Published in final edited form as:
Contemp Clin Trials. 2014 May ; 38(1): 102–112. doi:10.1016/j.cct.2014.03.005.

CAPABLE trial: a randomized controlled trial of nurse, occupational therapist and handyman to reduce disability among older adults: rationale and design.

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Abstract

Background—As the population ages, it is increasingly important to test new models of care that improve life quality and decrease health costs. This paper presents the rationale and design for a randomized clinical trial of a novel interdisciplinary program to reduce disability among low income older adults based on a previous pilot trial of the same design showing strong effect.

Methods—The CAPABLE (Community Aging in Place, Advancing Better Living for Elders) trial is a randomized controlled trial in which low income older adults with self-care disability are assigned to one of two groups: an interdisciplinary team of a nurse, occupational therapist, and handyman to address both personal and environmental risk factors for disability based on participants' functional goals, or an attention control of sedentary activities of choice. Both groups receive up to 10 home visits over 4 months.

Outcomes—The primary outcome is decreased disability in self-care (ADL). Secondary outcomes are sustained decrease in self care disability as well as improvement in instrumental ADLS, strength, balance, walking speed, and health care utilization. Careful cost tracking and analysis using intervention data and claims data will enable direct measurement of the cost impact of the CAPABLE approach. CAPABLE has the potential to leverage current health care spending

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Conclusion: This clinical trial, which tests a synergistic intervention targeting both modifiable intrinsic (person-based) and extrinsic (environmental-based) risk factors systematically in low-income older adults, will provide scientific evidence of the ability to preserve daily function and quality of life as well as save health care dollars in a growing community dwelling population. CAPABLE, utilizes services readily available on a societal level (RN, OT, and handyman services) and offers a strategy for coordinating interdisciplinary interventions to address significant assessed and self-determined needs. The effects of CAPABLE on functionally impaired community dwelling older adults may contribute significantly to health care service delivery.

in Medicaid waivers, Accountable Care Organizations and other capitated systems to save the health care system costs as well as improving low income older adults' ability to age at home with improved life quality.

1.0 Developing and testing new models of care to improve function and quality of life, and decrease the cost of care by reducing hospital and nursing home utilization is increasingly imperative. Because the prevailing model of health care payment is based on medical diagnoses, loss of physical function is often overlooked even though it drives health service utilization.[1]

1.1 Intervention rationale

Numerous interventions to reduce disability have been tested and reviewed recently by Beswick in 2008 and Daniels in 2010.[2,3] However, with few exceptions these interventions have focused on modifying the underlying impairment of the disabled adult. Few studies have systematically targeted both modifiable intrinsic (person-based) and extrinsic (environmental-based) risk factors, even though disability results from the combination and complex interaction of these factors. Low-income and African-American older adults have a particular need for interventions that address both intrinsic and extrinsic factors, because, compared to their white or higher-income counterparts, they have higher rates of disability,[4-7]chronic disease, pain,[8] and depression.[9,10] Further, low income older adults have less access to primary care[11] and greater odds of living in deteriorated housing (extrinsic factors)[12] and lack the resources necessary to modify that housing to increase its functionality and compensate for their difficulty performing self care tasks. Housing modification programs currently offered across the US by local communities offer minimal modification options which have not been tested with rigorous research designs. In this paper, we describe the rationale and design of a randomized controlled clinical trial evaluating the effectiveness of a bio-behavioral-environmental program to reduce disability among low income older adults.

1.3 Program origins

3A1. Our intervention, CAPABLE, provides time-limited Nurse, Occupational Therapist (OT), and handyman services to older functionally impaired community dwelling older adults to improve their specific limitations in daily function. CAPABLE was adapted from the ABLE program which was developed and tested by ourco-author (L.N.G) and her team with 319 urban older adults. ABLE is a home-based intervention that involves 5 visits by an OT,1 visit by a physical therapist and provision of assistive devices (e.g. grab bars, raised toilet seats) and other strategies designed to modify behavioral and environmental contributors to functional difficulties. ABLE, which cost only $1,222 per participant in 2006,[13] improved self care outcomes for all intervention participants and delayed mortality. At $13,179 per additional year of life saved ABLE would be judged extremely cost-effective by most criteria.[14-16] While successful, ABLE did not address intrinsic concerns such as pain, medication management, or depressive symptoms nor provide home repair in addition to home safety modification. We hypothesized that adding a nurse to address pain, depression, polypharmacy, and primary care provider communication and adding a

handyman to repair the home would increase the effects of the ABLE program. Based on this hypothesis, we conducted a pilot randomized controlled study of 40 older adults with ADL disability[17] using the methods described in this paper. Preliminary data provided by the pilot trial suggests that CAPABLE improves ADL activities and quality of life.[17]

