CAPABLE Transitions Protocol

November 2022

CAPABLE TRANSITIONS

A randomized, care-as-usual-comparator, unblinded, 60-subject clinical trial of an occupational therapy-led in-home intervention designed to help older adults successfully transition to their homes following a hospital or post-acute care facility discharge.

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Study Title

CAPABLE Transitions: A Home Health Agency-Based Intervention to Optimize the Hospital or Post-Acute Care Facility-to-Home Transition

Objectives

This study's primary objective is to serve as a feasibility study of an intervention to assist older adults in the hospital or post-acute care facility-to-home transition and to test and refine procedures as they relate to:

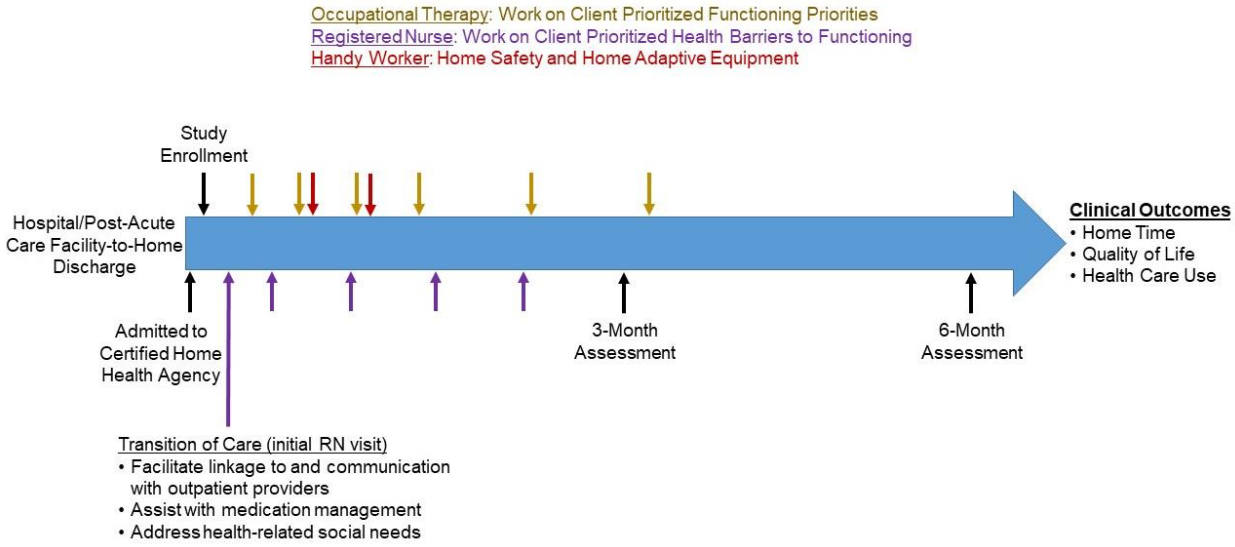
- screening, enrollment, and retention of study participants
- fidelity to and perceived benefit of the intervention
- data completeness with regard to our intermediate and primary outcomes

This study's secondary objective is to obtain preliminary data on home time, quality of life, and health care utilization at three and six months following post-acute care facility discharge.

Design and Outcomes

This study is a randomized, care-as-usual (CAU)-comparator, unblinded clinical trial of an occupational therapy (OT)-led in-home intervention designed to help older adults with and without dementia successfully transition to their homes following a hospital or post-acute care facility discharge. In total, we plan to recruit 60 adults (36 in the intervention and 24 in the CAU arms) aged 65 years and older recently discharged from a hospital or post-acute care facility and admitted to a Medicare-certified home health agency (CHHA). Throughout the study, we will continually seek to enhance and optimize the study protocol and procedures to enhance recruitment. Our pilot study's main outcomes relate to the feasibility of the study. These outcomes include study recruitment and retention, fidelity to and perceived benefit of the intervention, and data completeness with regard to our intermediate and primary clinical outcomes (home time, quality of life, health care utilization). We will assess participants at the time of study enrollment and three and six months following hospital or post-acute care facility discharge with a combination of in-person interviews and review of medical health records.

