Maintaining Exercise and Healthful Eating in Older Adults: The SENIOR Project II: Study Design and Methodology

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Abstract

The Study of Exercise and Nutrition in Older Rhode Islanders (SENIOR) Project II is an intervention study to promote the maintenance of both exercise and healthful eating in older adults. It is the second phase of an earlier study, SENIOR Project I, that originally recruited 1,277 community-dwelling older adults to participate in behavior-specific interventions designed to increase exercise and/or fruit and vegetable consumption. The general theoretical framework for this research is the Transtheoretical Model (TTM) of Health Behavior Change.

The current intervention occurs over a 48-month period, using a manual, newsletters, and phone coaching calls. Annual assessments collect standardized data on behavioral outcomes (exercise and diet), TTM variables (stage of change and self-efficacy), psychosocial variables (social support, depression, resilience, and life satisfaction), physical activity and functioning (SF-36, Up and Go, Senior Fitness Test, and disability assessment), cognitive functioning (Trail Making Test and Forward and Backward Digit Span), physical measures (height, weight, and waist circumference), and demographics.

The SENIOR Project II is designed to answer the following question as its primary objective: (1) Does an individualized active-maintenance intervention with older adults maintain greater levels of healthful exercise and dietary behaviors for four years, compared to a control condition? In addition, there are two secondary objectives: (2) What are the psychosocial factors associated with the maintenance of health-promoting behaviors in the very old? and (3) What are the effects of the maintenance of health-promoting behaviors on reported health outcomes, psychosocial measures, anthropometrics, and cognitive status?

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Keywords

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1. Introduction

The aging of the US population poses unprecedented public health challenges to our society, particularly in health promotion. The projected impact of the large cohort of baby boomers on health care services and costs is anticipated to be great [1]. However, the success of public health interventions in postponing the onset of chronic illness and providing effective management of existing disease and disability promises to have a positive impact on the quality of life of this rapidly expanding population group and potentially also on reducing Medicare costs in the future [2]. Calls have been made for the development of more public health interventions for older adults [3], and there is growing interest in the potential of research on health behavior to contribute to the design of interventions targeted on older adults [4, 5]. Population-based studies with older adults have highlighted the need for substantial improvement in health behaviors among this group and called for more public health intervention efforts to target motivation to acquire or maintain important health behaviors [6].

In particular, attention has been focused on the importance of both increased exercise levels and improved diet in older adults for enhanced health and quality of life [7]. Studies have increasingly targeted these two behaviors as critical for older adults [8-12]. In particular, the need for multiple behavior research with older adults to study interactions among interventions targeted on more than one behavior has been highlighted [13]. For example, if some health-related behaviors occur together, then it may be more efficient and less costly to intervene on these at the same time due to synergism between them. This focus reflects growing interest generally in multiple health behavior interventions and the need for more research in this area [14-16].

In addition, interest has recently expanded from the simple acquisition of healthful behaviors to their maintenance, especially in the face of some of the potential losses and physiological changes associated with aging that may cause setbacks leading older adults to get "off track" with their health-related behaviors. Research on the topic of resilience has recently gained considerable attention in the field of gerontology, focusing on why and how some older adults seem to bounce back or actually thrive in the face of adversity and setbacks in their lives [17-19].

For example, despite the health benefits of exercise, problems of motivational adherence are well documented. Fifty percent of individuals who initiate an exercise program drop out during the first three to six months [20, 21]. Little success has been achieved in improving long-term maintenance of exercise in any age group, including older adults [21, 22]. Older adults face an array of personal, socioeconomic, and environmental barriers to exercise adherence that are common to the general population, as well as those that are unique to this group [23, 24]. Similar issues with maintenance of healthy behaviors apply to diet. For

example, despite the health benefits of eating fruits and vegetables, problems of long-term behavior change and maintenance are well recognized [25].

2. Theoretical framework and background

2.1. Transtheoretical model of health behavior change

The Transtheoretical Model (TTM) of Health Behavior Change [26] suggests that individuals proceed through stages in their readiness to adopt healthy lifestyle behaviors, from precontemplation, to contemplation and preparation, and then into action and maintenance. The TTM integrates stages with processes of change, self-efficacy, and decisional balance. The stages represent a temporal dimension describing when cognitive and behavioral changes occur, processes of change capture how these shifts happen, and decisional balance focuses on the benefits (pros) and the costs (cons) of a behavior. Self-efficacy involves a judgment about one's ability to perform a behavior required to achieve a certain outcome. As people go through the stages, they employ the processes, self-efficacy, and decisional balance differently, making each stage unique.

For many older adults, maintenance of behavioral change (maintenance stage) is likely until some problem occurs that disrupts it. However, a setback becomes increasingly likely over time due to increased risk for chronic health problems and their impact on individuals' lives. As Wrosch and Schulz [27] suggest, "These facts imply that older adults are at risk of experiencing a downward spiral in which physical, psychological, and biological factors influence each other and compromise quality of life" (p. 537).

