The lifestyle interventions and independence for elders (LIFE) pilot study: Design and methods

W. Jack Rejeski, Roger A. Fielding, Steven N. Blair, Jack M. Guralnik, Thomas M. Gill, Evan C. Hadley, Abby C. King, Stephen B. Kritchevsky, Michael E. Miller, Anne B. Newman, Marco Pahor

Department of HES, Box 7868, Wake Forest University, Winston-Salem, NC 27109, United States
Boston University, United States
Cooper Institute, Dallas, TX, United States
National Institute on Aging, United States
Yale University, United States
Stanford University, United States
Wake Forest University School of Medicine, United States
University of Pittsburgh, United States

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Abstract

The LIFE study is a multicenter pilot for a proposed full scale, two-arm randomized controlled trial that will contrast the effect of a physical activity intervention with a successful aging education program on the occurrence of incident major mobility disability (the inability to complete a 400 m walk) or death in at-risk sedentary older adults. Four hundred older adults from 4 clinical sites will be recruited for this purpose. All participants will be followed for at least 1-year; however, we will continue to follow all participants until the final randomized individual has reached the 1-year mark. This will enable us to acquire additional information about maintenance. Additional outcomes will include lower extremity physical performance as well as gait speed over 4 m and 400 m. These latter measures will provide data on the efficacy of the intervention on intermediate endpoints linked to the primary outcome of interest. The goals of the pilot study are to (a) estimate the sample size needed for a full scale trial, (b) examine the consistency of the effects of the physical activity intervention on several continuous measures of physical function, (c) assess the feasibility of recruitment, (d) evaluate study adherence and retention, (d) evaluate the efficacy of a stepped care

* Corresponding author.
E-mail address: rejeski@wfu.edu (W.J. Rejeski).

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1. Introduction

The life expectancy of older Americans continues to increase with people over the age of 69 representing one of the fastest growing segments of the US population [1]. Although prolongation of life remains an important public health goal, of even greater importance is that extended life should include the capacity to live independently and to function well [2]. Mobility (ambulation) and activities of daily living represent tasks that are necessary for the maintenance of basic independent functioning [3]. The inability to perform these activities marks a serious decline in functional health, increasing the risk of institutionalization and death [4].

Many older adults aged 70 and above are sedentary, sarcopenic (i.e., have low muscle mass) [5], and either experience or are at high risk for declining mobility [6]. Whereas several observational studies suggest a benefit of physical activity in preventing the onset of mobility-related disability in this population [7], definitive clinical trial evidence is lacking. In this regard, it is important to recognize that short-term gains in intermediate outcomes of physical activity programs such as strength and aerobic capacity are insufficient to prove that such programs prevent long-term mobility disability. Existing examples in medicine that relate to the pharmacological treatment of cardiovascular conditions [8] and hormone replacement therapy [9] demonstrate the danger of relying exclusively on surrogate outcomes and observational data for public health recommendations.

The aforementioned gap in knowledge served as the impetus for a cooperative agreement with the National Institute on Aging and several institutions to conduct the Lifestyle Interventions and Independence for Elders (LIFE) study. LIFE is a multicenter pilot for a definitive, randomized, single-blind, controlled trial to examine the efficacy of a physical activity intervention, compared with a successful aging educational program, on the incidence of major mobility disability (the inability to walk 400 m without the use of an assistive device) or death in at-risk older adults.

2. Primary research goals

The primary research goals of the pilot study are to:

1. obtain data to project the sample size needed for a full-scale study by using the incidence rates of the combined outcome of major mobility disability, defined as the inability to walk 400 m, or death;
2. examine the consistency of the effects of the physical activity intervention on a variety of continuous measures of physical function by assessing its effects on lower extremity physical performance [10], gait speed over 4 m and 400 m, and self-reported disability;
3. assess participant adherence to and retention in the physical activity and successful aging interventions;
4. assess the rates of intercurrent illness and the efficacy of a stepped care protocol in managing these illnesses during the course of the trial;
5. assess the feasibility of recruiting an at-risk cohort from diverse communities and ethnic subgroups, and to determine recruitment yields in these subgroups;
6. evaluate predictors of response and adherence to the physical activity intervention; and
7. develop a comprehensive system to monitor and ensure participant safety and to acquire data on adverse events that may occur in conjunction with physical activity in this high-risk population.

