

## CLINICAL INVESTIGATION

# CAPABLE for People After Hospitalization: A Randomized Trial

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**Received:** 6 October 2024 | **Revised:** 4 September 2025 | **Accepted:** 7 September 2025

**Funding:** This work was supported by National Institute on Aging (R01 AG056607). The funder had no role in the preparation of this manuscript.

**Keywords:** disability | intervention | post-hospitalization

## ABSTRACT

**Background:** Following hospitalization, nearly 30% of older adults lose some independence. This can lead to rehospitalization, nursing home admission, and increased dependence. CAPABLE, an evidence-based program, increases independence among older adults with functional limitations but has not been tested in recently hospitalized people.

**Methods:** This randomized clinical trial enrolled 268 low-income community-dwelling adults who had been discharged to home from the hospital 60 days prior, had a home health episode, yet had remaining difficulties in at least one activity of daily living. Participants were randomized to no further care or to CAPABLE, which involved up to 10 home visits over 5 months with an occupational therapist, a registered nurse, and a handyworker to address an older adult's self-identified functional goals. Main outcomes were (1) improvement in difficulty with and assistance needed for 10 activities of daily living (range 10–50); (2) five instrumental activities of daily living and mobility: walking up a set of stairs and walking a block.

**Results:** The CAPABLE group decreased their ADL difficulty by  $-1.76$  (CI  $-2.98, -0.54$ ) and the control group decreased ( $-0.63$ ; CI  $-1.86, 0.60$ ) over 5 months, which was not statistically or clinically significant. However, the CAPABLE treatment group demonstrated greater improvement in a composite mobility measure than control participants ( $-0.52$  and  $-0.02$ , respectively,  $p=0.028$ ). Additionally, among participants with four or more co-morbidities at baseline, the CAPABLE group showed significantly improved ADL independence compared to control participants.

**Conclusions:** Among recently hospitalized persons receiving skilled home health care, CAPABLE did not improve ADLs. However, it improved functional mobility and benefited those with  $\geq 4$  comorbidities. This study provides novel information on targeting CAPABLE in the post-hospitalization period.

## 1 | Introduction

Almost 30% of recently hospitalized older adults have trouble with daily activities like bathing and walking [1] even up to a year later [2, 3]. These difficulties are associated with lower life quality, more hospitalizations, and nursing home admission [4]. Transitional care prevents re-hospitalization but does not

significantly affect disability [5, 6], hospitalizations for planned surgeries have different recovery trajectories than for chronic conditions exacerbations [7], and hospitalized older adults with multi-morbidity have worse recovery trajectories [8].

CAPABLE (Community Aging in Place Advancing Better Living for Elders) improves ADLs, mobility, and IADLs [9], by

## Summary

- Key points
  - The CAPABLE program, a time limited, person-oriented, function focused intervention that addresses the person and their environment did not significantly reduce activity of daily living disability among the overall sample of older adults recently hospitalized.
  - For older adults with fewer co-morbidities, control group participants improved as much as CAPABLE participants after hospitalization and home care episode. Those with four or more co-morbidities did improve significantly more with CAPABLE than with usual care.
- Why does this paper matter?
  - This study offers valuable clinical insights for integrating CAPABLE within the aging services ecosystem.
  - To prevent post-hospitalization disability, CAPABLE may be most effective when targeted at individuals with four or more comorbidities.

improving personal and environmental factors. In multiple clinical trials, CAPABLE helps older adults perform everyday activities of life better, with less difficulty, and lowers their chances of being hospitalized [10, 11]. However, CAPABLE has never been tested in a post-hospitalization population. Therefore, the aim of this study was to test the effects of CAPABLE on functional outcomes in a diverse group of older adults discharged from hospital to home with remaining post-discharge disability after a home care episode.

## 2 | Methods

This study reports on a two-arm, randomized trial with pragmatic elements performed in Blinded for Review between August 2018 and September 2023 registered as NCT03456128. The study protocol was approved by both the VNS Health and the Johns Hopkins Medical Institutions Institutional Review Boards and monitored by a data and safety monitoring board. Study participants provided informed consent; written prior to March 2020 and verbal thereafter. Study participants were interviewed in their home or on the phone at baseline and 5 months (main study endpoint) by trained field interviewers masked to group allocation.