This setback or "lapse" may progress to a "relapse" or "collapse" of intention to continue with the dietary or exercise behavior. In TTM terms, older adults in maintenance can (1) continue in maintenance in spite of the setback, (2) temporarily lapse but quickly return to the action stage, (3) relapse to a pre-action stage but intend to start taking action in the near future (preparation stage) or more distant future (contemplation stage), or (4) "collapse," meaning relapse with no intention of taking action in the foreseeable future (precontemplation stage).

2.2. Background to SENIOR Project II

The SENIOR Project II is the second phase of the Study of Exercise and Nutrition in Older Rhode Islanders, following an initial phase—SENIOR I—that focused on the acquisition of increased exercise and healthful eating (fruit and vegetable intake) in older adults. The SENIOR Project I was established in 1999 with an initial, five-year grant of $3.1 million from the National Institute on Aging (NIA). Its primary objective was to develop and assess interventions targeted on two behaviors (exercise and diet) within a single theoretical framework (the TTM).

An initial sample of 1,277 participants (mean age = 75 years) was randomized into four intervention categories: (1) exercise (EX) only, (2) fruits and vegetables (FV) only, (3) exercise and fruits and vegetables (EX+FV), and (4) control (C). The intervention consisted of behavior-specific manuals, newsletters, stage assessments, expert system reports, and telephone coaching calls. Following an initial assessment at time 0, the intervention was

delivered for 12 months, followed by a no-contact period of an additional 12 months. Data collection using standardized measures was conducted at times 0, 12, and 24 months. The theoretical framework for this initial project and the baseline data analysis have been reported previously [28, 29].

In terms of results from SENIOR Project I, to determine the long-term effects of the intervention on exercise behavior, participants who received the exercise intervention (EX only and EX+FV) were compared with the group that did not receive this intervention (FV and control). At the end of the study, there were no significant differences in stage progression, processes of change, self-efficacy, decisional balance, physical activity, or physical function between the two groups. However, when the large number of subjects who were in the maintenance stage for the entire study period were removed from the analysis, individuals who received the exercise intervention were more likely to progress in stage, and individuals who did not receive the exercise intervention were more likely to regress or remain stable in stage. The intervention was more effective in individuals who were not considering becoming physically active at the start of the study [30].

With regard to the effects of the SENIOR Project I intervention on fruit and vegetable consumption, the intervention group increased intake by 0.5 to 1.0 serving more than the control group over 24 months. The majority of the participants perceived that they maintained 5 or more servings per day for 24 months. These maintainers had a higher intake at each time point for all dietary measures and differed from those who failed to progress on most transtheoretical model variables. Participants who maintained their level of perceived intake as 5 or more servings per day consumed 2-4 servings per day more than those who failed to progress [31].

In 2006, an additional five-year grant of $1.9 million was awarded by NIA and the National Cancer Institute (NCI) to support the development of interventions targeted on the maintenance of physical activity and dietary behaviors over a 48-month period. The new intervention consists of a print manual, quarterly newsletters, and semiannual telephone coaching calls focusing on maintenance. The SENIOR Project II targets the maintenance of increased physical activity and healthful eating as its primary focus, within the broad theoretical context of the TTM.

2.3. Active maintenance

The goal of the SENIOR Project II intervention is to expand the study of maintenance from the relapse prevention and goal-setting models used for younger adults, to a novel construct of "active maintenance" in the face of physical and psychosocial declines associated with aging among the very old (80+). We define active maintenance as "proactive strategies used by an individual to continue a healthful behavior in the face of physical, psychological, social, and environmental changes that may threaten that maintenance" (such as the potential losses associated with aging) [32].

In contrast, the traditional concept of "relapse prevention" has a much more limited focus that is associated with the literature on addictions and is inconsistent with the long-term trajectory of the aging process. Active maintenance incorporates the public health concept of

tertiary prevention, focusing on sustaining maximal functioning in the face of chronic health conditions that may threaten to undermine functional independence. Such maintenance requires the empowerment of the individual to manage personal health behaviors with maximal effectiveness. Importantly, this empowerment is dependent on the principles of goal-setting [33] and selective optimization with compensation [34, 35].

2.4. Maintenance interventions with older adults

Long-term exercise adherence interventions for older adults include different approaches. Among them, structured home- or group-based exercise/activity programs [36-40], multiple risk factor reduction programs [11, 41, 42], and behavioral/cognitive and lifestyle change through counseling in person, by phone, and through mailings [43-46]. However, very few of these investigations included maintenance data of 24 months or longer or used a population with a mean age older than 65 years.

Various nutrition and behavior modification approaches have been shown to facilitate short-term changes in participants' diets, but few have been successful at maintaining these healthy behaviors long-term [25, 47]. Extended dietary change interventions for older adults include different approaches. Strategies that have helped people make permanent changes in their dietary habits have usually involved social learning theory and behavior modification approaches [47, 48]. Group and individual counseling methods have also been found to be effective in long-term weight reduction and sodium reduction for adults of all ages [49-51].