3. Study design

3.1. Overview

A total of 400 sedentary persons aged 70–85 years who are at elevated risk of disability will be randomized to either a physical activity or a successful aging educational intervention for the duration of the study. Our use of a successful aging comparison group is based on experience of the investigative team. Specifically, in order to effectively recruit older adults and to retain them in intervention studies, we have devised an education treatment that has been shown not to affect the primary outcomes of the study, yet will be viewed as interesting to older adults [11]. The term successful aging is appropriate because it has the desired effect from a scientific perspective and involves educating older adults about key issues that are important to successful aging; i.e., traveling, managing medications, getting the most out of health care, nutrition, etc. After baseline testing and randomization, follow-up assessments will occur semi-annually. All participants will be followed for at least 1-year; however, we will continue to follow all participants until the final randomized individual has reached the 1-year mark. This will enable us to acquire additional information about maintenance behavior. The main outcome of the trial is major mobility disability, defined as the inability to walk 400 m, or death. Four clinical sites and a coordinating center in conjunction with the active partnership of NIA have been organized for this purpose. The four clinical sites are Wake Forest University School of Medicine in Winston Salem, NC, the University of Pittsburgh in Pittsburgh, PA, the Cooper Institute in Dallas, TX, and Stanford University School of Medicine in Palo Alto, CA. The Administrative Coordinating Center and the Data Management and Quality Control Center are at Wake Forest University School of Medicine.

3.2. Eligibility

The eligibility criteria in this study are aimed at identifying persons who are sedentary and who have lower extremity functional limitations based on objective testing of physical performance but who have not yet developed major mobility disability; that is, they are able to walk 400 m. Eligibility is established through a multi-step process involving telephone screening and in-person assessments.

3.3. Inclusion criteria

- Men and women aged 70–85 years
- Summary score<10 on the SPPB [10,12]
3.4. Exclusion criteria

- New York Heart Association Class III or IV congestive heart failure, clinically significant aortic stenosis, history of cardiac arrest, use of a cardiac defibrillator, or uncontrolled angina
- Lung disease requiring either oral or injected steroids, or the use of supplemental oxygen
- Mini-Mental State Exam < 21
- Severe arthritis (either osteoarthritis or rheumatoid arthritis)
- Cancer requiring treatment in the past 3 years
- Development of chest pain or severe shortness of breath on the 400 m self-paced walk test
- Parkinson’s disease or other serious neurological disorders; renal disease requiring dialysis; other illness of such severity that life expectancy is considered to be less than 12 months
- Current diagnosis of schizophrenia, other psychotic disorders, or bipolar disorder
- Current consumption of more than 14 alcoholic drinks per week
- Clinical judgment concerning participant safety or noncompliance.

3.5. Temporary exclusion criteria

- Hip fracture, hip or knee replacement, or spinal surgery in the past 6 months
- Myocardial infarction, major heart surgery, stroke, deep vein thrombosis, or pulmonary embolus in the past 6 months
- Uncontrolled hypertension (systolic blood pressure > 200 mm Hg and/or diastolic blood pressure > 110 mm Hg)
- Uncontrolled diabetes with recent weight loss, diabetic coma, or frequent insulin reactions
- Serious cardiac conduction disorder (e.g., 3rd degree heart block), uncontrolled arrhythmia, or new Q waves or ST-segment depressions (> 3 mm) on ECG
- Undergoing physical therapy involving the lower extremities
- Currently enrolled in another randomized trial involving a pharmaceutical or lifestyle intervention.

3.6. Recruitment

The goal of the study is to randomize 400 participants across a 9-month interval of time with a minority participation rate of at least 25%. Recruitment in the LIFE study also has a target of at least 40% of participants with baseline SPPB scores between 4 and 7. All participants will complete an informed consent prior to baseline assessments.
3.7. Study run-in and randomization

Participants complete a 1-week behavioral run-in prior to randomization. They are asked to record, on a paper log, information about the number and type of fruits and vegetables eaten and type and frequency of daily physical activity during this period. The logs are then reviewed by a trained interviewer. The intent with this run-in was to ask participants to monitor lifestyle behaviors in general as opposed to physical activity alone. Conducted in this manner, the run-in makes sense to both treatment arms in that there is a nutritional component to the successful aging arm and participants are taught about the importance of self-monitoring. To pass the run-in, participants must have written entries for at least 6 of the 7 days for both fruits/vegetables and physical activity. If unsuccessful, participants may be given one additional opportunity to complete the behavioral run-in. In addition to the run-in, participants can be excluded on the basis of clinical judgment; that is, they are judged to pose a risk for adherence and/or retention.