Figure 1. CAPABLE Transitions Overview



Interventions and Duration

CAPABLE Transitions: The intervention group will receive an OT-led multidisciplinary in-home intervention in which the study OT (≤6 visits), RN (≤5 visits), and handyworker (≤2 visits) work with participants over three months. Study staff will follow participants for six months with assessments occurring at study enrollment as well as three and six months following hospital or post-acute care facility discharge. The intervention group also will receive CHHA CAU services. Figure 1 only shows the intervention and assessment sessions (CHHA CAU are not shown).

Care-as-Usual: The comparator group, receives CHHA CAU services, which can include nursing, home health aide, medical social work, and occupational, physical, and speech therapy services. CHHA clinicians will determine the types and duration of services that CHHA clients in this group receive, which will be completely independent of the research study. The duration of CHHA can vary dramatically across CHHA clients (e.g., range from a single visit to having weekly visits for more than a year). Regardless of the types or duration of CHHA services received, study staff will follow the CAU group for six months with assessments occurring at study enrollment as well as three and six months following hospital or post-acute care facility discharge. Even if study participants are receiving CHHA CAU services beyond six months, participation in the research study will end at the sixth month assessment.

Sample Size and Population

Our target population consists of English-speaking adults aged 65 years and older with and without dementia who live in the Rochester region and are admitted to a CHHA following a hospitalization or post-acute care facility stay. We will continue to revise the study protocol as needed to enhance recruitment. We will utilize a stratified random permuted block method of randomization.[1] Study staff will stratify participants into two groups based on the presence or absence of moderate or severe cognitive impairment as determined by a Mini-Mental Status Exam (MMSE) score. Following stratification, the study will use permuted block randomization to randomize participants to the intervention or CAU groups). We thereby anticipate enrolling 60 participants in this pilot study.

STUDY TEAM ROSTER

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Main responsibilities: Primary responsibility over the entire clinical trial, which includes hiring and training staff, developing study protocol and procedures in accordance with good clinical practice, developing study forms and materials, supervising study performance, ensuring that participants' well-being and safety are protected, monitoring and reporting adverse events, and submitting documents to regulatory bodies.

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PARTICIPATING STUDY SITES

Primary Study Site

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1 STUDY OBJECTIVES

1.1 Primary Objective

This study's primary objective is to serve as a feasibility study of an intervention to assist older adults in the hospital or post-acute care facility-to-home transition and to test and refine procedures as they relate to:

- screening, enrollment, and retention of study participants
- fidelity to and perceived benefit of the intervention
- data completeness with regard to our intermediate and primary outcomes

Achieving this objective will inform the development of a larger clinical trial. This larger clinical trial will test the hypothesis that, among older adults discharged from hospitals or post-acute facilities (e.g., inpatient rehabilitation facilities and skilled nursing facilities) and admitted to a CHHA, those who receive *CAPABLE Transitions* will spend more days alive in their homes, have a higher quality of life, and have decreased utilization of emergency department, acute medical, and SNF care compared to older adults who receive CHHA CAU.

1.2 Secondary Objectives

This study's secondary objectives are to obtain preliminary data on home time, quality of life, and health care utilization at three and six months following hospital or post-acute care facility discharge.

2 BACKGROUND AND RATIONALE

2.1 Background on Hospital and Post-Acute Care Facility-to-Home Transitions

Older adults with chronic illnesses often experience repeated transitions in care, especially people with dementia.[2-6] These transitions can be burdensome to individuals and their caregivers[7] and are associated with complications, health status decline, and poor quality of care.[2, 8-10] In 2018, 1.6 million fee-for-service (FFS) Medicare beneficiaries used SNFs at least once.[11] Although 84% of those admitted to SNFs desire community discharge,[12] only 56% of post-acute care SNF admissions are discharged to the community within 100 days.[13] Even among those discharged from the SNF, many struggle with the transition back to the community.[14, 15] For instance, among older adult post-acute SNF care Medicare beneficiaries in North and South Carolina, 22% use acute services within 30 days of SNF discharge (67% of whom were rehospitalized).[14] There is also wide variation in discharge outcomes between higher and lower performing SNFs (e.g., 30-day potentially avoidable readmission rates of 3.9% and 7.8% for the 25th and 75th percentiles),[11] indicating an opportunity for improving discharge outcomes. Furthermore, if SNF discharge outcomes were improved, SNF providers may be more willing to discharge "high-risk" patients to the community, potentially resulting in fewer post-acute care SNF patients transitioning to nursing home long-term care.