2. Materials and methods: study design

2.1 Overview

Overall design

We describe an intention-to-treat, single-blind, two-group randomized trial to test whether, compared to an attention control condition, a multi-component tailored intervention reduces disability (Activities of Daily Living)[18] in low-income disabled, urban older adults at 20 weeks (main trial endpoint). The secondary aims are to: 1) test the *long-term* effects of CAPABLE on Activities of Daily Living and Instrumental Activities of Daily Living [19]difficulty level at 52 weeks post-baseline; 2) test the immediate and long-term effects of CAPABLE on an objective measure of mobility (as measured by the objective Short Physical Performance Battery (SPPB))[20]health-related quality of life,[21] and home environmental safety, at 20 and 52 weeks post-randomization; and 3) test the economic value of the intervention by assessing its impact on total health care costs over the 52 weeks following randomization. We plan to enroll 300community-dwelling low-income older adults from community partners across Baltimore City. Immediately after the baseline home interview participants are randomized to experimental or attention control group condition.

Experimental group participants receive up to 10 in-home sessions which includes up to 6 sessions with an Occupational Therapist (OT), and up to 4 sessions with an Registered Nurse (RN), and ≤ $1200 of safety and functional modifications and repairs from a licensed handyman. These sessions occur in coordinated fashion over the course of 4 months. The attention-control participants receive comparable attention of the same number of in-home sessions as the treatment group (10 sessions) by interventionists who are different from those implementing the experimental condition. All participants are re-tested at 20 weeks (main study endpoint) and 52 weeks (long-term effects). Outcome measures are assessed by interviewers masked to treatment assignment and without interventionist contact. Each design component is described in more detail below.

2.2. Theoretical framework

The overarching theoretical framework for CAPABLE is resilience. We use the Szanton-Gill resilience model [22] which posits that all domains of societal, community, familial, whole individual, organ, and cellular characteristics have interacting resilient potential. This theory also posits that intervening on more than one level (in CAPABLE's case, physiologic, individual, and built environment) leads to more lasting effects on individual resilience to stressors compared to intervening on one level.

The other overarching conceptual framework that influences the design of CAPABLE is competence-environmental press.[23] Within that, we utilize the intrinsic(individual) and extrinsic (home) focus from Verbrugge and Jette's Disablement Process,[24] as both types of

factors modify disablement. (Figure 1) Using this theory, individualizing the fit between the person and his/her environment (increasing P/E fit) should result in better functioning within that environment.[25] Within the individual aspect of Verbrugge and Jette, we are guided by the Life Span Theory of Control [26] which proposes that the progression from pathology to disability increases threat to personal control, which in turn may result in negative health consequences.

Thus, the goal of CAPABLE is to intervene to increase control (such as problem solving, reframing), and decrease factors that undermine control (pain, depression, unsafe stairs).According to these frameworks, if we address intrinsic and extrinsic factors that provide more environmental control, people will experience less environmental stress and can practice their mobility tasks to become stronger. For example, an older adult living in a house with a shaky banister and a hole in the floor by the door may minimize the number of times that he/she goes upstairs or outside, leading to a vicious cycle of decreased activity that decreases muscle strength and confers higher risk for further disability. Fixing the banister and the holes may enable the participant to practice new exercises taught by the nurse, *have more leg strength and stamina to* prepare food, and reverse this cycle. These four models – resilience, competence-environment press, disablement process, and control -- together inform the person-directed approach to the built environment and the individual that guides CAPABLE.

2.3 Eligibility criteria

were determined to provide a sample of people who were functionally limited but medically stable and were cognitively intact enough to participate actively in the intervention. Older adults are eligible for the study if they are: a)ages 65 years or older who are cognitively intact based on the Short Portable Mental Status Questionnaire;[27] b) reported difficulty with at least 1 ADL[18] or at least 2 IADLs;[19] c) report income of 200% or less of the Federal Poverty Level ($22,980 or less for a household of one); d)able to stand with or without assistance. Participants are excluded from the study sample if they have been hospitalized more than 3 times in the previous 12 months, if they are receiving in-home physical therapy, nursing or occupational therapy if they have a terminal diagnosis (<1 year expected survival) or are receiving active cancer treatment, if they plan to move houses within 1 year or if they live in an apartment.

3. Recruitment, enrollment and randomization

Recruitment is a multi-faceted community effort with numerous community partners including collaboration with the Baltimore Meals on Wheels, the Baltimore City Health Department, the Baltimore Housing Department Green and Healthy Homes Initiative, area Senior Centers, and the National Civilian Conservation Corps. We also conduct targeted direct mailing recruitment by sending study brochures to specific Baltimore City zip codes of high poverty with a high proportion of older adults. When potential participants callor return a postcard in follow up to these mailings, research staff members telephone screen for eligibility and explain study procedures to potential participants. If eligible by phone screen, research staff members schedule the baseline interview within 10 days of the call. During the in-home interview, research staff re-explains the study, obtains written consent, and

conducts baseline data collection. Within 48 hours of the baseline interview, a non-study staff member stratifies enrolled participants by sex and randomizes into either receiving the nurse-occupational therapist-handyman intervention or attention control using a computer-based assignment scheme and communicates the assignment to the participant by letter. The study was approved through the Johns Hopkins Medical Institutional Review Board.

