasize these elements of fitness. Moreover, most physical activity interventions are promoted as center-based programs, often posing threats to adherence and generalizability.

The *FlexToBa*^{TM} trial is designed to determine the effects of a 6-month home-based intervention targeting flexibility, toning, and balance on physical activity, functional performance, functional limitations, and quality of life in older adults. We frame the trial in social cognitive theory [7] in an effort to (a) reduce potential attrition and (b) determine

whether self-efficacy mediates the effects of physical activity on functional performance, function limitations, and quality of life in older adults. Moreover, we apply the principles of the RE-AIM framework [6] to the planning, design, and analysis of our intervention in an effort to bridge the gap between research and practice.

We believe that the innovative design of the *FlexToBa*^{TM} trial has significant implications for advancing clinical practice as a function of knowledge gained. Specifically, our approach, if successful, will be easily distributable to practitioners and it underscores the implementation of social cognitive factors in physical activity programs by focusing on modifiable factors to promote function and well-being. Third, we propose to test the role of *modifiable* factors that appear to mediate the physical activity-functional limitations-QOL relationships in the context of an intervention. This will allow us to further disentangle some of the underlying mechanisms of these relationships. The next step in our research agenda would be to move forward with an effectiveness trial to implement the program in more diverse populations and settings. Finally, our findings are likely to have implications for concepts, methods, and treatments by underscoring the fundamental importance of low-cost, targeted delivery of physical activity programs of flexibility, toning, balance, and endurance as a *whole package* in protecting against functional limitations in late life.

Acknowledgments

The project described was supported by Grant Number 2R01 AG20118-05 from the National Institute on Aging. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes on Aging. The authors express their appreciation to: Susan H. Herrel, project coordinator for this study; Bill Yauch and RiellyBoy Productions; Erica Urrego, DVD exercise leader; and Grant Henry, Lynda Matejkowski, Joyce O'Donnell, Bernard Puglisi, Paula Smith, and Peter Tan, DVD exercise models. The authors also extend their thanks to Andrew Weil MD for the generous contribution of the *Healthy Aging* DVDs.

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Figure 1.
FlexToBa™ Participant Flow-Chart

Table 1

Primary Study Measures

Scale *	Construct	Subscales	Range	Reliability	Validity	Original Source
Physical Activity Scale for the Elderly (PASE)	Physical Activity	leisure-time activity; household activity; work-related activity	multiply time in activity by respective weights, sum over all activities	NA	Martin et al., 1999; Washburn et al., 1999	Washburn et al., 1993
Godin Leisure Time Exercise Questionnaire (GLTEQ)	Exercise	strenuous exercise; moderate exercise; mild exercise	frequency of activities multiplied by 9, 5, and 3 METS, respectively	NA	Jacobs et al., 1993; Miller et al., 1994	Godin & Shephard, 1985
Late-Life Function and Disability Instrument (LL-FDI)	Functional Limitations	basic lower extremity function; advanced lower extremity function; upper extremity function	0...25 (subscale); 0...75 (total score)	ICC 0.91 – 0.98	McAuley et al., 2005	Haley et al., 2002; Jette et al., 2002
Exercise Self-Efficacy Scale (EXSE)	Self-Efficacy	none	0...100	0.90	McAuley et al., 2003; McAuley et al., 2007	McAuley, 1993
Lifestyle Self-Efficacy Scale (LSE)	Self-Efficacy	none	0...100	≥ 0.95	NA	McAuley et al., 2009
Gait Efficacy Scale (GES)	Self-Efficacy	none	0...100	0.91	Rosengren et al., 1998; McAuley et al., 2006	McAuley et al., 1997
Function Self-Efficacy Scale (FXNSE)	Self-Efficacy	basic lower extremity function; advanced lower extremity function; upper extremity function	0...100 (subscale); 0...100 (total score)	NA	NA	NA
12-Item Short Form Health Survey (SF-12)	Health Status	physical health status; mental health status	based on scoring algorithms from the general population	0.89 (physical); 0.76 (mental)	Jenkinson et al., 1997	Ware Jr. et al., 1996
Satisfaction with Life Scale (SWLS)	Global Quality of Life	none	5...35	0.87	Pavot et al., 1991; Siedlecki et al., 2008	Diener et al., 1985

* All measures assessed at baseline, 6 months, and 12 months

Note secondary measures include: the Perceived Stress Scale [30]; the Fatigue Symptom Inventory [31]; the Pittsburgh Sleep Quality Inventory [32]; the Physical Self-Perception Profile [33]; the Rosenberg Self-Esteem Scale [34]; the Hospital Anxiety and Depression Scale [35]; the Positive and Negative Affect Schedule [36]; the Physical Activity Enjoyment Scale [37]; and the Multidimensional Outcome Expectations for Exercise Scale [38]