### 2.1 | Study Population

A skilled home health care agency, research-intensive University, and community-based non-profit collaborated on this study. We recruited older adults 60 days after hospital discharge. Sixty days coincides with the end of a skilled home health care episode for most patients [12].

Inclusion criteria for the study were: (a)  $\geq 65$  years; (b) 60 days after an acute care hospitalization followed by a skilled home care episode; (c) self-reported difficulty with at least one ADL;

(d) able to stand with or without assistance; (e) reported three or fewer hospital admissions in the prior 12 months; (f) in the New York area during the 4-month intervention/study period. Excluded participants (a) had significant cognitive impairment identified by the Callahan screening tool [13]; (b) spoke neither English nor Spanish; (c) were receiving cancer treatment; or (d) planned to move soon. We designed these exclusions so that participants were available for the intervention over time and cognitively capable of action planning.

Participants were identified through Electronic Health Records (EHR) of the home care agency, based on recent hospitalization and subsequent discharge from home care services. Research staff screened by telephone to determine eligibility and explain study procedures to potential participants.

If eligible by screen, participants were scheduled for a baseline interview within 14 days. Prior to March 2020, participants received an in-person visit to complete consent and the baseline interview. With the onset of the COVID pandemic, we paused recruitment from mid-March 2020 until June 2021. Subsequent participants completed data collection activities over the phone. The sample size calculation prior to the study was 268, which is the number we randomized. This was based on two-sided tests of 0.05 significance and assumed an attrition rate of 25% during the 20-week follow-up period; we would need to enroll 134 participants per treatment arm to detect, with 80% power, an intervention effect size of 0.40, standard deviation units, respectively, at 20 weeks after baseline. By enrolling at least 268 participants, we anticipated having 20-week outcome data (primary endpoint) on 200 participants after 25% attrition.

### 2.2 | Randomization

We used a random assignment schedule, within variable-sized blocks from four to eight participants, to stratify assignments by surgical (including joint replacement) versus non-surgical hospital admission due to the groups' difference in functional recovery.

### 2.3 | Intervention

CAPABLE has been previously described [10, 14]. In brief, CAPABLE consists of an assessment-driven, individually tailored package of interventions delivered over the course of 4–5 months by an Occupational Therapist (up to 6, hour-long home visits), a Nurse (up to 4, hour-long home visits), and a handyworker to make home modifications and repairs as needed. The total number of visits depends on the participant's self-identified goals elicited by the occupational therapist or the nurse. Sessions are spaced so that participants have opportunities to practice new strategies or activities together with CAPABLE staff and then on their own. Every participant received each component of the intervention (assessment, goal setting, interactive problem-solving, training), but interventionists clinically tailored content to each participant's functional goals. All Occupational Therapists and nurses met twice monthly to review cases and discuss particularly challenging or illustrative

cases. One of the Occupational Therapists and the project manager took the lead in processing work orders and coordinating handyworker services. The handyworkers were sourced from the community-based organization which provided other older adults through home modifications.

## 2.4 | Control Group

As a pragmatic trial, participants randomized to the control condition received no additional services from the study team. Their only contact with the study team was for data collection interviews at baseline, 5 months, and 12 months.

## 2.5 | Measures

Trained field interviewers conducted interviews unaware of treatment assignment.

Participant demographic characteristics included age, gender, race (African American/White/Other), ethnicity (Hispanic/not Hispanic), language (English/Spanish), marital status (married/domestic partnership, single, divorced/separated, widowed), and living arrangement (alone/with others).