Measurements

Table 1 describes the data collection schedule. Participants are compensated $25 for their time at each completed evaluation, including the baseline, 5 month and 12 month assessments for a total of $75. All measures are conducted with participants in their homes.

5. Measurements

Primary outcome - Activities of Daily Living (Katz. Modified by Branch) *Similar to classic interventions on disability*, [28] we will collect self-report information about whether the participant has difficulty in performing one or more of eight essential activities of daily living (ADLs): walking across a small room, bathing, upper and lower body dressing, eating, using the toilet, transferring in and out of bed, and grooming.[1829] . This method of self-report has high test-retest reliability and sensitivity and predicts future morbidity. [28] In keeping with prior research,[28] functioning on each task is classified from 0 to 2 depending on whether the person did not have difficulty in the prior month and did not need help (0),had not needed help but did have difficulty (1), or did need help regardless of difficulty (2). A summary disability score ranges from 0 – 16 and a change in one point can be considered clinically meaningful and a change in two points is associated with increased risk of nursing home or death.[30]

Secondary outcomes

Instrumental Activities of Daily Living[19] provides self-report information on independent living skills. The domains are using the telephone, shopping, preparing food, light housekeeping, washing laundry, traveling independently, taking medications independently, and managing finances independently. Performance on each task can range from 0 to 2 depending on whether the person did not have difficulty in the prior month and did not need help (0), had not needed help but did have difficulty (1), or did need help regardless of difficulty (2). The summary score ranges from 0-16.

Short Physical Performance Battery - SPPB(SPPB),[20]is derived from three objective tests of physical function: 4-m walking speed, repeated chair stands, and standing balance in progressively more-challenging positions. Walking speed is defined as the faster time of two usual-pace walks over a 4-m course. For the chair-stand test, participants are asked to rise five times from a seated position as quickly as possible with their hands folded across their chest. Performance is expressed as total time to complete the test. For the standing balance tests, participants stand in three progressively more-difficult positions for 10 seconds each: feet in side-by-side, semi-tandem, and full-tandem positions. Each test is scored 0 to 4 by previously determined criteria.[31]Scores from the three tests are summed into a composite score ranging 0 to 12, with higher scores reflecting better physical function. The SPPB has

excellent reliability,[32]is highly sensitive to important change such as self-reported decline in ability to walk a block or to climb one flight of stairs. Decreased SPPB is a strong predictor of nursing home admission, disability in self-care tasks, and mobility in older adults.[20,33] The loss or gain of 1 point is considered a clinically meaningful change.[34] *and it has strong inter-observer reliability*. The Late-Life Function and Disability Instrument (LLFDI) is a self-report measure of disability that evaluates physical functioning and disability.[35] It is correlated with both performance tests of physical functioning (the SPPB) and self-report report function questions. The function component evaluates self-reported difficulty with 32 physical activities of lower extremity and upper extremity.

The Sociodemographic Questionnaire is a self-report assessment of basic characteristics such as race, age, gender, supplemental health insurance status, and education level. The Patient ActivationScale[36] measures patient activation in relation to medical visits. Reliable (Cronbach alpha=0.89), and valid with low-income African-American populations, it has 13 items which assess beliefs, confidence and knowledge of how to take action for one's health. It has been responsive to interventions,[37]showing that activation is not an unchangeable patient trait. Patient Health Questionnaire-9 consists of nine items asking for the presence of depressive symptoms. These parallel the nine symptoms of depression described in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition. It has been validated both for diagnosing depression and determining level of severity[38] of depression and it has clinical relevance with African-Americans. The Brief Pain Inventory (short form),[39] suggested by the American Geriatrics Society guidelines, measures intensity, distress, and interference with life from pain. Both test-retest reliability and inter-rater reliability are strong.[40]The Centers for Disease Control Home Safety Checklist – is a 43 item checklist developed at the Centers for Disease Control filled out by the Research Assistant (who is masked to treatment group). Its domains are general household, kitchen, bathroom, bedroom and stairways. It focuses on fall risks but also includes other safety risks such as whether the gas range dial is difficult to read, and whether the water temperature is too hot. This does not have strong psychometric testing. We plan a subset who will get test-retest reliability on their houses by two different raters on consecutive days. Health-related quality of life is measured with the 5 item EuroQol questionnaire (EQ-5D). [21] This questionnaire asks individuals to indicate whether they have no problem, a small problem, or a large problem in each of five domains: usual activities, self-care, pain, anxiety/depression, and mobility. It also asks the participant to rate their health on a visual analogue scaleof 0-100. Control-Oriented Strategy Use is a measure of behavioral and cognitive processes that facilitate adaptation to life challenges.[41] We used an eight-item measure to assess use of control-oriented behavioral, cognitive, and environmental strategies. Items reflect approaches for managing the threat to loss of control over daily activities due to functional difficulties. Participants rate the extent to which each item is true on a 4-point scale. A control-oriented strategy score is derived by averaging responses across the eight items (Cronbach alpha 0.69).[15] Frailty is measured using the Fried measure [42]of 5 possible domains (walking speed, grip strength, low activity, weight loss or BMI less than 18, and exhaustion). Individuals with at risk scores in 3 or more domains are considered frail. Those with 2 or more are pre-frail and those with 0-1 are considered robust. This measure successfully discriminates between the construct of frailty and disability. [42] Lifespace measures the

