Effect of a Biobehavioral Environmental Approach on Disability Among Low-Income Older Adults
A Randomized Clinical Trial

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**IMPORTANCE** Disability among older adults is a strong predictor of health outcomes, health service use, and health care costs. Few interventions have reduced disability among older adults.

**OBJECTIVE** To determine whether a 10-session, home-based, multidisciplinary program reduces disability.

**DESIGN, SETTING, AND PARTICIPANTS** In this randomized clinical trial of 300 low-income community-dwelling adults with a disability in Baltimore, Maryland, between March 18, 2012, and April 29, 2016, aged 65 years or older, cognitively intact, and with self-reported difficulty with 1 or more activities of daily living (ADLs) or 2 or more instrumental ADLs (IADLs), participants were interviewed in their home at baseline, 5 months (end point), and 12 months (follow-up) by trained research assistants who were masked to the group allocation. Participants were randomized to either the intervention (CAPABLE) group (n = 152) or the attention control group (n = 148) through a computer-based assignment scheme, stratified by sex in randomized blocks. Intention-to-treat analysis was used to assess the intervention. Data were analyzed from September 2017 through August 2018.

**INTERVENTIONS** The CAPABLE group received up to 10 home visits over 5 months by occupational therapists, registered nurses, and home modifiers to address self-identified functional goals by enhancing individual capacity and the home environment. The control group received 10 social home visits by a research assistant.

**MAIN OUTCOMES AND MEASURES** Disability with ADLs or IADLs at 5 months. Each ADL and IADL task was self-scored from 0 to 2 according to whether in the previous month the person did not have difficulty and did not need help (0), did not need help but had difficulty (1), or needed help regardless of difficulty (2). The overall score ranged from 0 to 16 points.

**RESULTS** Of the 300 people randomized to either the CAPABLE group (n = 152) or the control group (n = 148), 133 of the CAPABLE participants (87.5%) were women with a mean (SD) age of 75.7 (7.6) years; 126 (82.9%) self-identified as black. Of the controls, 129 (87.2%) were women with a mean (SD) age of 75.4 (7.4) years; 133 (89.9%) self-identified as black. CAPABLE participation resulted in 30% reduction in ADL disability scores at 5 months (relative risk [RR], 0.70; 95% CI, 0.54-0.93; P = .01) vs control participation. CAPABLE participation resulted in a statistically nonsignificant 17% reduction in IADL disability scores (RR, 0.83; 95% CI, 0.65-1.06; P = .13) vs control participation. Participants in the CAPABLE group vs those in the control group were more likely to report that the program made their life easier (82.3% vs 43.1%; P < .001), helped them take care of themselves (79.8% vs 35.5%; P < .001), and helped them gain confidence in managing daily challenges (79.9% vs 37.7%; P < .001).

**CONCLUSIONS AND RELEVANCE** Low-income community-dwelling older adults who received the CAPABLE intervention experienced substantial decrease in disability; disability may be modifiable through addressing both the person and the environment.

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Nearly 1 in 3 older Americans receives help with 1 or more basic daily activities, and as many as half of these individuals report difficulty. Disability is associated with poor quality of life, depression, hospitalization, nursing home placement, and further disability progression, with few exceptions. Despite all of this, geriatric clinic and transitional care models have not addressed or succeeded in reducing the difficulty or dependence when performing daily activities.

Disability is an especially pressing issue for low-income older adults because they have a higher prevalence of disability and often have housing conditions that exacerbate the effect of disability (such as broken flooring). Contemporary payment and delivery reform initiatives create opportunities to address social determinants, such as housing conditions, to improve health while saving costs. Drawing on evidence that person-directed strategies that target individual priorities are especially effective, we tested a person-directed, tailored intervention to improve daily function and to meet the needs of low-income older adults. This intervention, called Community Aging in Place—Advancing Better Living for Elders (CAPABLE), recognizes individual contextual factors, such as preferences, and home environmental factors related to health, family, and housing circumstances.

The CAPABLE program addresses personal and environmental factors that contribute to disability. It extends a successful program called Advancing Better Living for Elders (ABLE), which is designed to help older adults engage in everyday activities of their choice by reducing their difficulty with physical function, improving their quality of life, and lowering their mortality risk through a person-directed approach consisting of occupational therapy, physical therapy, and home environmental modifications. CAPABLE extends ABLE by including management of pain, medications, and depressive symptoms; communication with primary care practitioners; and home repair. Through pilot work, we identified these areas as crucial to amplifying the disability outcomes.