Each eligible participant is randomized by a web-based system to one of the two study arms. Randomization is stratified by gender and by field center to ensure nearly equal sample sizes of men and women for the two intervention groups within each center.

3.8. Measures

Table 1 provides a summary of the types and schedule for the conduct of all assessments in the LIFE study. All measures are obtained by personnel blinded to participants’ randomization assignment. Below is a brief description of the main study outcomes:

- **400 m walk test.** The primary outcome in LIFE is time to the onset of the combined outcome of major mobility disability or death. The outcome of major mobility disability is defined objectively as the inability to complete a 400 m self-paced walk within 15 min without sitting and without the use of an assistive device (including a cane) or the help of another person. At each follow-up clinic visit, participants and their proxies are also independently asked a distinct set of mobility-related questions that can serve as surrogates for the 400 m walk test. One sub-goal of the pilot study is to refine the definition of this outcome by potentially using surrogate self-report data when 400 m performance is missing.

- **Short physical performance battery (SPPB).** The SPPB consists of a 4 m walk, repeated chair stands, and three hierarchical standing balance tests [12]. Each of the three performance measures is assigned a categorical score ranging from 0 to 4, with 4 indicating the highest level of performance and 0 the inability to complete the test. A summary score ranging from 0 (worst performers) to 12 (best performers) is calculated by adding walking speed, chair stands, and balance scores.

- **Self-reported physical function/disability.** The measure of self-reported function is based on a 23-item self-report questionnaire that inquires about perceived difficulties in basic and more advanced activities of daily living during the last month [13]. In addition to being a valid measure, it has been shown to be responsive to change in previous physical activity intervention studies among various disease populations [14,15]. In the LIFE study, we have added two other items to the scale, “walking across a small room” and “walking a quarter of a mile” (about 2 or 3 blocks). These two items have been used previously as a single outcome of interest for studies on mobility disability [16]. For basic ADL questions, we also ask whether the participant receives help from another person to complete the
task. This allows us to calculate a Katz ADL score. Finally, the Late Life Disability questionnaire developed by Jette and colleagues [17] is used as a measure of self-reported disability.

- Health-Related Quality Of Life (HRQL). HRQL will be assessed using the Quality of Well-Being Scale [18,19], the Center for Epidemiologic Studies Depression Scale (CES-D) [20], sleep quality by means of the 5-item Women’s Health Initiative Insomnia Rating Scale [21,22], energy/fatigue by the 6 fatigue and energy items from the Modified Exercise-Induced Feeling Inventory [23], and pain using a modified 12-item pain scale that has been used in previous physical activity trials [14,24].

3.9. Physical activity arm

The physical activity intervention will employ a combination of aerobic, strength, balance, and flexibility exercises. The intervention is divided into 3 phases: adoption (weeks 1–8), transition (weeks 9–24), and maintenance (weeks 25 to end of trial). Exercise training will be primarily center-based during the adoption phase with a systematic transition to home-based exercise.

As undertaken in other programs with older adults [11,25], each participant randomized to the physical activity group receives a 45-min individualized, face-to-face introductory session prior to beginning exercise training. The purpose of this session is to create a collaborative relationship with each participant, describe the program in detail, and answer questions. Additionally, participants attend two lectures with the exercise physiologist to review the components of the FITT principle (the role of frequency, intensity, time, and type of activity in an exercise prescription) and to examine the difference between exercise and physical activity.

The physical activity intervention is based on social cognitive theory [26] and a recent group-mediated approach for promoting physical activity among older adults [27]. The training regimen includes 10 weekly closed-group counseling sessions that focus on physical activity and the prevention of physical disability. Emphasis is placed on the development of motivation and skills to promote adherence and an increase of all forms of physical activity throughout the day, including leisure sports, advanced ADLs (e.g., yard work), use of stairs as opposed to escalators, and leisurely walks with friends (see Table 2).
Walking is the primary mode of physical activity, given its widespread popularity and ease of administration in older persons [28,29]. Other forms of endurance activity (e.g., stationary cycling) are, however, utilized on a limited basis when regular walking is contraindicated. According to the Surgeon General’s recommendations, the walking component has a weekly goal of at least 150 min performed 5 or more days of the week, which will be approached in a progressive and individualized manner across the first 3 months of the trial [14,30].