extent to which participants are using rooms in their house other than their bedroom as well as other buildings and neighborhoods besides their own house.[43]We are using the Allman et all measure of homebound life space as the original measure is focused on higher functioning older adults. The Family Support Satisfaction Scale is a 13 item measure determining satisfaction with family social support (instrumental, affective, and informational) when self-managing chronic diseases. Psychometric properties have been reported along with use in African American older adults[44,45]

Falls efficacy is measured by asking each participant to rate from 0-10 their confidence in doing each of the following 10 activities without falling: cleaning house, getting dressed and undressed, preparing simple meals, bathing, shopping, getting into or out of a chair, going up and down stairs, walking in their neighborhood, reaching into cabinets or closets, and hurrying to answer the phone. This measure has a strong relationship to function, mediates fall prevention improvement *and has strong reliability and validity.*[46]

Measurement of Costs is achieved through multiple methods. The sum of the intervention costs include interventionist training time, intervention delivery, travel, supervision, preparation, care coordination between OT, RN and handyman, intervention materials (e.g. caregiver notebook, Health passport) cost for housing modifications, and assistive devices. For details on cost collection, see the analysis section. As we seek to determine of whether the intervention costs exceed the medical costs saved, the medical costs are also assessed via claims data available through the Research Data Assistance Center (ResDAC) of the Center for Medicare and Medicaid. Medical costs will be estimated based on claims data from both the control and treatment cohorts (see analysis plan).

6. Interventions

Overview of CAPABLE

CAPABLE is informed by theory and evidence-based practices. It involves ≤10 home sessions each of 60-90 minutes duration over a 4 monthperiod. It draws upon clinical approaches to enhance uptake and adoption of intervention strategies by study participants such as patient-centered care and motivational interviewing.[47-50]Each intervention participant receives every component of the intervention (assessment, education, interactive problem-solving) but interventionists clinically tailor contentto each participant's risk profile and goals.See Table 2 for an overview of the intervention.

Intervention Delivery Characteristics

CAPABLE consists of an assessment-driven, individually tailored package of interventions delivered by an OT (≤ 6 home visits for ≤ 1hour), an RN (≤ 4 home visits for ≤ 1hour) and a handyman (HM) team. (See Table 3) The number of visits is usually 10 total but can be less if the participant has few goals to address with either the OT or the Nurse. Sessions are spaced so that participants have opportunities to practice new strategies or activities with the health professional and then on their own. Communication between the OT, Nurse, and Handyman are enhanced by a secure share site which can be remotely logged into by the interventionists and enable electronic documentation that can be reviewed for fidelity and also contribute to understanding intervention costs.

Intervention Protocol: OT

In the **1st and 2nd sessions,** the OT meets with participants and conducts a semi-structured clinical interview using the Client-Clinician Assessment Protocol (C-CAP) tested for its psychometric properties for use in home-based and home modification programs.[51]The C-CAP provides a systematic approach from which to identify and prioritize performance areas that are problematic to participants. For each area identified, the OT observes the participant's performance and evaluates safety, efficiency, difficulty, and presence of environmental barriers and supports. The OT provides a CAPABLE notebook to each participant which contains educational materials, contact information and a calendar to integrate the sessions by the nurse and Handyman interventionists. Also in the course of this session, the OT assesses the environmental home safety (common safety and mobility risks our team finds include holes in walkways, uneven carpeting, and absent railings or banisters). Based on the environmental assessment, observation of ADL activities, and identification of the participant's goals, the OT and participant discuss possible environmental modifications. The OT then provides a list of agreed upon assistive devices and housing repairs to the Handyman coordinator via email (see appendix 2 for typical orders).In **OT sessions 3-5,** the OT engages the participant in problem-solving to identify behavioral and environmental contributors to performance difficulties and strategies for attaining functional goals. The OT trains participants to use specific strategies such as conserving energy during tasks, simplifying tasks and the environment, and using assistive devices. Also, the OT provides balance and fall recovery techniques to decrease fear of falling. In each session, the OT reinforces strategy use, reviews problem-solving, refines strategies, and provides education and resources to address future needs. Home modifications (grab bars, rails, raised toilet seats) are coordinated with the Handyman to assure that they are provided in a timely manner and meet the needs of the participant. The OT follows up with training in their use. In the **final** (6th) **OT** session, the OT reviews all techniques, strategies and devices, and helps the participant to generalize success to other situations.