CAPABLE has been studied in a randomized pilot study and in the Centers for Medicare & Medicaid Services (CMS) Innovation Center demonstration program. Both studies found CAPABLE to have a strong effect on reducing disability, but the pilot was underpowered with only 40 participants, whereas the CMS Innovation Center study was limited by a 1-arm study design with a matched comparison group. In this CAPABLE randomized clinical trial, we addressed both limitations. We hypothesized that participants randomized to the CAPABLE program would experience a reduction in disability 5 months after baseline compared with participants randomized to the attention control group.

Methods

This single-blind, 2-arm CAPABLE randomized clinical trial was conducted in Baltimore, Maryland, between March 18, 2012, and April 29, 2016. The trial protocol was approved by the Johns Hopkins University Institutional Review Board. Written informed consent was obtained from all study participants. The trial was monitored by a data and safety monitoring board. Details of the methods have been published elsewhere, and the full protocol is included in Supplement 1. All study participants were interviewed in their home at baseline, 5 months (main study end point), and 12-month follow-up by trained research assistants who were masked to the group allocation.

Study Population

The sample was recruited using a variety of strategies, including direct mail marketing (35%), self-referral (30%), sign-ups through government programs (19%), word of mouth (15%), and enrollment through community programs (7%). The screening process for these community-dwelling participants has been described elsewhere and is depicted in Figure 1.

Eligible participants were 65 years of age or older; were cognitively intact, according to a Mini-Mental State examination score (from 0-30, with scores of 24-30 indicating no cognitive impairment) of at least 24 of 30 at the time of the in-person baseline visit; and reported difficulty with at least 1 activity of daily living (ADL) or at least 2 instrumental activities of daily living (IADLs). Eligible individuals also had to document income of less than 200% of the federal poverty level (in 2018, this amount is $22,980 annually for a 1-person household in the 48 contiguous US states).

Exclusion criteria included self-report of active cancer treatment, more than 3 acute hospitalizations in the past year, inability to stand, apartment dwelling, plans to move within a year, or use of home-based physical or occupational therapy services at enrollment.

Participants were randomized to either the intervention (CAPABLE) group or the attention control group through a computer-based assignment scheme, which was stratified by sex in randomized blocks. Investigators and study staff were masked to assignment scheme.

Intervention Group

The CAPABLE program has been described in detail elsewhere. Briefly, the program includes (1) a multidisciplinary assessment performed by an occupational therapist (OT), who evaluates the functional disability and home safety risks as well as asks participants about their functional goals, and by a registered nurse (RN), who inquires about participant goals regarding pain level, depression, medication un-
The OTs and RNs were trained in the CAPABLE approach through readings, didactic sessions, shadowing experienced OTs and RNs to observe the protocol in the field, and bimonthly supervision meetings. The OTs and RNs documented the duration and content of each home session within 24 hours of completion. All study visits were audiotaped to ensure fidelity; study staff listened to a random 10% of the recordings and evaluated the tapes on the basis of a priori criteria.

Attention Control Group
The attention control group was designed to match the amount of social engagement that the intervention group received (10 home visits of 60 minutes each). The group research assistant helped participants identify sedentary activities they would like to learn or enjoy. Common choices were reminiscing about life, learning to use the internet, playing board games, and listening to music. The duration of each session was monitored.

Measures and Outcomes
Race/ethnicity, age, and sex information was self-reported by each participant. The primary outcomes were disability as measured by difficulty or dependence in self-reported ADLs and IADLs at 5 months (after program completion).

Activities of daily living refer to self-reported difficulty or need for help when performing 8 essential ADLs: walking across a small room, bathing, upper-body dressing, lower-body dressing, eating, using the toilet, transferring in and out of bed, and grooming. This method of self-report, which has high test-retest reliability and sensitivity, predicts future morbidity. Functioning on each task was classified from 0 to 2, depending on whether in the previous month the person did not have difficulty and did not need help (0), did not need help but had difficulty (1), or needed help regardless of difficulty (2). A summary disability score for the 8 items ranged from 0 to 16 points; a 1-point change was considered clinically meaningful.