2.2 Study Rationale

There are numerous barriers to a successful hospital and post-acute care facility-to-home discharge: Although care transitions are common among older adults,[3-5] these transitions are fraught with risk that older adults and their caregivers may be poorly prepared to manage.[7] The reasons why many older adults struggle with the hospital or

post-acute care facility-to-home transition are complex and multifactorial. For example, patient-level (e.g., male gender, cognitive impairment, functional impairment, Medicaid eligibility) and SNF-level (e.g., SNF quality) factors can affect an older adult's ability to return to and remain in the community.[14, 16-22] Additionally, following discharge, the medical care of the older adult must transfer from the hospital or SNF providers to the PCP and other outpatient medical providers in a timely and effective manner, and there can be breakdowns in communication between health care providers. Transitions of care also can exacerbate medication-related issues[7] (e.g., ability to manage medications, redundant medications). Furthermore, unmet health-related social needs are frequently overlooked during health care transitions and can negatively affect health outcomes and services utilization.[23] Many older adults discharged from the hospital or post-acute SNF care also have had a significant medical event that has decreased their level of functioning, placing their ability to manage in the homes at risk. Over the past two decades, there have been many efforts to address these issues to improve care transitions – efforts that have successfully reduced rehospitalizations, SNF readmissions, and mortality.[24]

Prior to the COVID-19 pandemic, many older adults were referred to home health agencies from SNFs. However, there is evidence that the pandemic is dramatically changing post-acute and home health care- in 2018, 66% of home agency referrals nationally came from doctors' offices.[25] Due to the dramatic reduction in SNF referrals to home health agencies and in consideration of the likely dramatic post-acute care changes nationwide, our recruitment criteria will include referrals from hospitals, inpatient rehabilitation facilities, and skilled nursing facilities. A review of Medicare inpatient hospital claims from June 2020 estimates a 4.6% increase in home health care compared to June 2019, and a 25.4% decrease in SNF discharges.[26] Although we designed our intervention with the SNF-to-home transition in mind, CAPABLE Transitions is a care transitions intervention that will work similarly in the hospital-to-home transition and would involve no additional modifications to do so.

Care transition interventions overview and knowledge gap: Care transition interventions have included advanced practice nurses who serve as transition coaches,[27-29] nurse discharge coordinators,[24, 30, 31] pharmacists,[30] telemonitoring,[32, 33] telephone support,[32, 33] and home visits,[24, 29, 33] which have emphasized educational components (e.g., medication self-management) and care coordination. Complex interventions targeting the patients' capacity for self-care appear particularly effective[34] as do interventions bridging pre- and post-discharge settings.[24] *"The vast majority of care transitions literature has been hospital-focused…"*,[24] however, and the evidence to inform post-acute care facility-to-home discharges, specifically, is limited. Additionally, many of the interventions designed for the hospital settings are too resource-intensive (e.g., reliance on nurse practitioners, pharmacists) for post-acute care SNFs to easily adapt and adopt. A 2015 review found only two SNF-based interventions designed to reduce hospital readmissions.[35] *Project ReEngineered Discharge* ("Project RED") is one such intervention, which reduced 30-day hospitalization following SNF discharge from 18.9% to 10.2%. Although effective, this intervention is unlikely to be widely disseminated as it consists of 11 components that necessitate comprehensively overhauling the SNF discharge process and requires actions by social workers, nurse practitioners, secretaries, nursing, and home care liaisons and coordinators.[36] The second intervention consisted of a specialized geriatric rehabilitation unit that included a comprehensive geriatric assessment, a geriatrician, a geriatric nurse practitioner, and follow-up telephone case management. A pilot study suggested that this intervention resulted in fewer ED visits and hospital readmissions after SNF discharge.[37] This pilot study was conducted in 2005 and, to our knowledge, has not been examined in a follow-up randomized clinical trial. Efforts are

underway to optimize the SNF-to-home transition, and Connect-Home is a four-step transitional care intervention to be delivered by SNF staff. Connect-Home's four steps are as follows: step 1 is to create transition of care plan, step 2 consists of a care plan meeting, step 3 is to implement the care plan, and step 4 consists of a social worker calling the patient or caregiver within 72 hours of discharge.[38] Overall, there is little empirical evidence on how to optimize the SNF-to-home transition, however. To our knowledge, no study has examined a CHHA-based intervention to assist older adults in transitioning from the SNF to home.