Each session is preceded by a brief warm-up and followed by a brief cool-down period. Moreover, participants perform 10-min lower extremity strengthening exercises by using variable weight ankle weights followed by a brief lower extremity stretching protocol. Supplemental materials are supplied to reinforce the strength training so that it can be generalized to the home environment. Balance training [14] is also introduced during the initial (adoption) phase of the program.

### 3.9.1. Intensity of training

The physical activity intervention begins with lighter intensity activity, which gradually increases over the first 2–3 weeks. LIFE promotes walking at a moderate intensity as assessed by Borg’s ratings of perceived exertion scale [31,32], which has a range from 6 (no exertion at all) to 20 (maximal exertion) [33]. Participants are asked to walk at an intensity of 13 (SOMEWHT HARD); they are discouraged from exercising at levels ≥15 (HARD) or ≤11 (FAIRLY LIGHT). Strengthening exercises are performed (2 sets of 10 repetitions) at an intensity of 15 to 16.

### 3.9.2. Contact mode and frequency

The intervention is divided into 3 phases: adoption (weeks 1–8), transition (weeks 9–24), and maintenance (week 25 to end of trial). In the adoption phase, participants attend center-based exercises (40–60 min) 3 times each week, have group counseling sessions once a week, and receive a telephone contact one time each month. The center-based contacts are used to initiate the walking program and to introduce participants to the strength, stretching, and balance portions of the program in a safe and effective manner [34]. A gradual phasing in of home-based physical activity begins at week 4 (see Table 2).

During the transition phase, center-based exercise occurs 2 times each week, with group counseling contacts during the first 2 weeks, and phone contacts each month. These sessions are supplemented by

<table>
<thead>
<tr>
<th>Phase</th>
<th>Center-based physical activity</th>
<th>Group-mediated counseling</th>
<th>Home-based physical activity</th>
<th>Telephone counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adoption (weeks 1–8)</td>
<td>3× week; shaping to: 40 min walking, 10 min leg strength, 10 min balance</td>
<td>8 contacts following a physical activity session each week</td>
<td>None until wk 4; 1× a week for weeks 4 and 5; 2× a week for weeks 6–8</td>
<td>1 time per month</td>
</tr>
<tr>
<td>Transition (weeks 9–24)</td>
<td>2 times each week 40 min walking, 10 min leg strength, 10 min balance</td>
<td>2 contacts; once each week following an exercise bout for the first 2-weeks</td>
<td>3× per week</td>
<td>1 time per month</td>
</tr>
<tr>
<td>Maintenance (week 25 on)</td>
<td>Offered once per week (optional)</td>
<td>None scheduled; optional open sessions possible</td>
<td>5 or more days a week</td>
<td>1 time per month</td>
</tr>
</tbody>
</table>
home-based endurance/strengthening/flexibility exercises [29] performed at least 3 times each week. Appropriate community based exercise facilities (e.g., YMCAs; senior centers) are identified for those preferring to undertake center-based activities on a more frequent basis. During the maintenance phase, center-based exercise is offered one time each week (optional) with monthly phone contacts. Thus, most, if not all, physical activity occurs in either the home or community. Quarterly newsletters are used to promote ongoing support, participation, and adherence to physical activity.

3.9.3. Tracking progress
The interventionists use a web-based tracking system to track session attendance, telephone contacts, and information on center- and home-based exercise sessions and to generate reports for use in weekly staff meetings.

3.9.4. Restarting a suspended physical activity program
Physical activity may be suspended due to a hospitalization, injury, or other health events. Evaluation for restarting physical activity depends on the functional impact of the illness and any activity limitation prescriptions that may have been provided by the participant’s health care team, including the primary care physician, surgeon, consultants, or therapists. Irrespective of the phase of the intervention that a suspension may occur, all restarts will be conducted in a supervised setting until such time that the participant in question may engage safely in home-based physical activity.