RN Intervention protocol

The RN meets with participants for up to 4 sessions during the same four months of the OT sessions. **The first RN session** follows the first OT session within one month. In this session, the RN assesses the participant using the C-CAP RN developed specifically for CAPABLE [52] in which the RN focuses on how and whether pain, depression, strength and balance, medication management and ability to communicate with the PCP impact daily function. In this assessment, the RN and the participant identify and prioritize goals, and make plans to achieve those goals. The RN also adds educational resources to the CAPABLE notebook to reinforce its use as a resource. In **RN visits 2 and 3,** the RN and the participant work on the goals identified through the C-CAP RN. In each session, the RN reinforces strategy use, reviews problem-solving, refines strategies (examples in Table 5 such as Otago-based exercises or pain management), and provides education and resources to address future needs (e.g. pill box for medication management). In the **final** (4th) **session,** the RN reviews the participants' strategies and helps to generalize them to other possible challenges.

Handyman Intervention protocol

The Handyman portion is contracted with Civic Works www.civicworks.com which is an AmeriCorps site located in the urban area where the study is being conducted. The contractor at Civic Works coordinates the ordering of the assistive devices as well as the repair and modification supplies. The Handyman makes as many home visits as it takes to provide the renovations/modifications that the OT orders. Generally there is one visit to assess what supplies will be required to implement the work order and then a full day's work to complete it. The budget for this work is up to $1300 per household based on real expenditures in the CAPABLE pilot study [17] *to achieve participants' three functional goals.* We found this dollar amount adequate for most renovations necessary to achieve safer, more functional homes such as patching holes in floors, installing safety equipment such as raised toilet seats and grab bars, and adding a double banister. It is not enough money for major modifications such as stair glides or most ramps.

7.1. Attention/Education Control—we designed an attention-control group to mirror the amount of social attention and engagement provided to the experimental group by the OT and RN interventionists.[53]Participants receive the same amount of time and interaction in the control group as they do in the intervention group. They receive 10, 60 minute sessions with a trained Research Assistant but no sessions with an OT or RN. The attention control RA engages participants in reminiscence[54] and sedentary activities of their choice such as making scrapbooks together. The attention control group also receives printed National Institute on Aging materials on exercise, fall prevention, and home modification. In **Session 1,** the attention control interventionist re-explains the nature of the visits and assesses the participant's desire for particular sedentary activities using a standard pleasant events/activity checklist. In **Sessions 2-9,** the interventionist and the participant work together on a range of sedentary activities based on the participant's interests. These activities include making scrapbooks, playing card games, listening to music, and reminiscing about historical Baltimore. The RA obtains feedback from the participant about what is engaging, and modified activities accordingly. In **Session 10,** the RA and the participant evaluate the time together. Time with the attention-control RA is documented on a tracking sheet for each session and signed by the participant.

8. Fidelity Plan

The fidelity plan is based on the NIH Behavior Change consortium.[55]We addressed fidelity through design (interventions are distinct, based on theory), training (using an intervention manual and separate interventionists for each group), delivery (reminder calls the night before intervention sessions, records of home sessions (by date and duration), receipt (checklist completed by study team member about intervention engagement) and enactment (participants in the CAPABLE group demonstrate the exercises and the new ways to perform ADLs to the interventionist).Ten percent of both intervention and control sessions are audio taped. Audiotapes are reviewed by the research coordinatorusing monitoring checklists. Feedback is provided to each interventionist through case presentations and supervisory sessions. Bi-weekly meetings of the OTs and RNs with the PI assures fidelity to the intervention.

9. Data collection and management

Standardized data are collected by trained interviews via tablet computers at participants' homes and uploaded to the RedCap data entry and management system. Data are collected by home visit at baseline, and follow up at 5 months and 12 months. See Table 1 for outcome measures assessed and timing.

10. Sample size calculation and analysis of aims

The sample size for this study was determined based on the effect size of the CAPABLE randomized pilot trial on the primary outcome of ADL limitations, where the effect size measures the difference between the intervention group and attention-control group in the standardized change in the ADL score from baseline to 20 weeks. Based on those calculations, a sample size of 57, 80, and 150 subjects per group to detect with 80% power a minimal effect size of 0.6, 0.5, and 0.36, respectively, at 4 months from baseline with two-sided two-sample T-tests at a 0.05 significance level. Given that the estimated effect size was 0.63 for ADL limitations in the pilot, by recruiting 300 subjects into the trial, we will have sufficient power to detect meaningful differences between the intervention and the attention control groups accounting for a projected 25% attrition rate.