Instrumental activities of daily living refer to self-reported difficulty or need for help when performing 8 tasks: using the phone, shopping, preparing food, light housekeeping, washing laundry, traveling independently, taking medications, and managing finances independently. The response category for each IADL task ranged from 0 to 2, depending on whether in the previous month the person did not have difficulty and did not need help (0), did not need help but had difficulty (1), or needed help regardless of difficulty (2). The score ranged from 0 to 16 points.

Perceived Program Benefits
We evaluated participant assessment of study benefits using a survey adapted from previous trials that addressed the following 10 questions: (1) How much benefit did you perceive from the CAPABLE program? (2-9) How much did the program help you … take care of yourself? keep living at home? make life easier? make home safer? gain confidence in managing daily challenges? be less upset, distressed, or overwhelmed? take care of others? help others in similar situations? (10) Did the study require too much work or effort? Each
Results

We screened 1229 people for participation. Of these individuals, 300 were eligible, interested in participating, and then randomized to either the intervention group (n = 152) or the control group (n = 148) (Figure 1). Of the 152 participants in the intervention group, 133 (87.5%) were women and 19 (12.5%) were men, with a mean (SD) age of 75.7 (7.6) years, and 126 (82.9%) self-identified as black. Of the 148 participants in the control group, 129 (87.2%) were women and 19 (12.8%) were men, with a mean (SD) age of 75.4 (7.4) years, and 133 (89.9%) self-identified as black.

The study attrition rate was low, with 37 participants (12.3%) not completing the assessment at 5 months and 40 participants (13.3%) not completing the follow-up at 12 months. A total of 130 participants (85.5%) in the intervention group and 133 participants (89.9%) in the control group completed the study at 5 months, and 130 participants (85.5%) in the intervention group and 130 participants (87.8%) in the control group completed the study at 12 months. Those who did not get reassessed were older and had higher ADL disability scores. No demographic or functional differences were observed between the treatment and control groups at baseline (Table 1) except for pain distress in the previous week, tiredness, and unintentional weight loss, each of which was statistically significantly worse in the treatment group than in the control group.

Statistical Analysis

On the basis of the pilot study,\textsuperscript{13} we assumed 15% attrition by 5 months and 90% power to detect a moderate effect size. We set the significance level at $\alpha = .05$. Given these numbers, we planned to randomize 300 participants to the CAPABLE group or control group. The sample size calculation was based on 2-sided, 2-sample $t$ tests at a $P = .05$ significance level and detected an effect size of 0.36 or greater with 80% power. The effect size was based on standardized mean difference in the ADL (or IADL) score at 5 months between the intervention and attention control groups.

We compared the baseline characteristics of study participants to assess the balance between the CAPABLE and control groups. Both crude and covariate-adjusted effect sizes were presented to evaluate the robustness of findings. We used intention-to-treat analysis to assess the intervention effects. We were unable to use analysis of covariance to test the differences in primary outcomes between the groups because so many participants scored a 0 on their disability assessment after the intervention. This result led to overdispersion, shown in a significant likelihood ratio test.\textsuperscript{24} Therefore, we used the negative binomial regression model, a generalized linear model that accounts for non-negative integer-valued outcome variables.\textsuperscript{25}

To implement the intention-to-treat analysis, we modeled the ADL and IADL scores as a longitudinal outcome consisting of up to 3 measurements taken at baseline, 5 months, and 12 months, using the random-effect overdispersion negative binomial regression model.\textsuperscript{26} In this model, the random effect refers to the distribution of the dispersion parameter on the assumption that the dispersion is constant within a person but varies from person to person, such that the inverse of 1 plus the dispersion follows a beta distribution. We included in the model a binary indicator for treatment allocation, dummy indicators of study visits (ie, baseline, 5 months, and 12 months), and interaction terms between the treatment indicator and visit time to allow varying effect size during the intervention phase compared with the maintenance phase. The effect-size estimates were presented, separately at 5 months and 12 months, as the ratio of means between the CAPABLE and the control groups after adjusting for race/ethnicity, sex, and prognostic factors such as pain distress, tiredness, and unintentional weight loss in the past year at baseline. These prognostic factors were determined by forward stepwise selection, with 0.1 significant level for variable entry into and with 0.15 significant level for removal from negative binomial models of posttreatment ADL and IADL scores, weighted by factors associated with the likelihood to drop out. Attrition at the primary end point (5 months) was low at 12.3%. With the maximum likelihood estimator, the random-effect model was robust to data missing at randomization, conditional on the covariates in the model. All analyses were conducted using STATA, version 15 (StataCorp LLC).