The primary outcome measure was difficulty and assistance needed for ADLs. The secondary outcome was difficulty and assistance needed for instrumental ADLs and mobility. These are modeled from the measurement approach in the National Health and Aging Trends Study [15]. For each ADL, IADL, and mobility item, participants were asked “how difficult” it was to do each task with response levels consisting of: usually did with no difficulty (1), usually did with a little difficulty (2), usually did with some difficulty (3), or unable to do (4). They were also asked if they relied on any assistive device or special equipment (Yes, No) and if they received help from another person (Yes, No). A total score for each item was derived by taking the difficulty rating and adding one point if they received help from another person and ½ point if they used an assistive device or equipment. For ADLs, 10 items were assessed: dressing above the waist, dressing below the waist, grooming, bathing/showering, toileting, eating, getting in/out of car, walking indoors, moving in/out of chair, and moving in/out of bed. In addition to the transfer items included as part of the ADLs, two additional mobility-related items were assessed: (1) walking one block and (2) climbing one flight of stairs. For IADLs, five items were assessed: light housework, shopping, preparing meals, telephone use, and taking medications. Thus, each of the three areas of function was analyzed as a score of difficulty weighted by assistance needed and use of a device to complete activities. The possible scores were 10–50 for ADL difficulty, 5–25 for IADL, and 2–10 for mobility, with higher scores indicating greater difficulty in each area.

**Other measures included:** Count of comorbidities from Charlson Index and whether their hospitalization had been for surgery or not. Patient-Reported Outcomes Measurement Information System (PROMIS) was administered to collect self-reported physical, mental, and social health. Depression

was measured using the Patient Health Questionnaire (PHQ-8).

## 2.6 | Statistical Analysis

We used a modified intention-to-treat (ITT) approach to analyze results; data from all participants who provided outcome data at 5 months were analyzed based on their assigned study group. Sensitivity analyses were conducted for the primary outcome using multiple imputation for the 48 participants with missing data at the 5-month assessment. The results of those imputation analyses were not substantively different from the complete case analyses, so only findings from the complete case analyses are further reported here. Difference scores (5 months minus baseline) were calculated for the primary outcome measure (ADL summary disability score) and secondary outcome measures. For each outcome, a separate analysis of covariance (ANCOVA) was conducted on that 5-month difference score, with treatment group as the primary independent variable and the baseline score on that outcome variable as the primary covariate. Age was also included as a covariate in these models because it was imbalanced across groups (see Table 1) [16]. Both patient age and baseline score were centered at baseline mean. Two tests from these models were pre-specified. The first was the intervention effect. For that, we tested whether changes from baseline were significantly different for treatment and control participants. We calculated standardized effect sizes (*d*) by dividing the difference in adjusted change scores between intervention and control groups by the baseline overall standard deviation of each outcome variable. For the second pre-specified test, we examined whether overall change across treatment and control groups differed significantly from zero by examining the intercept effect from the ANCOVA models.

We also conducted planned exploratory analyses to examine subgroup effects and heterogeneity of intervention response. Key subgroups included those defined by age, gender, living arrangement (e.g., lives alone or lives with others), financial strain, type of hospitalization (e.g., surgical vs. nonsurgical), and medical complexity at baseline (number of Charlson comorbidities). For each outcome and each potential moderating/subgroup variable, we added the moderator main effect and a treatment\*moderator interaction term to the models to test whether intervention efficacy was significantly modified as a function of that moderating variable.

## 3 | Results

We screened 5100 potentially eligible participants from August 2018 to September 2024, pausing for the COVID-19 pandemic from March 2020 to June 2021. Of these, 268 were eligible, interested in participating, provided informed consent, and randomized to the intervention (*n* = 134) or the control (*n* = 134) (see Figure S1). At 5 months, 220 participants completed the main outcome measures; 111 (82.8%) in the intervention group and 109 (81.3%) in the control group.

Table 1 depicts participants' baseline sociodemographic, functional status, comorbidity, and health status. No demographic