3. Methods

3.1. Overview and specific aims

The SENIOR Project II is designed to answer the following question as its primary objective: (1) Does an individualized active-maintenance intervention with older adults maintain greater levels of healthful exercise and dietary behaviors for four years, compared to a control condition? In addition, there are two secondary objectives: (2) What are the psychosocial factors associated with the maintenance of health-promoting behaviors in the very old? and (3) What are the effects of the maintenance of health-promoting behaviors on reported health outcomes, psychosocial measures, anthropometrics, and cognitive status?

3.2. Study design

Of the 968 participants who completed the time 24-month assessment for SENIOR Project I, 470 who were in action or maintenance for either or both of the two targeted healthful behaviors at that time point were recruited for Senior II, after a gap of 3.5 years. The assessment for stage for exercise is described in Section 3.5.2.1 below, and for fruits and vegetables in Section 3.5.2.2. Senior II participants were randomized into the intervention described below or placebo control (generic health-related manual and quarterly newsletters). All SENIOR II participants are assessed annually using a standardized battery of anthropometric, dietary, physical activity, psychosocial, cognitive, and physical performance measures. Participants will be followed for 4 years.

3.3. Study participants

3.3.1. Human subjects review—Research project approval was given by the Institutional Review Board (IRB) at the University of Rhode Island. In addition, a Data Safety and Monitoring Board (DSMB) has been established to monitor annually the findings of the study and to ensure participant safety.

3.3.2. Subject screening—Screening was done at baseline and each assessment point annually to identify individuals who have had a change in health status that may alter their ability to participate in this study.

3.3.2.1. Cognitive screening assessment: Levels of cognitive functioning are assessed using the Folstein Mini-Mental State Examination, MMSE [52]. The MMSE is a widely used method for assessing cognitive mental status, both in clinical settings and in epidemiological studies. Based on a 30-point scale, the MMSE provides a total score that places the individual on a scale of cognitive function. It also has established population-based norms [53].

The following protocol has been implemented in the cognitive screening (scores are out of a total possible of 30): (1) an MMSE score of 24 or higher does not require medical release to participate in the project, (2) any participant who demonstrates a moderate degree of cognitive impairment on the MMSE (score of 15-23) will be referred to their primary care physician for medical clearance to participate in the project, and (3) if a participant's score is below 15, he or she will be excluded from the study if there is no caregiver to help with compliance.

3.3.2.2. Medical screening questions: A series of 11 screening questions, developed by the project's medical director, is administered to each participant at baseline and each annual interview. A "yes" answer to any question is followed up with the participant's primary care physician. The questions are: (1) Have you been hospitalized for a heart or lung condition in the past year? (2) Do you experience shortness of breath with physical exertion that does not settle within 5 minutes of rest? (3) Do you experience pain, heaviness, or discomfort in the chest with physical exertion? (4) Has your doctor told you not to exercise? (5) Do you get leg cramps or burning in the lower legs with exertion that gets better with rest? (6) Do you have any open sores on your feet? (7) Do you wake up at night short of breath or gasping for air? (8) Do you have periods of rapid heartbeat or palpitations? (9) Have you fainted in the last year? (10) Are you a diabetic? If you are, have you had any symptoms of lethargy, confusion, or severe sweating as a result of low blood sugar? and (11) Has your doctor told you that you cannot eat fruits and vegetables?

3.3.3. Assignment—Following screening, participants were assessed and assigned to intervention or control groups using a modified Urn randomization procedure that took into account gender, age, and previous group assignment from the SENIOR I study [54]. Participants assigned to the control condition receive intervention neutral materials (i.e., ones not focusing on exercise or diet), including a manual on healthy living for older adults and quarterly newsletters on general health-related topics.

3.3.4. Study retention and participant compensation—Participants receive a $25 gift card to a local supermarket and a small incentive gift at each annual assessment, as well as a card on their birthday and invitations to attend special "participant appreciation" parties and get-togethers held annually. Both intervention and control group participants are invited to these gatherings, as they do not focus on health specifically, and it is considered unlikely that participants will discuss their involvement in the study in a way that would be more than normal "background noise" in any intervention.

3.4. Intervention

The SENIOR Project II intervention includes: (1) two-behavior manual, (2) newsletters, and (3) phone coaching calls. The theoretical framework for the coaching calls incorporates three interrelated concepts: (1) goal-setting [33], (2) selective optimization with compensation (SOC) [34, 35], and (3) the shift from primary to secondary control [34].