To address this critical gap in knowledge and improve outcomes for older adults experiencing the SNF-to-home transition, we are proposing to conduct a pilot study of a targeted intervention, *CAPABLE Transitions*, which will assist older adults who are discharged not only from the hospital, but also from post-acute care facilities (SNFs or inpatient rehabilitation facilities) to CHHA services in the community.

Original *CAPABLE*: *Community Aging in Place, Advancing Better Living for Elders* (*CAPABLE*) includes an interdisciplinary team of a registered nurse (RN), OT, and handyworker. The *CAPABLE* intervention consists of an assessment-driven, client-specific package of interventions that are delivered over approximately four months by an OT (≤6 visits), RN (≤4 visits) and a handyworker team.[39] *CAPABLE* has been shown to decrease ADL impairment (by 30% and 45% when compared to an active control or baseline impairment, respectively) [40] as well as home hazards and depression in community-dwelling older adults.[39, 41] *CAPABLE* also reduces utilization of inpatient and outpatient medical services among older adults.[42] *CAPABLE* is becoming widely disseminated. Of note, *CAPABLE* was originally designed for functionally limited, but medically stable and cognitively intact older adults. *CAPABLE* excluded those who had 4+ hospitalizations in the prior 12 months or were receiving in-home physical therapy, OT, or nursing services. These exclusions are pertinent to older adults transitioning from the hospital or post-acute care facility-to-home as this group has high levels of acute medical care use, cognitive impairment, and home health services utilization.[14, 43] Whether *CAPABLE* performs similarly in those with more acute medical needs and/or cognitive impairment is uncertain. It is also unclear whether *CAPABLE* can be delivered from within a CHHA organization. We therefore have developed *CAPABLE Transitions*, an intervention that adapts *CAPABLE* to this more vulnerable population, adds a transitions of care component, and is designed to be delivered within a CHHA.

***CAPABLE Transitions* – A home health agency-based intervention for older adults transitioning from the hospital or post-acute care facility to home**: We have designed *CAPABLE Transitions* to help older adults return to and remain in the community. Similar to *CAPABLE*, *CAPABLE Transitions* consists of an OT-led multidisciplinary team in which the study OT (≤6 visits), RN (≤5 visits), and handyworker (≤2 visits) deliver an in-home intervention over approximately three months. Also similar to *CAPABLE*, *CAPABLE Transitions* aims to harness the older adult's motivation by addressing functional goals that the older adult or dyad prioritizes as well as changing home factors in support of these functional goals and to improve home safety. *CAPABLE Transitions* expands upon *CAPABLE*, however, by also focusing on care transitions, and thereby has two core elements. The first element consists of an RN-delivered brief care transitions intervention. The care transitions element is informed in part by Coleman's Care Transitions Intervention Model.[27] This element seeks to ensure connection to and communication with the PCP and outpatient medical services, to address barriers to medication management, and to screen for and link older adults to appropriate services for unmet health-related social needs.

Whereas the first element primarily aims to facilitate the transfer of care from the hospital or post-acute care facility to the outpatient and home settings, *CAPABLE Transitions'* second element seeks to optimize the ability of the older adults to function in their homes. To do so, we modified *CAPABLE* in four ways. First, given the acuity of the older adults our intervention targets, the Study OT and RN visits will occur more frequently in the first few weeks following the transition relative to the original *CAPABLE* intervention (e.g., every 1-2 weeks rather than every 2-4 weeks, with flexibility to account for participant preference, participant availability (e.g., may be hospitalized), and varying CHHA clinical demands). Second, following the transition home, all the CHHA clients in our study will be receiving CHHA nursing services and many also will be receiving CHHA OT services. For CHHA clients randomized to our intervention arm, in addition to CHHA RN +/- CHHA OT services, they will receive *CAPABLE Transitions* RN and OT services delivered by the same CHHA RN and CHHA OT. The *CAPABLE Transitions* intervention can be delivered either at the end of a CAU RN and OT in-home session or at a separate in-home visit. Of note, *CAPABLE Transitions'* OT services focus on client-prioritized functional goals while *CAPABLE Transitions'* RN services target client-prioritized conditions and syndromes that may be impairing function (e.g., depression, pain, incontinence) as well as fall prevention and communication with the PCP. In contrast, CHHA CAU OT and RN services are generally directed by a physician's order and tend to focus on a specific medical problem identified by the physician (e.g., wound care, diabetes management, upper extremity mobility). Third, our intervention will include those with moderate or severe cognitive impairment (including dementia), regardless if they have live-in caregivers, who may potentially live alone. Optionally, we may deliver the intervention to a caregiver-participant dyad, regardless of cognition, if there is a caregiver willing to serve as a study partner. An MMSE score of 20 or less indicates that a moderate or severe cognitive impairment is present.[44, 45,86] Fourth, CHHA clients and dyads will determine the dose of the intervention and whether to participate in the various components of the intervention. The different intervention components include:

- RN care transitions home visit
- OT comprehensive assessment and development of client-prioritized functional goals
- client-OT work towards addressing functional goals
- handyworker home safety repairs
- handyworker home modifications to support patient-prioritized functional goals
- RN in-depth assessment on pain, depression, strength/balance, medication concerns, and outpatient medical provider communication and development of client-prioritized goals as they relate to these issues
- client-RN work on addressing RN domain goals

It is important to note that the services provided by the Study OT and RN differ from those offered by CHHA CAU OT and RN visits. Whereas CHHA CAU OT and RN services are often focused on a specific problem or on disease management (e.g., diabetes, wound care, heart failure), Study OT and RN visits are designed to: 1) Let the client drive the treatment plan, 2) enhance client self-efficacy (e.g., change comes from the client), 3) customize treatment strategies to client-identified concerns, capabilities, and environment, 4) address the environment (e.g., assess the clients' functioning in their home), 5) coordinate with handyworker services to optimize the environment for function and safety, and 6) focus on function rather than disease management.

We expect that this clinical trial will present minimal risk to study participants. This study will involve questionnaires, interviews, function-focused physical activity and exercises, and examination of medical records for which the primary risk is invasion of privacy, breach of confidentiality, or the participants becoming fatigued or stressed.

Theoretical foundation: Our intervention is based on several different theoretical foundations. First, Freedman's Disability Framework (which is informed in part by the World Health Organization's International Classification of Functioning and Disability, Nagi's disability model, and others) indicates that environment impacts an older adult's health conditions, impairments, and capacity, which can in turn be mitigated by accommodations (e.g., changes to the environment, compensatory strategies).[46] Second, Andersen's Behavioral Model considers how predisposing (e.g., sociodemographics), enabling (e.g., social support, environment, insurance), and need (e.g., medical conditions, functional and cognitive impairment) can impact health care access and utilization as well as health outcomes.[47, 48] Third, the Cumulative Complexity Model considers how the balance of older adult workload (illness management requirements) and capacity (ability to manage illness) help determine (along with other factors) the success or failure of transitions of care.[49] Lastly, we will draw upon Dr. Coleman's Care Transitions Intervention framework, which identifies "four pillars" (e.g., medication self-management, dynamic patient-centered record, PCP follow-up, identification of red flag symptoms) as being critical to care transitions.[50]

Table 1. Overview of *CAPABLE Transitions* – An Intervention to Optimize the hospital or post-acute care facility-to-Home Transition

Study Population: older adults with and without dementia admitted to a certified home health agency (CHHA) services after being discharged from a hospital or post-acute care facility.

Inclusion Criteria: aged 65 years or older, English-speaking, admitted to CHHA following a hospitalization or post-acute facility admission, live in the Rochester, NY region.

Exclusion Criteria: have a terminal diagnosis, receiving active cancer treatment, plan to move within one year, and who are COVID-19 positive, have suspected COVID-19 infection, or resides with a person who is COVID-19 positive or has suspected COVID-19.