**TABLE 1** | Participant characteristics at baseline.

Variable	Total sample (N=268)	CAPABLE intervention (N=134)	Usual care control (N=134)
Age at baseline, <i>M</i> (SD)	75.4 (7.2)	76.6 (7.0)	74.2 (7.3)
Gender			
Female, <i>N</i> (%)	192 (71.6)	95 (70.9)	97 (72.4)
Male, <i>N</i> (%)	76 (28.4)	39 (29.1)	37 (27.6)
Race			
Black, African American, <i>N</i> (%)	121 (45.2)	58 (43.3)	63 (47.0)
White, <i>N</i> (%)	76 (28.4)	40 (29.9)	36 (26.9)
Mixed, <i>N</i> (%)	21 (7.8)	8 (6.0)	13 (9.7)
Other, <i>N</i> (%)	46 (17.2)	25 (18.7)	21 (15.7)
Missing, <i>N</i> (%)	4 (1.5)	3 (2.2)	1 (0.8)
Hispanic ethnicity, <i>N</i> (%)	57 (21.3)	27 (20.2)	30 (22.4)
Language			
English, <i>N</i> (%)	246 (91.8)	123 (91.8)	123 (91.8)
Spanish, <i>N</i> (%)	22 (8.2)	11 (8.2)	11 (8.2)
Marital status <i>N</i> (%)			
Married/domestic partnership	61 (22.8)	29 (21.6)	32 (23.9)
Single, never married	73 (27.2)	39 (29.1)	34 (25.4)
Divorced/separated	60 (22.4)	31 (23.1)	29 (21.6)
Widowed	72 (26.9)	33 (24.6)	39 (29.1)
Live alone, <i>N</i> (%)	113 (42.2)	56 (41.8)	57 (42.5)
Surgery in the last 60 days, <i>N</i> (%)	58 (21.6)	26 (19.4)	32 (23.9)
Comorbidity count at baseline, <i>M</i> (SD)	3.3 (2.1)	3.4 (2.2)	3.1 (2.0)
ADL score at baseline, <i>M</i> (SD)	23.3 (8.0)	23.3 (8.2)	23.2 (7.7)
IADL score at baseline, <i>M</i> (SD)	14.1 (4.4)	14.1 (4.4)	14.1 (4.3)
Other mobility score at baseline, <i>M</i> (SD)	6.5 (2.0)	6.6 (2.0)	6.4 (2.0)
PROMIS physical health, <i>M</i> (SD)	11.2 (2.6)	11.1 (2.5)	11.2 (2.7)
PROMIS mental health, <i>M</i> (SD)	12.1 (3.5)	12.2 (3.2)	12.0 (3.7)
PHQ9 depression, <i>M</i> (SD)	7.4 (5.8)	7.2 (5.5)	7.7 (6.0)

or functional differences were observed between the intervention and control groups at baseline (Table 1) except for age.

### 3.1 | Treatment Dose

One hundred intervention participants (74.6%) received 8–10 sessions, considered the minimum amount for completing the intervention. The other 34 participants who were assigned to the intervention condition had lower intervention doses including 3 who died.

### 3.2 | Intervention Effects on Outcomes

The CAPABLE group decreased ADL difficulty by  $-1.76$  (CI  $-2.98, -0.54$ ) and the control group decreased ( $-0.63$ ; CI  $-1.86, 0.60$ ) over 5 months. While the CAPABLE group experienced a statistically significant change on its own, it was not statistically or clinically significant compared to the change over time in the control group (Tables 2 and S1). For the other outcome measures, there was a significant group improvement between the treatment and control groups on the “other mobility” score, which is walking a block and climbing a flight of stairs (adjusted  $M = -0.52$  vs. adjusted  $M = -0.02$ ;  $p = 0.028$ ).

### 3.3 | Treatment Moderation Effects

In pre-planned analyses, treatment condition and comorbidity count significantly interacted in affecting ADL disability scores ( $p = 0.025$ ). Higher comorbidity counts in the control group were associated with less ADL improvement but not in the CAPABLE group (Figure 1).

There were no other statistically significant treatment moderation effects.