Goal-setting underscores the importance of each individual choosing the personal goals that are important to them and on which they want to work. SOC explains how an individual coordinates and balances gains and losses—in this case, those associated with aging—to meet meaningful personal goals. The shift from primary to secondary control embodies a lifespan perspective: primary control is directed at behaviors related to the external environment when an individual attempts to change that environment to fit individual needs, whereas secondary control can assist an individual with disappointment and minimize losses in areas of primary control by directing motivational resources toward selected personal goals.

3.4.1. Manual—An integrated, two-behavior print manual has been developed for this intervention—based on the concepts of goal setting, SOC, and maintaining control over one's health—that are operationalized in the following strategies: (1) setting appropriate, personalized goals (e.g., it is okay if you cannot walk a mile, as long as you remain mobile and can visit your friends), (2) getting the most out of resources (e.g., making the best use of time, energy, and abilities) as one experiences the gains and losses of growing older, and (3) trying to maintain control over your life in spite of challenges (e.g., if you can no longer drive to the store and shop, you can still make a list for someone else to pick up what you need).

Chapters provide: (1) information on the four types of exercise that are important for good health and how to exercise safely, (2) information on healthful eating and fruits and vegetables, (3) strategies on how to keep on track with healthful lifestyle choices and cope with changes and setbacks, and (4) specific suggestions about exercising and eating fruits and vegetables when one has a chronic health condition. An Appendix at the end of the manual provides worksheets to keep track of goals and objectives, as well as strategies to achieve them.

3.4.2. Newsletters—The maintenance intervention includes quarterly newsletters for each of the four intervention years (16 total) with diet and exercise components integrated in each newsletter. Newsletters are formatted in two columns using Adobe PageMaker software, printed in full color, and contain graphics-reinforcing key messages.

Each newsletter is one page (printed front to back), has the SENIOR Project logo on the front page to readily identify the newsletter as a credible source of information, and generally incorporates the following features: (1) modeling of successful maintenance by older adults in the face of age-related changes, (2) strategies for maintaining physical activity and a healthful diet in the face of the challenges that accompany aging, (3) presentation of the concept of "excess disability" (i.e., if older adults are facing increased frailty, then stopping exercise or healthy eating will likely make their problem worse), (4) brief take-home messages provided as bullets, (5) a healthful recipe, and (6) an example of an appropriate exercise. Incorporating the psychological concept of SOC, information regarding exercise modification for individuals with functional limitations is stressed, and various forms of fruits and vegetables (fresh, canned, and frozen) are included to help accommodate changes in dental health.

3.4.3. Coaching calls—The coaching calls are used to personalize the intervention and assist participants in making adaptations necessary for active maintenance. Calls also enhance and integrate the print materials. The behavior change coaches have been trained in maintenance counseling as well as brief motivational interviewing strategies [55], and are monitored on a regular basis for the fidelity and appropriateness of the intervention by a clinical geropsychologist. Participants' motivation for each behavior, and confidence in completing it, are assessed at each coaching call. Motivation is enhanced, if necessary, through a collaborative process of empathic listening and guided questioning. Participants are encouraged to identify goals that are realistic and meaningful to them. Coaches summarize the participants' stated goals and ask them to commit to them for the next six months.

Each call starts with a brief assessment of stage of change for diet and exercise followed by reinforcement and goal-setting, emphasizing participants' actual and perceived barriers for maintaining healthy behavior. When a participant is meeting his or her goal, encouragement to continue is given. However, in situations where participants are struggling with the fact that what they have been doing for years may not work anymore (e.g., they can no longer walk a mile), counselors help participants re-define goals that are realistic in the context of their abilities and support systems, thereby increasing confidence.

A major focus is to challenge "all or nothing" thinking, e.g., "I can't walk now, so I won't do anything" by (1) re-defining behavioral goals if physical/cognitive changes make maintaining previous behaviors unrealistic, and (2) exploring how to access different resources as needed, such as social supports. For participants who may not be in maintenance for both target behaviors concurrently, the call enables the coach to emphasize progress toward acquiring the one behavior while staying in maintenance for the other.

The tone of the interaction style is positive, encouraging, empathic, and non-confrontational. Two calls are scheduled per year per participant, a frequency based on our earlier experience with the SENIOR Project I and consistent with a community-based, public health intervention approach. Participants have the option of requesting additional phone calls, if they have experienced an event or obstacle for which they need added support. Personalized goal-setting cards are mailed out after each contact to reinforce the goals agreed upon in the

call; each card includes a reminder of what was discussed at the call, as well as one specific exercise and fruit and vegetable goal. Overall, the objective of the coaching calls is to maintain a systematic, replicable intervention while allowing flexibility to permit the coach to meet the individual needs of the participant.

3.4.4. Treatment fidelity—Fidelity is an issue in this study primarily with respect to the coaching calls. A scripted protocol for the coaching calls has been developed, piloted, and implemented by a clinical geropsychologist on the research team, who also provides initial and ongoing training and follow-up with the phone coaches at periodic meetings. A computer-counselor interface has also been developed that combines the coaching protocol with data entry from the actual coaching calls themselves. This enables the core project team to monitor data regarding intervention fidelity (e.g., call length, focus, stage of change, and recommendations made) for the coaching calls. The print intervention materials are standardized across the project.