Analytic approach

The primary outcome is changes from baseline to 4 months in the ADL score. We follow three general principles for analysis. First, we rely on intention-to-treat analysis (ITT) to present the results of the trial: all participantswill be counted in their assigned study group once assignment has been made. Second, analyses that utilize the post-randomization data (e.g. treatment compliance)[56,57,58,59]will be evaluated in supplementary analyses. We will distinguish non-compliance with intervention from non-compliance with data collection. Finally, numerous comparisons of effect sizes for the secondary outcomes must be performed. Rather than adjusting p-values for multiple comparisons, p-values will be interpreted as descriptive statistics of the evidence, and not as absolute indicators for a positive or negative result. We will control for non-intervention home care service use. This should be limited due to our exclusion criteria but if someone starts to receive home-based services, we will identify with the medical claims data. To assess potential benefits of the intervention on the primary outcomes, we will analyze the data in two ways. First, for ease of interpretation, we will create binary indicators for the presence or absence of clinically meaningful improvement, defined by a decrease in ADL score by ≥two points or a decrease in IADL score by ≥1point from baseline (i.e. lesser difficulty). We will start with crude analyses comparing the proportions of study subjects meeting the above criteria at 4 months between the two treatment arms using the Chi-square test. We will use logistic regression to adjust for residual differences in baseline characteristics by treatment group. In the second approach, to maximize power, we will also analyze the pre-post treatment differences in the number of ADL limitations as continuous outcomes using linear regressions as in the pilot study. Other research has shown differential treatment effects by gender, self-efficacy, and age. [60] We will test moderation hypotheses by including interactions between treatment assignment and the potential effect modifiers: baseline functional level, history of falls, age, and gender. We will test mediation by modeling the outcome with and without the proposed

mediators (falls efficacy and control strategy use) and assess the change in the estimate of intervention effect [61];a much weakened intervention effect after adjusting for the mediators will provide preliminary evidence in support of the mediation hypothesis.Secondary analyses will evaluate the effects of the intervention on several secondary outcomes including 12 month outcomes, mobility, IADLS, health related quality of life and home environmental safety.

Cost analyses—Finally, we will test the economic value of the intervention by assessing its impact on total health care costs over the 52 weeks following randomization compared to the control condition. This will be achieved by measuring direct costs of the intervention (person-hours of interventionists plus supplies) and comparing them to Medicare and Medicaid (if applicable) claims data. Intervention data on person-hours required for the intervention will subtract out research costs and will estimate the required staffing to run the program at full capacity. Claims data will be converted to cost estimates using Maryland's cost-charge ratio. An incremental analysis comparing the ratio of incremental costs to incremental effects on health will be used to assess cost effectiveness, and sensitivity analysis will determine how the incremental cost effectiveness ratio varies with the uncertainty range around program costs and program impact.

Discussion

This novel trial is the first clinical trial to comprehensively intervene at both the level of environment and person to decrease the disability-defining gap between an individual's capacity and home environment. The study implements rigorous clinical trial methodology in the ultimate translational context— the home—which leads to strong external validity. ADLs, the primary outcome, measured in this trial, are predictive of nursing home placement and thus important areas of function targeted in this unique individualized intervention approach. Further, although extensive evidence demonstrates that a decline in mobility, as measured by the Short Physical Performance Battery (SPPB), is predictive of increased health care costs, this is one of the first studies to examine whether a home-based intervention can improve SPPB and whether an *increase* in the SPPB is associated with a *decrease* in health care costs. While some Area Agencies on Aging provide home modifications and repair services, they do so without a strong evidence base or standardized approachand home modifications are not integrated with tailored plans to improve self-care. If the CAPABLE study is successful, these same programs will provide immediate venues for translation.

The novel features of the CAPABLE program are the following: It is participant-directed in that individual participants determine goals that are important to them, thus potentially impacting quality of life as well as function. A second novel feature is the integration of a nurse, occupational therapist and handyman as a team to achieve these goals. These three disciplines integrate their work within those functional goals, coordinating efforts interdisciplinarily which is known to improve health outcomes in other settings. Together with these disciplines, participants make small changes that make a large difference in daily life, such as being able to get up stairs to sleep in their own bed, or being able to stand longer to cook to prepare food.

In the larger Aging in Place movement, many service delivery models and approaches have been advocated. These range from naturally occurring retirement communities (NORCs), to the Village Movement, to disease self-management programs. Colleagues in Europe and the U.S. have tested preventive nurse visits and geriatric assessment but not this unique combination of nurse, occupational therapist plus home repair/modification based on participant's functional goals. CAPABLE deliberately targets the home environment and the participants' functional goals through a new model of inter-disciplinary collaboration build upon an already successful preventive model (ABLE). Because 10,000 people are turning 65 each day in the U.S., and in some nations the demographic tsunami is even more pronounced, society will need to develop, test and implement many different kinds of strategies to promote aging in place by maintaining and improving function while decreasing cost of health care for older adults.

Cost and policy implications

Preliminary cost analyses for the first 250 participants show that the cost of the RN visits, OT visits, handyman repair and coordination cost approximately $3,300 per participant for the entire 4 month program. As nursing home care is $6000 per month, if CAPABLE can delay nursing home admission by 3 weeks, it can save money. If the annual number needed to treat is 5 to avert a $15,000 hospitalization stay by avoiding a fall, then CAPABLE would be cost neutral. Careful cost tracking and analysis using intervention data and claims data will enable us to directly measure the cost impact of the CAPABLE approach.