### 4 | Discussion

To our knowledge, this is the first randomized controlled study to examine the effects of the CAPABLE model in a population of

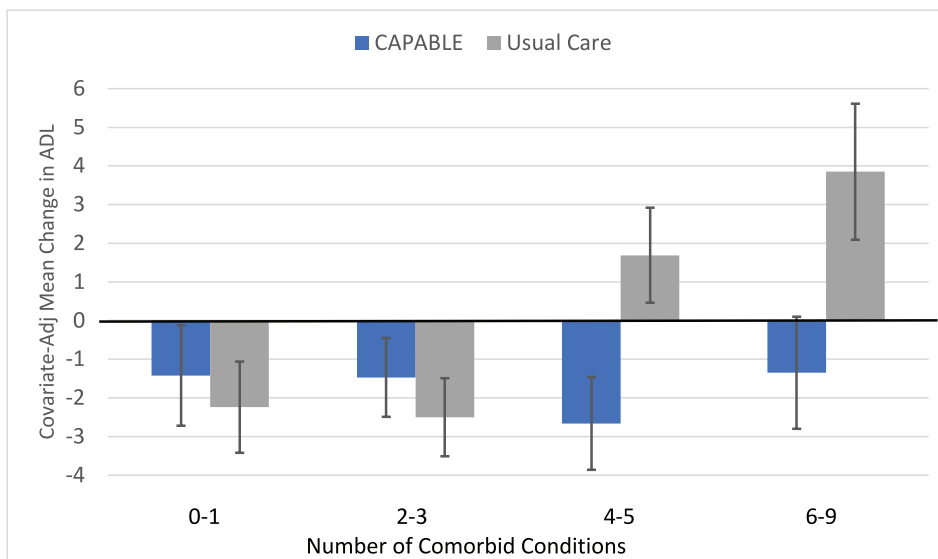
older adults following hospitalization and an episode of skilled home health care. We found that both treatment and control groups improved their ADLs, and patients in the CAPABLE group demonstrated greater improvement in walking and climbing stairs. Importantly, patients in the CAPABLE group demonstrated significantly improved ADL independence in the pre-hypothesized subgroup of individuals with multiple (4 or more) co-morbidities at baseline.

The current study differs from prior studies of CAPABLE in two key respects, namely the target population and the provision of CAPABLE immediately after both an acute hospitalization that was also followed by an episode of skilled home health care. To date, published clinical trials of CAPABLE have focused on community-dwelling, lower-income older adults with *chronic* disability and have

**TABLE 2** | Effects of the intervention on outcomes at 5 months.

Outcome	Total sample mean at baseline	Adjusted change at 5 months for CAPABLE		Adjusted change at 5 months for Control		Difference (CAPABLE – Control)		SE of the difference	p	d
		M	95% CI	M	95% CI	M	95% CI			
ADL score	23.27	-1.76	-2.98, -0.54	-0.63	-1.86, 0.60	-1.13	-2.88, 0.62	0.89	0.204	-0.14
IADL score	13.98	-0.93	-1.60, -0.26	-0.58	-1.26, 0.10	-0.35	-1.31, 0.61	0.49	0.475	-0.08
Other mobility score	6.46	-0.53	-0.84, -0.21	-0.02	-0.34, 0.30	-0.51	-0.97, -0.05	0.23	0.028	-0.25
PROMIS—physical	11.24	-0.09	-0.53, 0.36	-0.07	-0.52, 0.39	-0.02	-0.66, 0.62	0.33	0.954	-0.01
PROMIS—mental	12.20	0.49	-0.05, 1.03	0.44	-0.08, 0.97	0.05	-0.71, 0.80	0.38	0.903	0.01
PHQ9—depression	7.26	-0.77	-1.66, 0.12	-0.27	-1.18, 0.65	-0.50	-1.79, 0.79	0.65	0.443	-0.09

Note: 95% CI is the 95% confidence interval. SE is standard error. *d* is a standardized difference in standard deviation units (difference/baseline SD for the total sample from Table 1).



**FIGURE 1** | ADL change by comorbidity quartile—higher comorbidity counts were associated with less ADL improvement for those in the control group but not for those in the CAPABLE group.

demonstrated benefits in reducing disability and health care utilization.

Functional impairment following hospitalization represents a different construct. Prior studies of functional impairment and recovery following acute hospitalization among older adults find that approximately 1/3 of patients over age 70 develop new disability in ADLs attributable to the hospitalization [17] and that recovery, when it occurs, is typically incomplete and prolonged, and that mobility-related activities of daily living, such as walking, recover more slowly [3].