3.5. Core measures

The following measures are used for the baseline assessment of participants and thereafter every 12 months over the total 48-month duration of the SENIOR Project II. A few measures, indicated below, were added for either the 12- or the 24-month assessment. These assessments are conducted as interviews in the participants' homes or at our research project office located in the City of East Providence. Interviewers were trained in the administration of the different project measures at the beginning of the study, and their training is updated annually to insure accuracy and uniformity in the assessments.

3.5.1. Primary behavioral outcome variables for exercise and diet

3.5.1.1. Exercise: The Yale Physical Activity Survey (YPAS) is a comprehensive, interviewer-administered survey specifically designed to measure physical activity in older adults [56]. Subjects are asked to estimate time spent in a list of 25 activities in a typical week during the preceding month. These activities range from low- to high-intensity and are categorized into work, yard work, care taking, exercise, and recreation. Time spent in each activity is multiplied by an intensity code and then summed across all activities to create an index of weekly energy expenditure. Subjects are also asked to estimate participation in five activity dimensions: vigorous activity, leisurely walking, moving on feet, standing, and sitting. Weights are assigned to each category. The frequency and duration scores are multiplied together and then multiplied again by each dimension's weighting factor to calculate an index for each dimension. The five individual indices are summed to calculate the Summary Index, which serves as the primary outcome variable for exercise in this study.

3.5.1.2. Diet: Servings of fruits and vegetables a day are assessed by a brief food-frequency type instrument. The NIH All-Day Fruit and Vegetable Screener (FVS) is a 19-item instrument with assessment of portion size for each item [57]. The FVS was chosen to measure the primary dietary outcome due to its superiority over other brief instruments and to facilitate comparisons with results from other intervention studies. Although dietary recall methodology has greater validity than the use of brief screeners and food frequency questionnaires, both recalls and food frequency questionnaires have high subject burden and

administrative expense [58]. The FVS has a higher correlation with fruit and vegetable intake estimated from multiple dietary recalls, as well as with serum carotenoids, compared with other brief instruments [59]. It is a validated instrument that is superior to previous measures [57, 60], and has been widely used in other intervention studies [61].

3.5.2. Secondary outcome variables for exercise and diet: Stage of readiness to change—For both behaviors, maintenance of behavior change is defined as being in the maintenance stage of change based on perceived achievement of the criterion behavior for six months or more.

3.5.2.1. Stage of change for regular exercise: Stage of change for regular exercise is measured using a standard questionnaire [62-64]. Regular exercise is defined as "*planned* physical activity performed to increase *physical* fitness 3 *or more* times per week for 20 minutes per session." Recommendations, based on American College of Sports Medicine guidelines [65], do not distinguish between younger and older adults. Subjects are classified by stage (precontemplation, contemplation, preparation, action, and maintenance) based on a series of four questions, administered in a skip pattern depending upon the subject's responses [63, 64, 66, 67]. The first question asks if the subject engages in physical activity as described above. If the participant says, "No" and has no intention of doing so in the next six months, then s/he is classified in precontemplation. Contemplation is the classification when the participant does not meet the exercise criterion and s/he intends to become active in the next six months, but not in the next 30 days. If the participant does not meet the criterion but intends to become active in the next 30 days, then s/he is categorized in preparation. If the participant reports achieving the behavioral criterion, but for less than 6 months, s/he is classified in action. A subject is considered to be in maintenance if s/he reports achieving the behavioral criterion and has been doing so for 6 months or longer.

3.5.2.2. Stage of change for diet: The stage of change measure for fruits and vegetables measures an individual's motivational readiness to eat 5 servings of fruits and vegetables a day [68, 69]. It is a two-step algorithm consisting of a series of 4 possible questions that includes a skip pattern. All subjects are asked initially to respond to the question: "How many servings of fruits and vegetables do you usually eat each day? (a serving is 1/2 cup cooked vegetables, 1 cup of salad, a piece of fruit, 3/4 cup of 100% fruit juice)," with responses ranging from 0 to 6 or more. Subjects who respond from 0 to 4 are directed to the question: "Do you intend to start eating 5 or more servings of fruits and vegetables a day in the next 6 months?" Subjects who respond "No" are classified in precontemplation; those who respond "Yes" are asked "Do you intend to start eating 5 or more servings of fruits and vegetables a day in the next 30 days?" Those responding "No" are classified in contemplation; individuals responding "Yes" are classified in preparation. Subjects who indicate on the initial question that they are eating 5 or more servings of fruits and vegetables daily are asked: "Have you been eating 5 or more fruits and vegetables a day for more than 6 months?" Subjects who respond "No" are classified in action and subjects responding "Yes" to this question are classified in maintenance.