CAPABLE also has potential for being a reimbursable service through Medicare or Medicaid. Our research team is also testing CAPABLE with a Center for Medicare and Medicaid Innovations Cooperative Agreement through the Affordable Care Act. If CMS actuaries calculate that CAPABLE both improves health and decreases health care costs the Affordable Care Act authorizes CMS to scale up CAPABLE as a national benefit that older adults on Medicaid could access. An initial step in scaling up CAPABLE is that the State of Michigan is pilot testing CAPABLE within its Home and Community Based Services Waiver Program designed to prevent Medicaid funded nursing home admissions by directing those same funds to programs that promote aging in place in the nursing home eligible population. In the context of Medicaid waivers, CAPABLE has the potential to augment services yet not add costs by leveraging the interplay of the disciplines already involved in care with the participant's functional goal achievement.

In addition, PACE (Programs of All-Inclusive Care for the Elderly) programs, Medicaid waivers, and Accountable Care Organizations that have capitated risk for institutional care may have incentives to adopt CAPABLE if the cost results prove compelling.

A limitation of CAPABLE is it is short intervention with disabled older adults who will likely continue their, perhaps slowed, disability trajectory. Longer term strategies may be required to achieve benefit over several years. Testing a yearly booster visit or other long term strategies will be important.

Acknowledgments

This study is supported by the National Institute on Aging grant #R01-AG040100 and the Robert Wood Johnson Nurse Faculty Scholars Program #69351. We gratefully acknowledge the participants in this study who willingly gave their time to participate and the study staff, Alice Delaney, Laken Roberts, Allysin Bridges, Wanda Clark Smith, Allyson Evelyn-Gustave, Karen Harrison, Raquel Jarrett, Jolene Lambertis, Ashley Lawrence, Amelia Ozemoya, Manka Nkimbeng, Jill Roth, Jessica Savage, Gerard Shorb, Felicia Smith, Kathleen McMaines and Kathleen Becker who implemented the project.

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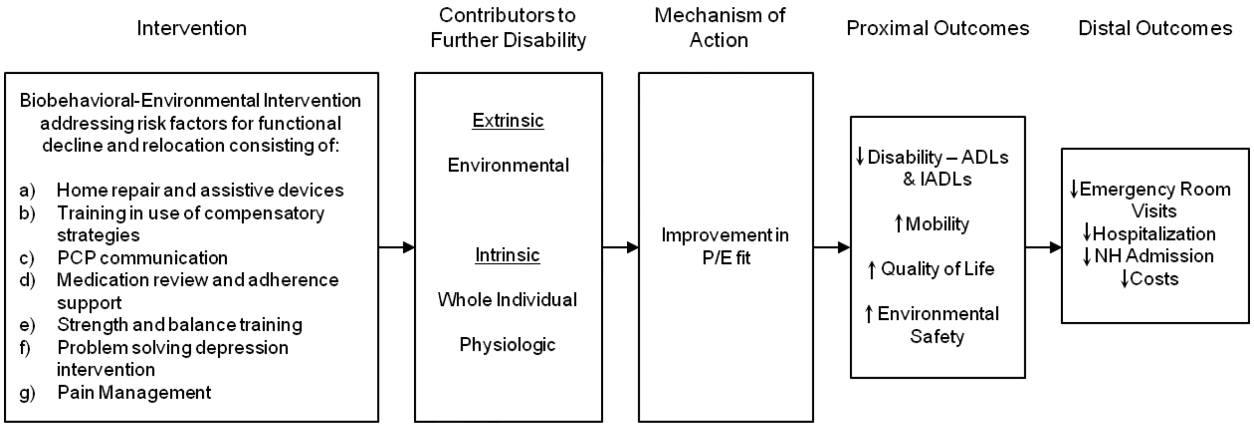