3.10. Successful aging arm
An active control intervention will be used in LIFE as a comparison group to the physical activity intervention and is framed in the context of health education for successful aging. This program is based on workshops on a variety of health topics relevant to older adults (e.g., healthful nutrition, how to effectively negotiate the health care system, how to travel safely, recommended preventive services and screenings at different ages, where to go for reliable health information, etc.) and also involves a short instructor-led program (5–10 min) of upper extremity stretching exercises. This brief stretching program is performed during each class to provide direct behavioral attention to participants and to help foster adherence to the intervention arm without directly affecting the study outcomes. The education sessions and stretching component of the successful aging program provide instructor support and promote group interaction. Participants also learn how to actively ‘take charge’ of their health in seeking out appropriate medical information and services.

3.10.1. Contact mode and frequency
The successful aging program meets in small groups weekly for the first 24 weeks and monthly thereafter. Telephone calls are made after each missed session to problem-solve barriers to attendance and to encourage regular participation. Participants are encouraged to actively ‘take charge’ of their ongoing program experience with respect to topic areas of interest, guest speakers, etc.

3.11. Participant safety
The LIFE study considers safety in both the context of participant screening and monitoring. During the screening phase, potential participants are closely monitored during study assessments and those at high
risk for medical complications for the physical activity intervention are excluded. During the intervention phase, participants are monitored during supervised physical activity sessions and coached on safety for their unmonitored sessions. The study re-evaluates participants who experience a serious illness during the course of the study that could pose a medical risk for continued involvement in LIFE (see the section on restarting a suspended physical activity program on the previous page). The study also monitors adverse events and assesses their potential relationship to the intervention. All adverse events are reported to the Data Safety Monitoring Board (DSMB), the Institutional Review Board (IRB), and the NIH.

3.12. Statistical considerations

To project the sample size for the full scale study, the 1-year rate of major mobility disability or death will be estimated in the successful aging educational control group as the proportion of participants who are unable to do the 400 m walk at either 6 months or 12 months or who have died. The marginal incidence distributions for the two components of the primary outcome measure (400 m walk and death) will be estimated separately using life-table methods. Sensitivity analyses will be performed by calculating rates both with and without proxy reports included and through the use of propensity score methods to adjust for non-response. We will explore how these components of the primary outcome separately relate to other secondary outcomes to provide additional information as to whether congruous intervention effects are observed for both components of the endpoint. We will also estimate the proportion of successful aging intervention participants who “drop-in” to the physical activity intervention through the initiation of a physical activity program, physical activity condition participants who “drop-out” of the intervention, and participants who are completely lost to follow-up. To explore the use of several alternative components of a composite endpoint, a series of supportive secondary analyses will be conducted. Specifically, one analysis will determine the sensitivity/specificity of proxy and self-reports of disability in comparison to observed measures of 400 m walk performance.

4. Study management

4.1. Field centers

Each of the four Field Centers is responsible for recruiting LIFE participants and performing standardized assessments/interventions. Appropriate staff from each field center attends central training and certification at the coordinating center for the intervention protocol and for all assessment. Annual site visits are conducted to review protocol adherence and overall study management.

4.2. Centralized study management

The administrative functions for the LIFE study are carried out by the Administrative Core at the coordinating center. It is responsible for the development and dissemination of all study materials, committee support, and the financial management of the study. A data management Core is also present at the coordinating center and is responsible for the management and storage of all data using a web-
based interface. This system facilitates the rapid efficient collection of clinical information using the existing technology of the Internet as well as the ease of use and familiarity with Web browsers. The data entry screens, which are very similar to the study forms, are developed using hypertext mark-up language (HTML). Participant data entered by clinic staff reside on an NT server at the coordinating center, with Cold Fusion middleware providing connectivity to the SQL Server database. Data security in the Web-based data system uses 128-bit encryption and Secure Socket Layer (SSL).

A Lifestyle Resource Core monitors the intervention delivery and assists interventionists throughout the course of the intervention. The core consists of a behavioral scientist, a geriatrician, and an exercise therapist. This core reviews monthly tracking reports on adherence to various components of the intervention from the coordinating center on a site-by-site basis. Interactions between core experts and interventionists are facilitated by monthly calls and an e-mail contact system. Interactions typically include, but are not limited to, review of protocol issues, adherence problems, and strategies for delivering the group-based behavioral sessions.

4.3. Steering committee

The steering committee is responsible for the overall governance of study conduct as well as for developing all scientific and administrative policies. The committee consists of the co-chairs, chairs of the main study committees, selected investigators of the Field Centers, and the NIA Project Officers.