3.5.3. Secondary outcomes: Psychosocial variables

3.5.3.1. Self-efficacy: An existing instrument measuring self-efficacy for exercise [70] is used in this study. The exercise self-efficacy scale is a 6-item instrument that uses a 5-point Likert scale to assess respondents' confidence in their ability to exercise regularly in challenging situations.

The Situational Self-Efficacy Questionnaire for Seniors (SSEQS) measures overall confidence in one's ability to eat fruits and vegetables in challenging situations [71]. It consists of 6 items and provides a total score measuring a global self-efficacy construct that covers a variety of different situations that older adults find challenging. Subjects are asked to use a 5-point Likert scale to rate each statement with regard to how confident they would be to eat vegetables and fruits in each of the situations presented.

Finally, the Activities-specific Balance Confidence (ABC) Scale is used to assess each participant's level of confidence in performing specific activities without losing their balance or becoming unsteady [72]. The scale consists of 16 items, scored on a range of confidence of 0 to 100%.

3.5.3.2. Social support: The Medical Outcomes Study (MOS) Social Support Survey contains 19 items measuring four dimensions of functional social support as well as an overall support scale [73], Participants are asked, "How often is each of the following kinds of support available to you if you need it?" using a 5-point Likert scale ranging from "none of the time" to "all of the time."

3.5.3.3. Geriatric depression: The Geriatric Depression Scale (GDS) is one of the most frequently used tools to assess depressive symptoms in older adults [74]. The GDS – Short Form (SF) was developed using items from the longer 30-item GDS [75]. It is a 15-item tool with scores ranging from 0 to 15, with a score greater than or equal to 5 being indicative of depression. Overall, the GDS-SF has been found to be as reliable and valid as the GDS with general older adult populations [76].

3.5.3.4. Resilience: The Resilience Scale of Wagnild and Young [77] was added to the annual project assessments at time 12 months. This is a 25-item scale, with a 7-point Likert response set of "disagree" to "agree." It consists of two factors: personal competence and acceptance of self and life. It has been positively correlated with adaptational outcomes, such as physical health, morale, and life satisfaction, and negatively correlated with depression.

3.5.4. Secondary outcomes: Quality of life and functional status

3.5.4.1 SF-36: The Medical Outcomes Study (MOS) Short-Form (SF-36) is used to collect basic data regarding perceived health and health status. The MOS SF-36 is a multi-item scale that assesses eight health concepts and has been tested for its suitability in a broad range of clinical populations, including older adults [78]. The scales on the SF-36 assess role limitations due to physical and mental problems (separate scales), bodily pain, social

functioning, general mental health, vitality, general health perceptions, and physical functioning.

3.5.4.2. Satisfaction with Life Scale: The Satisfaction with Life Scale (SWLS) is a 5-item scale that measures global life satisfaction [79] and has been used with older adults in research on physical activity [80]. It was added to the annual project assessments at time 24 months.

3.5.4.3. Up-and-Go: The timed Up-and-Go is a practical and reliable measure of functional mobility in older adults [81, 82]. It measures, in seconds, the time taken by an individual to stand up from a standard arm chair, walk a distance of three meters, turn, walk back to the chair, and sit down again. The Up-and-Go is performed at the site of the interview.

3.5.4.4. Senior Fitness Test: The Senior Fitness Test, SFT [83], assesses functional fitness, defined as the physical capacity to perform normal everyday activities safely and independently without undue fatigue. It was designed for independent-living older adults, ages 60 to 90+, across a wide spectrum of ability levels, ranging from the borderline frail to the highly fit. Age group percentile norms (5 year increments) are available for men and women, aged 60 to 94. Specific items include chair stand, arm curl, back scratch, 2-minute step, and chair sit and reach to measure upper and lower body strength, upper and lower body flexibility, and aerobic endurance.

3.5.4.5. Pepper Assessment Tool for Disability: The Pepper Assessment Tool for Disability [84, 85] was added to the basic annual assessments at time 24 months. It consists of 19 questions, in which respondents are asked to indicate how much difficulty they experienced performing each activity during the past month. Responses are scored on a 6-point Likert-type scale ranging from "usually did with no difficulty" to "usually did not do for other reasons." There are five subscales: (1) basic, (2) transfer, (3) ambulation/climbing, (4) upper extremity, and (5) complex.

3.5.4.6. Physical measures: Additionally, physical measures including participant body weight, height, and waist circumference are taken. Weight is measured using a strain gauge digital floor scale (Model UC-321, A & D Engineering, San Jose, CA). Height is taken using a portable, rigid stadiometer (Seca Road Rod, Seca North America, Hanover, MD). Body Mass Index, BMI (kg/m^2), is calculated using measured height and weight. Waist circumference is measured using a Gulick tape with tensometer (Gulick Co., Bolingbrook, IL) at the top of the ileac crest.