Intervention Time Frame. Although we will have optimal visit timeframes, these timeframes are guidelines. We expect that real-world situations will sometimes result in intervention visits that occur outside of these "optimal" timeframes:

- OT Home Visits (6 total visits):
  - #1 ideally as soon as possible after RN visit #1 (optimally within 1-2 weeks; may occasionally occur prior to RN visit #1),
  - #2-4 optimally within 1-2 weeks thereafter OT visit #1,
  - #5-6 optimally within 3-4 weeks thereafter OT visit #4,
- Handyworker Home Visits: as soon as possible after OT visit #2 (ideally completed within 3 weeks from CHHA admission, which typically occurs within several days of hospital or post-acute care facility discharge)
- RN Home Visits (5 total visits):
  - #1 will occur as soon as possible after CHHA admission (optimally within 1-2 weeks),
  - #2 optimally within 1-2 weeks after RN visit #1,
  - #3-5 optimally within 2-4 every weeks thereafter RN visit #2.

- As this is a feasibility study, we will have relatively broad study windows for when the intervention can be administered. The study intervention will not extend past 5 months following hospital or post-acute care facility discharge, however. Of note, the intervention will be discontinued for study participants with a prolonged hospitalization as described in Section 8 of the protocol.

- After each OT or RN visit, the study participants will be asked whether they would like to continue with the intervention.

	Core Function ("Objectives")	Forms ("Activities")	Theory	Intermediate Outcomes	Primary Outcomes
Care Transition Component (RN Home Visit #1)	Ensure linkage to PCP and other medical providers.	CHHA clients create list of medical providers, recent or scheduled appointments, and barriers to attending appointments; RN assists clients in overcoming barriers and in linking to outpatient medical services. CHHA clients identify key symptoms as well as questions and concerns for their medical providers; RN assists clients in identifying key symptoms, answering questions, and communicating with medical providers.	Andersen's Behavioral Model, Coleman's Care Transitions Intervention Model	Increased timeliness and frequency of outpatient medical appointments Increased communication with providers (e.g., office visits or calls, electronic messaging)	1) Increased home time (i.e., days spent alive at home or in the community) 2) Improved quality of life 3) Decreased emergency department, hospitalization, and SNF utilization

	Reduce barriers to effective medication management.	CHHA clients complete a comprehensive medication management assessment; based on the assessment, study RN assists the client in developing strategies to more effectively management medications.	Andersen's Behavioral Model, Coleman's CTI Model	Increased medication adherence	
	Address health-related social needs.	CHHA clients complete a health-related social needs questionnaire[23]; based on the screener, RN completes referrals for identified health-related social needs.	Cumulative Complexity Model, Andersen's Behavioral Model	Decreased anxiety symptoms Decreased depression symptoms	
OT and Handyworker in the Home (OT Home Visits #1-6)	Develop and implement a treatment plan based on patient-determined functional priorities.	CHHA clients complete comprehensive functioning assessment. CHHA clients work with OT to develop a priority list of functional goals; based on this list, OT assists client in addressing client-prioritized functional goals (e.g., via education, exercises, obtaining and practicing with devices).	Freedman's Disability Framework, Cumulative Complexity Model	Improved self-efficacy[51] Improved ADL functioning Improved IADL functioning	
	Improve home safety.	OT completes a home safety assessment. CHHA clients work with OT to develop a priority list of home repairs. Handyworker works with CHHA client and OT to make appropriate repairs.	Freedman's Disability Framework, Cumulative Complexity Model	Fewer home hazards Decreased fear of falling Improved mobility	
	Optimize home environment for function.	Based on the CHHA clients' comprehensive functioning assessment and prioritized list of functional goals, client works with OT to create a list of home modifications for HM to complete and accommodative devices for OT to obtain. CHHA clients work with OT to enhance clients' ability in using the home modifications and accommodative devices.	Freedman's Disability Framework, Cumulative Complexity Model	Improved self-efficacy Improved ADL functioning Improved IADL functioning	

RN in the Home (RN home visit #2-5)	Identify and decrease barriers to daily functioning such as pain, depressive symptoms, strength/balance difficulties, medication issues, and poor communication with medical providers.	CHHA clients complete an RN assessment focused on pain, depression, strength and balance, medication management, and communication with medical providers that impact functioning. CHHA clients work with RN to develop a priority list of functional goals; based on this list and with a behavioral activation approach, client and RN develop a plan to address these goals (e.g., pain management techniques, balance exercises).	Freedman's Disability Framework, Cumulative Complexity Model	Improved ADL functioning Decreased pain Decreased depressive symptoms Improved mobility Improved medication adherence Increased communication with providers (e.g., office visits or calls, electronic messaging)	