5. Discussion

The LIFE study is a multicenter pilot for a definitive trial targeting the combined outcome of preventing major mobility disability or death in older adults who have compromised physical function; that is, scores on the SPPB between 4 and 9. To our knowledge, the proposed combined outcome of major mobility disability or death is novel. Such a definitive clinical endpoint has not been used in previous RCTs. The 400 m walk is an objective test of mobility and the loss of ability to complete the task represents a significant clinical event in the care of older adults. The current lack of definitive evidence on whether physical disability can be effectively prevented represents a potential hindrance to the practice of evidence-based geriatric medicine and further development of novel interventions to prevent mobility disability.

The full-scale trial would determine whether long-term adherence to a physical activity program is an attainable goal and whether the health benefits of exercise continue beyond the first 4 to 6 months, the usual follow-up time of most exercise interventions. According to preliminary estimates, the full trial would require approximately 3000 to 4000 participants from 15–20 field centers with an average follow-up duration of 3 to 4 years; however, a major purpose of the pilot is to develop more accurate estimates of the target recruitment goal.

The physical activity intervention for LIFE is grounded in social cognitive theory [26] and involves multiple components of fitness including aerobic, strength, balance, and flexibility training. Early center-based sessions in this treatment group are augmented with time-limited group counseling. These behavioral groups foster the motivation, skills, and resources that have been shown to be effective with older adults in promoting commitment to physical activity as a strategy to cope with the process of
physical disablement [27]. This physical activity intervention has been designed to be potentially delivered in community settings and may have broad applications for public health.

One question that may arise in the mind of the reader is how we expect a 1-year pilot study to provide efficacy for a long-term (3–4 year) full trial. First, the pilot study is not an efficacy study for the main outcomes. Recall, that it was designed to enable us to project the sample size needed for a full scale study and was requested by the National Institute of Aging. In the full trial, the first major assessment will occur at year 1 even though we will follow participants for 4 years. And second, we will continue to follow participants in the pilot study until all participants have completed at least 1 year of treatment. This procedure will enable us to learn more about what to expect and how to intervene with the challenges of promoting maintenance behavior in the full trial.

6. Conclusions

The study of whether physical activity can prevent major mobility disability among at-risk older adults is an unanswered question that is of major importance to public health and social policy. A positive result in a full-scale trial would fill an important gap in knowledge for practicing evidence-based geriatric medicine, and for other health care and health maintenance practices. This could lead to the development of translational studies to increase physical activity in a variety of health care settings that would be critical to addressing the growing challenge that health care will face with physical disablement in an aging population. On the other hand, failure to reject the null hypothesis would suggest that the progression of underlying disease processes in at-risk persons continues on to disability despite any potential benefits from physical activity. This would be an important study outcome as well and imply that efforts to curb the process of physical disablement in this population should be directed elsewhere.

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1. Research investigators for pilot phase of LIFE

Clinical sites
Wake Forest University in Winston-Salem, NC:
Stephen B. Kritchevsky, PhD Site PI
Peter Brubaker, PhD
Jamehl Demons, MD
Jeffrey Katula, PhD
Anthony Marsh, PhD
Barbara Nicklas, PhD
W. Jack Rejeski, PhD
University of Pittsburgh in Pittsburgh, PA:
   Anne B. Newman, MD, MPH Site PI
   Nancy Glynn, PhD
   Bret Goodpaster, PhD, MS
   Stephanie Studenski, MD, MPH

Cooper Institute in Dallas, TX:
   Steve Blair, PED Site PI
   Timothy Church, MS, PhD, MPH
   Andrea Dunn, PhD

Stanford University in Palo Alto, CA:
   Abby King, PhD Site PI
   William Haskell, PhD, MS
   Ami Laws, MD
   Leslie Pruitt, PhD

Administration center
Wake Forest University in Winston-Salem, NC:
   Marco Pahor, MD Principal Investigator
   Mark Espeland, PhD
   Curt Furberg, PhD
   Jeffrey Katula, PhD
   Stephen B. Kritchevsky, PhD
   Michael E. Miller, PhD
   W. Jack Rejeski, PhD

Data management and quality control
Wake Forest University in Winston-Salem, NC:
   Michael E. Miller, PhD Chair
   Mark Espeland, PhD
   Fang-Chi Hsu, PhD
   Jeffrey Katula, PhD
   Stephen Kritchevsky, PhD
   W. Jack Rejeski, PhD

References