Providing CAPABLE following hospitalization and an episode of skilled home health care is also notable. Skilled home health nurses play a critical role in managing symptoms such as dyspnea, fatigue, and weakness, which are common among older multimorbid older adults in the post-acute hospital period. Further, skilled occupational and physical therapies are commonly provided in a skilled home health care episode. In this CAPABLE study, we examined the impact of extending care beyond the standard home health episode through continued goal setting and interdisciplinary intervention by the CAPABLE nurse and occupational therapist. Among participants with four or more comorbidities, which is likely associated with more chronic underlying disability, this extended intervention was associated with significant improvements in mobility.

Importantly, the complex education and therapeutic strategies initiated during the home health care episode were reinforced and expanded to include home modifications during the CAPABLE intervention. This continuity may have provided patients with additional time and support to translate health knowledge into sustained behavioral change, thereby stabilizing symptoms and enhancing ability and confidence to move about their home.

These findings suggest that post-acute older adults with high levels of medical complexity, and perhaps for those who experienced functional impairments prior to an acute hospital admission, may benefit from longer episodes of home health care, greater incorporation of CAPABLE goal-setting strategies and tactics into standard skilled home health care process, and/or continued attention via CAPABLE that extends beyond traditional home health services. Future research should investigate the specific care plans and goal-setting strategies employed to elucidate the mechanisms underlying these mobility improvements. Exploring effects in those with cognitive impairment and other specific patient groups, for example, post-stroke or injurious falls, is also needed.

The finding that participants randomized to CAPABLE improved more in being able to walk a block or climb stairs without difficulty is important because these measures of functional mobility are vital to social participation and occur earlier in the disability trajectory [18, 19]. The composite mobility score, derived from participant ratings of difficulty and their need for assistance or adaptive equipment when walking one block and climbing a flight of stairs, provides a nuanced picture of real-world mobility in older adults recently discharged from the hospital with disability. On this scale, a 0.5-point improvement corresponds to either reducing the level of difficulty by a full

category (e.g., from “some difficulty” to “a little difficulty”) or eliminating the need for an assistive device or personal assistance for one mobility task.

Such a change is consistent with published criteria for minimal clinically important differences (MCID) in functional outcome measures for older adults. For example, studies have shown that changes equivalent to a single level of difficulty or independence on multi-level scales—such as the National Health and Aging Trends Study (NHATS) disability and functioning measures—are perceived as meaningful improvements by patients and clinicians [15, 20]. In this high-risk, post-hospitalization population, a 0.5-point improvement indicates a substantial functional gain, likely to have a direct impact on independence, community participation, and quality of life.

Our study adds to the evidence supporting CAPABLE by demonstrating its effectiveness for racially and ethnically diverse older adults, many of whom were Hispanic and non-English speakers. This diversity is a key strength, given the increasing diversity of the US population. This study had two important limitations. It did not include people with dementia, limiting its generalizability. Although CAPABLE has since been adapted for individuals with mild cognitive impairment and early dementia, this was not reflected in our sample. Another limitation is that only 5% of the pool of people identified from the home health encounters ended up consenting and engaged in the study.

In conclusion, while CAPABLE did not improve ADLs more than recovery from hospitalization for the general population, it was beneficial for those with multiple co-morbidities. This study provides valuable clinical precision for implementing CAPABLE within the aging-in-community ecosystem.

#### Author Contributions

Study design: Sarah Szanton, David Roth, Kathryn Bowles, Bruce Leff, and Laura Gitlin. Data management: Nicole Onorato and David Roth. Analysis and interpretation of the data: David Roth and Sarah Szanton. Preparation of the manuscript: Sarah Szanton, David Roth, Kathryn Bowles, Nicole Onorato, Bruce Leff, and Laura Gitlin.

#### Conflicts of Interest

Sarah Szanton and Laura Gitlin are inventors of the CAPABLE training program, for which they, Johns Hopkins University, and Thomas Jefferson University are entitled to fees. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflicts of interest policies.

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### Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Figure S1:** Trial consort diagram. **Table S1:** Descriptive means and standard deviations for outcomes.