3 STUDY DESIGN

This study is a randomized, CAU-comparator, unblinded clinical trial of an in-home multidisciplinary intervention, *CAPABLE Transitions*, designed to help older adults successfully transition to their homes following hospital or post-acute care facility discharge. We plan to conduct this study for three years and to recruit 60 adults (36 in the intervention and 24 in the CAU arms) aged 65 years and older with and without dementia recently discharged from a hospital or post-acute care facility and admitted to a CHHA. Prior to randomization, we will stratify the 60 participants based on the presence or absence of moderate or severe cognitive impairment. *CAPABLE Transitions* consists of an OT-led multidisciplinary team in which the study OT (≤6 visits), RN (≤5 visits), and handyworker (≤2 visits) deliver an in-home intervention over three months. Study staff will follow participants for six months with assessments occurring at study enrollment as well as three and six months —following hospital or post-acute care facility discharge.

Our pilot study's primary outcomes relate to the feasibility of the study and include study recruitment and retention, fidelity to and perceived benefit of the intervention, and data completeness. The pilot study's secondary outcomes are to obtain preliminary data on home time, quality of life, and health care utilization at three and six months following hospital or post-acute care facility discharge.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

This study's target population is older adults living in an urban area who are admitted to a CHHA after discharge from a hospital or post-acute care facility. To participate in the study, with few exceptions (e.g., active cancer treatment, terminal diagnosis), there will be no restrictions based on sex, health status, or medical conditions, and all of the following inclusion criteria must be met:

- admitted to CHHA following a hospitalization or post-acute care facility stay (if not referred from CHHA, we will collect data on where patient referral is from)
- live in the Rochester, NY region
- aged 65 years or older
- English-speaking
- agree to study participation

We will deliver this intervention within a CHHA and with CHHA clinicians to enhance the scalability and the ease of dissemination if *CAPABLE Transitions* is effective. However, it is acceptable if patients have been admitted and then discharged from CHHA within the screening timeframe, or if participants may be working with other CHHA (staff such as PT or OT) and do not currently have an assigned CHHA registered nurse.

CHHA clients, regardless of their cognition, will have the option to include a study partner that may live with the study subject and be a primary caregiver to the study subject. Study partners may attend home visits and intervention sessions and be available via phone to answer questions from the research assistant. If needed, they must be available for other information via phone to be obtained from study staff. They may be asked general questions (e.g., age, sex) and about their relationship to the study participants and the participant's daily functioning, wellbeing, and health services use.

4.2 Exclusion Criteria

We will exclude potential participants from study participation who do not satisfy all of the inclusion criteria or meet any of the following exclusion criteria at baseline:

- plan to move within one year
- has a terminal diagnosis (e.g., <1 year life expectancy, in hospice)
- receiving active cancer treatment (active treatment includes surgery or a course of radiation or chemotherapy; it does not include long-term maintenance treatment such as daily hormonal treatment of prostate cancer)
- inability or unwillingness of individual or legal guardian/representative to give written informed consent.
- has been discharged to home from a hospital or post-acute care facility for more than 28 days
- are COVID-19 positive, have suspected COVID-19 infection, or resides with a person who is COVID-19 positive or has suspected COVID-19.

4. 3 Study Enrollment Procedures

We will recruit older adults newly admitted to UR Medicine Home Care following discharge from a hospital or post-acute care facility. UR Medicine Home Care is a CHHA that provides services to a six-county region in Upstate New York.