3.5.4.7. Cognitive measures: Two cognitive assessments are used to examine basic executive functioning processes that have been shown to be influenced by age, fitness, and functional ability.

The Trail Making Test [86] is a valid and reliable tool that is useful in indicating ability to execute and modify a plan of action [87]. It times individuals in their ability to complete paths between numbers and number-letter sequences, and involves spatial organization,

vigilance, planning, graphomotor speed, and ability to learn and apply an organizing principle. It has been a useful indicator of functional differences in older adults [88].

The second assessment used is the Forward and Backward Digit Span Subtest of the Wechsler Adult Intelligence Scale-III [89]. In the task, participants repeat a random sequence of numbers both forward and backwards. The test assesses attention and working memory, as well as auditory memory. It has been shown to differ with age [90] as well as with fitness levels [91].

3.5.5. Demographic measures—Subject demographics include gender, age, race/ethnicity, marital status, educational level, employment status, and income.

4. Planned statistical analyses

The basic study is a factorial repeated measures design with 2 groups (intervention vs. no intervention) and 5 occasions (times 0, 12, 24, 36, and 48 months). We will use an intent to treat approach where feasible, and multiple imputations of missing data depending upon the statistical approach.

4.1. Primary outcomes

The primary aim of the study is to determine if older adults in an individualized active-maintenance intervention maintain greater levels of healthful exercise and dietary behaviors for four years when compared to a control condition. Repeated measures multivariate analyses of covariance (MANCOVA) and univariate analyses of covariance (ANCOVA) will be used to investigate differences between groups over time on the behavioral outcome measures for exercise and diet. These analyses will also assess whether there is an interaction between group assignment and time. Data obtained from the full assessments at times 0, 12, 24, 36, and 48 months will be used for these analyses. The general analytical approach will be a 2 x 4 MANCOVA with repeated measures across occasions and using scores at 0 months, age, education, and previous intervention group assignment as covariates. The behavioral outcome for exercise is the summary index of the Yale Physical Activity Survey; the behavioral outcome for diet is the number of servings of fruits and vegetables from the NIH Fruit and Vegetable Screener. Significant MANCOVA effects will be followed by ANCOVA for each dependent variable; they will also be followed up with tests of simple and main effects as appropriate.

More sophisticated and sensitive approaches, such as repeated measures regression analysis under the generalized estimating equation (GEE) method [92] and latent growth curve modeling, may also be used to analyze intervention effects. GEE is a powerful and versatile method for analyzing discrete and continuous longitudinal data under minimal assumptions about time dependence and represents a potentially superior analytical procedure, especially when the objective is to make inferences about group differences. Models will include dummy variables representing the intervention group, occasions, and intervention by occasions interaction term. Intervention efficacy is demonstrated by the groups by occasions interaction effect (i.e., the treatment group shows greater change over time relative to the control group).

An especially critical covariate that will be included in the analyses is the treatment condition that study participants were randomized to in the previous SENIOR Project I. While study participants may well be expected to vary in what they bring to the proposed study as a result of their previous experiences, the urn randomization procedure helps ensure that these influences will be balanced across groups without bias. We recognize that randomization does not solve all problems of equalization among groups. Therefore, we will include treatment group membership in the previous study as a covariate in the primary outcome analyses described above. Two such covariates will be included as main effects in the model: (1) previous assignment to the exercise intervention group, and (2) previous assignment to the diet group. In addition, we will include an interaction term (exercise by diet) to control for the effects of the combination of two previous treatment conditions.

4.2. Secondary outcomes

The extensive data collected across time points will provide for a variety of secondary outcome analyses. These analyses will be conducted to address the two secondary aims of the study; namely, to determine the role of psychosocial constructs in behavioral maintenance and the effects of behavioral maintenance on reported health outcomes, anthropometrics, psychosocial measures, and cognitive status.

4.2.1. Psychosocial factors associated with perceived maintenance of health-promoting behaviors—These analyses are concerned with determining which theoretical constructs are important for behavioral maintenance as both moderators and mediators of intervention effects. They will use the variables of social support, depression, and resilience as psychosocial measures. Perceived maintenance is defined as classification into the maintenance stage of change for each behavior assessed at each time point (0, 12, 24, 36, and 48 months). These analyses will be conducted both separately and jointly for the two behaviors. This class of analyses is often termed process-to-outcome analysis and will use structural equation modeling (SEM) to examine the causal chain between maintenance and the various process measures as well as intervention effects. This approach is ideally suited to investigate the potential moderating and mediational role of psychosocial factors in predicting long-term maintenance rates across time.

These analyses will serve two purposes: (1) intervention improvement; since this treatment package includes several components, process analyses allow a partial determination of the effectiveness of the components and permit continued improvement of the intervention package by identifying how the intervention is working and for which subgroups it is effective; and (2) theoretical model testing. Since process-to-outcome analyses have been extensively utilized for smoking cessation [93], but not for diet and exercise in older adults, this will be an important contribution of this study.