Figure 1.
Conceptual Framework

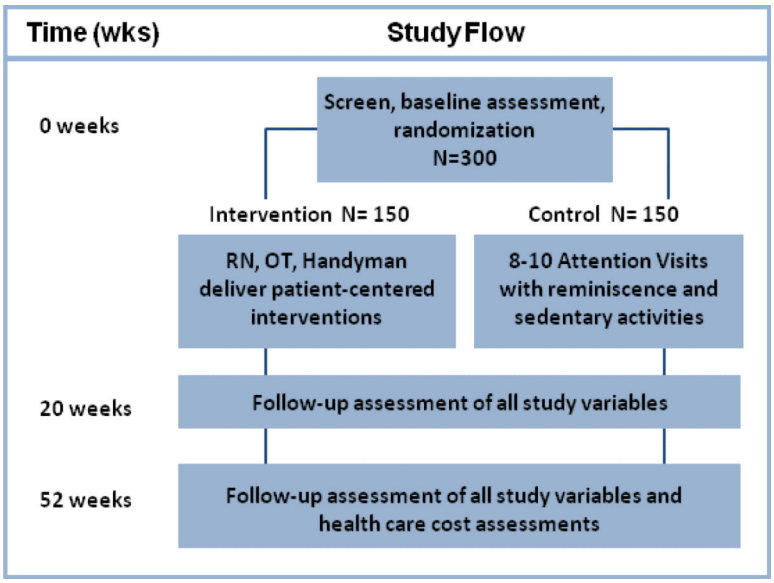

Figure 2.
study design

Table 1

	Measures	Baseline	5 months	12 months
	Demographics	x	x	x
Proximal Outcomes	ADLS	x	x	x
	IADL	x	x	x
	Late Life Disability	x	x	x
	SPPB	x	x	x
	Quality of Life	x	x	x
	Home hazards	x	x	x
Distal Outcomes	Medical costs			x
Mechanisms of Action	Depression	x	x	x
	Pain	x	x	x
	Frailty	x	x	x
	Life Space	x	x	x
	Patient Activation	x	x	x
	Control Strategy Use	x	x	x
	Falls Efficacy	x	x	x
Cost of intervention	Intervention costs	Measured throughout intervention		

Table 2

CAPABLE Targeted areas, goals, and treatment approaches by Verbrugge and Jette dimensions

Dimension	Target Target::Approachoal
Extrinsic:	Housing safety: Repair built environment to ↓ fall risk, ↑ mobility, and ADLs/IADLs Ability to access primary care and appropriate specialists
Intrinsic: Individual Factors	Self-care: ↑ ability to independently conduct ADLs and IADLs
	Communication with PCP: ↑ patient activation to facilitate better chronic disease management
	Medication Management: ↑ ability to adhere to medication regime
Intrinsic: Physiologic factors	Strength/balance: ↑ ability to stand, balance, and recover from falls, near-falls
	Depression: Enhance skills for mood management
	Pain: To decrease pain to facilitate function

Table 3

– Intervention content by visit and discipline

Session number	Who	When	Content	Interventionist follow-up
1	OT #1	Within 10 days of baseline data collection	Introduction to OT portion of CAPABLE. Issue Intervention folder. Function-focused OT assessment including functional mobility, activities of daily living and instrumental activities of daily living (C-CAP). Determine participant's functional goals. PT screen.	
2	OT #2	1-2 weeks later	Fall risk and recovery education. Conduct home safety assessment & identify necessary repairs or modifications.	Develop work order for home repairs/ modifications & send to liaison who will send to HM.
3	HM #1	After receiving work order	Visit home to assess which materials to purchase for ordered modification and repairs.	Purchase materials
4	RN #1	One month after baseline data visit	Introduction to RN portion of CAPABLE. Function-focused RN assessment including pain, mood, strength, balance, medication information, need for Healthcare Provider (PCP) advocacy/communication.	Make medication calendar for participant. Review participant's medications including side effects, interactions and possible changes. Consult with pharmacist if on high-alert or >15 medications.
5	HM #2	Once have supplies	Repair and modify home based on participant goal-prioritized work order.	HM will notify OT when this is complete.
6	OT #3	2-3 weeks after last OT session	Brainstorm and develop Action Plan with participant for participant-identified goal #1 (Examples include safely bathing, going upstairs, or preparing food)	
7	RN #2	3-4 weeks after initial RN session	Determine goals in RN domain together, start to brainstorm goal #1. (Examples include pain in standing, fall prevention) Demonstrate CAPABLE exercises. Review medication calendar. Discuss participant/PCP communication.	Develop correspondence to PCP if necessary
8	OT #4	1 month after last session	Review Action Plan #1. Brainstorm and develop Action Plan with participant for participant-identified goal #2. Review HM work and train participant on new assistive devices as able.	Issue assistive devices or medical equipment as available
9	RN #3	3-4 weeks after last session	Complete Brainstorming/ Problem-solving process. Develop Action Plans for identified goals with participant. Assess PCP response to communication of participant needs. Review/assess/trouble-shoot exercise regimen. Issue Healthcare Passport.	
10	OT #5	1 month after last session	Review Action Plan #2. Brainstorm and develop Action Plan with participant for participant-identified goal #3; Issue AE and DME (if not already done) and train participant on new assistive devices and modifications.	
11	RN #4	3-4 weeks after last session	Review progress and use of strategies for all target areas. Issue and review RN section of Flipbook that summarizes program. Evaluate achievement of goals and readiness to change scale.	

Session number	Who	When	Content	Interventionist follow-up
			Help participant generalize brainstorming process for future health issues. Ask if participant has any final questions.	
12	OT #6	3-4 weeks after last session	Review OT section of the Flipbook. Help participant generalize solutions for future problems and problem solving techniques. Review and sign work order. Review goals and participant's achievement of them. Review readiness score. Ask if participant has any final questions.	

HM=Handyman, OT = Occupational Therapist, RN= Nurse