Effect of a Biobehavioral Environmental Approach on Disability Among Older Adults

Tables

Table 1

Table 2

Effects of treatment allocation were evaluated with random-effects models, with 0.15 significant level for removal from negative binomial models of posttreatment ADL and IADL scores, weighted by factors associated with the likelihood to drop out. Attrition at the primary endpoint (5 months) was low at 12.3%. With the maximum likelihood estimator, the random-effect model was robust to data missing at randomization, conditional on the covariates in the model. All analyses were conducted using STATA, version 15 (StataCorp LLC).
Discussion

In this randomized clinical trial, participants randomized to the CAPABLE (intervention) group reported a substantial reduction in disability scores after treatment (5-month outcome) compared with the attention control group. The 30% magnitude of the reduction is comparable to results of the 1-armed study of CAPABLE funded by the CMS Innovation Center, which used multiple matched Medicare beneficiaries for comparison. Participants in the control group who received individualized attention also improved, reporting smaller magnitude reductions in ADL and IADL disability scores.

Disabilities are common among adults aged 65 years or older and are associated with poor quality of life, increased mortality, and triple the medical costs. We tested the CAPABLE program, a person-directed intervention that helps older adults identify and achieve their own functional goals through a combination of strategies, including targeting the individual and the home environment. Our findings extend the body of literature on person-directed care, and the power of both person and goal-directed care, and the power of both person and environment interventions to decrease disability scores by more than 4 times the SE of the primary outcomes. Other studies have used 0.5-SD reduction as a clinically meaningful cutoff in main outcomes.

Reducing disability scores among low-income older adults has clinical, fiscal, and policy relevance. In a nonrandomized evaluation of the CMS Innovation Center demonstration of CAPABLE, CMS evaluators estimated cost savings to Medicare of $22,000 over 2 years for the average CAPABLE participant (at a total cost per participant of $2825), compared with a propensity score-matched comparison group. The CAPABLE program has subsequently been adopted by health care organizations in 22 cities and rural areas in 11 states, through varied innovations in payment policy such as Medicaid waivers (which provide community-based resources for people deemed eligible for a nursing home); accountable care organizations; and hospital readmission prevention programs. This well-powered, randomized trial provides further support that the CAPABLE intervention reduces disability scores in
a high-risk subset of the older adult population. As such, the program merits consideration of inclusion in payment innovations, such as those from CMS that allow Medicare Advantage to pay for nonmedical costs with the medical budget or through a Special Needs Plan geared toward people with disabilities who are dually eligible for Medicaid and Medicare.

Despite its predictive value and strong relevance to value-based care and population health efforts, functional status is not commonly prioritized in primary and specialty care. Functional status is often a hidden feature in electronic medical records, if the feature exists at all, the reason for which may be the widely held belief that functional decline is not modifiable. Our work suggests that function can be improved. The effect of the CAPABLE intervention diminished between 5 and 12 months, which may suggest that a booster visit or call could be useful. In addition, a screening for possible benefits like the Supplemental Nutrition Assistance Program or involvement by a social worker, community health worker, or physical therapist could augment the effect. Some of the new CAPABLE sites are experimenting with these extensions.

Limitations

This trial has a few limitations. Participants who responded to recruitment may be different in unmeasured ways from individuals who did not respond. Older adults who are referred to as high-cost utilizers are often harder to engage and may not have the same uptake or same results. In addition, this study was limited to low-income older adults in Baltimore, Maryland, and the sample was predominantly black women, which may limit generalizability. However, few studies of geriatric models have been conducted among low-income older adults and with a predominantly black sample.

Conclusions

Meeting the near-universal goal of supporting older adults to age in place will require models that address more than medical conditions. Findings from this trial suggest that disability may be modifiable through addressing both the person and the environment.
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ORIGINAL INVESTIGATION Research

Accuracy of the data analysis.

Responsibility for the integrity of the data and the

Data Sharing Statement:
The content is solely the responsibility

Disclaimer:

We thank all of the

Additional Contributions:

Critical revision of the manuscript for important

Conflict of Interest Disclosures: Drs Szanton and Gitlin reported being inventors of the CAPABLE training program, for which the Johns Hopkins University is entitled to fees. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies.

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REFERENCES