Hypotheses about long-term maintenance can be examined with five wave models covering the entire assessment period (0 to 48 months). Indeed, these analyses can be extended to include the data from SENIOR Project I, resulting in a ten-year longitudinal assessment of the predictors of maintenance.

4.2.2. Effects on health outcomes, anthropometrics, psychosocial measures, and cognitive status—In these analyses we are not necessarily interested in intervention effects per se, but rather the effects of continued behavioral maintenance. Individuals will therefore be grouped into those that maintained (1) both behaviors over all time points, (2) diet alone over all time points, (3) exercise alone over all time points, or (4) neither as indicated by the respective stage of change measure. This will allow us to utilize the full data set to examine the impact of differential patterns of behavioral maintenance effects. Data evaluating the effects of maintenance on reported health outcome measures, anthropometrics, psychosocial measures, and cognitive status will be analyzed using repeated measures MANCOVA and ANCOVA. Data obtained from the full assessments at times 0, 12, 24, 36, and 48 months will be used for these analyses.

The general analytical approach will be a 4 groups (both, exercise, diet, neither) by 4 occasions MANCOVA with repeated measures across occasions and using measures at 0 months as covariates. If the proportion perceiving they maintain behaviors is lower than anticipated based on current SENIOR data, redefinition of the 4 groups is possible, e.g., maintenance at 0 and 48 months rather than on all 5 occasions. Intervention group assignment will also serve as a potential covariate. Secondary outcomes include SF-36 subscales and composite scores, the Satisfaction with Life Scale, the timed Up-and-Go measure, social support, BMI, depression score, Trail Making Test, and Forward and Backward Digit Span. The general analytical sequence for significant effects will be the same as described for the primary outcome analyses. GEE analyses can also be used for these secondary outcome analyses.

5. Discussion

Promoting healthy lifestyles for older adults promises to be an increasingly important goal in the future, as this population dramatically increases in the US over the next two decades. Efforts to reduce the burden on the health care system represented by chronic diseases will continue to be a high priority in an aging society. In particular, the maintenance of health-related behaviors, such as exercise and healthful eating, will become more critical public health goals. To achieve these objectives, we need a new model of health maintenance, one that is based on innovative, positive concepts and frameworks rather than on the old, negative structure of relapse prevention.

The SENIOR Project II is designed to determine whether an individualized active-maintenance intervention helps older adults maintain greater levels of healthful exercise and dietary behaviors for four years, compared to a control condition. An emphasis on health promotion shifts our thinking toward an understanding of how most effectively to maintain, rather than simply acquire, healthful behaviors. This research may provide new insights into how to design and develop more powerful interventions to achieve this goal—an objective that is especially important for older adults, who face many challenges to their ability to continue healthful behavior in the face of increasing age. Results of this study promise to expand our understanding of resilience in older adults and, more importantly, how to intervene to support and enhance it.

The study also has the ability to analyze data from individuals from their enrolment in SENIOR I, providing nearly 10 years of behavioral and psychosocial data. Such analyses would be nearly unprecedented in any population, but especially so in a sample of older adults. These analyses should provide considerable insight into how the interventions may be effecting change and will be especially useful for their continued development and refinement.

Thus, one of the secondary goals of the SENIOR Project II, to understand what are the psychosocial factors associated with the perceived maintenance of health-promoting behaviors in the very old, should help to expand our understanding of critical factors that can enhance resilience. That these factors might become targets for further interventions is a logical extension of the current study. Planned analyses will also give us an opportunity to explore the potential moderator role of cognitive functioning on outcomes. Given the cognitive demands involved with reading, processing, and planning intentional behavior change that are required for the intervention to be successful, this can be an important initial investigation of these relationships.

Finally, and perhaps most importantly, determining the interrelationships among the perceived maintenance of health-promoting behaviors and reported health outcomes, psychosocial measures, cognitive status, and anthropometrics can provide further evidence of the links between processes and outcomes in health promotion. Insofar as aging is a multifactorial experience—drawing on physical, psychological, and social factors—understanding all of these dimensions and how they interrelate and interact with each other becomes increasingly important.

This study has several limitations; in particular, how the original research participants were recruited from the community may have led to potential self-selection biases in the subjects in the current study. In addition, the creation of a *de facto* longitudinal study from an original design that was not intended to be longitudinal has led to problems with variability among measures for which data were collected at different time points, as well as a substantial gap in time between phases 1 and 2 of the project.

Conclusion

We have described the basic rationale and design of the SENIOR Project II and its evolution from the earlier SENIOR I. The substantial amount and richness of data being collected over a several-year period promise to substantially improve our understanding of how to intervene to support the maintenance of healthful behavior, as well as of the factors and the interrelationships among them that underlie resilience in older adults. Overall, the findings should enhance our ability to develop improved interventions to enhance the quality of life of one of our society's fastest growing demographic groups, older adults.

Acknowledgements

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