- **Identification**: The CHHA has clinical teams based on geographic region. The study OT and RN will be on the same CHHA team, which will be assigned to a region in Monroe County, NY that includes the Rochester region. The study RN and OT will regularly screen all of their CHHA intakes to identify potential study participants (e.g., discharged from post-acute care facility, does not have a terminal condition). The study RN and study OT will ask clients passing the initial screen if they are interested in participating in our research study. The study RN and OT will also offer participants a recruitment brochure to introduce and provide information to home health patients if they are interested. For residents indicating an interest to participate in the research study and agree to have a study staff member visit them to provide more information, the study RN, OT, and CRC will work together to schedule an in-person screening visit that is convenient to the potential participant. In addition to the URMHC interventionists recruiting participants among their new admissions, we will contact potentially eligible URMHC clients who have indicated that they are interested in participating in research when they complete the new consent process via URMHC. This new consent process is for ALL URMHC patients admitted to URMHC services in which they can "opt in" or "opt out" of being contacted by a UR researcher if there is a study they qualify for. Only patients who have consented will be contacted by the CRC.
    - **Study sample representativeness**: At each stage of the screening and recruitment process, we will document the proportion of CHHA clients who are not eligible for our study, are not interested in participating in our study, or are lost to follow-up. For these CHHA clients we will only keep basic demographic information such as age, sex, and race and ethnicity to allow us to track those who do and do not participate in our study; those older than 89 will be grouped in a 90+ age category. We will also utilize ICD-10 codes as part of the

screening process for the CHHA to help us identify participants that have dementia or cognitive impairment. However, we will not base our recruitment criteria or numbers based on this dementia category but will prioritize people with dementia. This information will help us determine the representativeness of our study sample and to examine whether there are subgroups that are unlikely to participate in the study (in which case, we made need to bolster recruitment efforts for certain subgroups).

- **Consent procedures**: As part of the consent process, study staff will systematically assess capacity for consent with a series of open-ended questions administered to the potential participant that follows explanation of the study (see Determination of Consent Capacity Form). These questions will address the participant's knowledge and understanding of the study's objectives, the voluntary nature of participation, ability to withdraw at any time, and possible risks and benefits of participation. For those unable to demonstrate capacity for consent, we will seek to obtain surrogate consent. Surrogate consent for dementia research is widely accepted by the general public,[54, 55] and we will only enroll older adults with a surrogate consent if the older adult also assents to participate in the study and the surrogate consenter is able to demonstrate capacity for consent. We will not enroll any older adult who is unable to demonstrate capacity to provide informed consent if they do not have surrogate consent available. Although we will not enroll these older adults, we will compensate them with $10 for completing the screening procedures.
- **Randomization**: Immediately following termination of the baseline assessment interview, study staff will randomly assign participants via a stratified random permuted block method.[1] Randomization will be stratified based on cognitive impairment status (moderate/severe cognitive impairment present: MMSE score $\leq$ 20; moderate/severe cognitive impairment absent: MMSE $\geq$ 21).[44, 45,86] Block randomization will then occur within each strata to ensure appropriate allocation to the treatment and CAU groupings. REDCap[56] will track the randomization groupings.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

***CAPABLE Transitions* overview**: *CAPABLE Transitions* is informed by theory and evidence-based practices (Table 1) and consists of $\leq$11 in-home visits by an OT and RN over three months. Every participant that completes the *CAPABLE Transitions* intervention will receive each component of the intervention (e.g., care transitions assistance, assessment, education, problem-solving activities), but the interventionists will tailor the content to each participant's goals and risk profile. University of Rochester Medicine Home Care will document information about study participation in the older adults' electronic health records. Table 2 provides a detailed overview of the intervention timeline and content. The RN/OT visits will occur as soon as possible following the minimum possible number of weeks after the prior visit. The study visit timeline will be flexible to accommodate for both the interventionists and the participants needs. In instances where there is a deviation from our protocol, we will complete a Note to File in our regulatory file (e.g., if an interventionist is on sick leave or if the participant has been hospitalized). To help ensure fidelity to the intervention, the Study OT and RN will

complete standardized training for *CAPABLE* provided by Johns Hopkins School of Nursing. We will augment this training with training specific to *CAPABLE Transitions* that accounts for the care transitions RN visit and other adaptations we are making to *CAPABLE* (e.g., increased frequency of visits early on, involvement of a Study Partner).

Table 2. *CAPABLE Transitions* timeline and content.			
Session	Timing	Content	Interventionist (OT, RN, Handyworker) Follow-up
Occupational Therapy			
Visit #1	As soon as possible after RN visit #1 (or, in some unusual circumstances, as soon as possible after CHHA admission)	Introduction to OT portion of *CAPABLE*. Issue intervention folder. Function-focused OT assessment, including functional mobility, ADL, and IADL. Determine participant's functional goals. Physical therapy screen.	
Visit #2	As soon possible after visit #1 ideally 1-2 wks after OT #1	Fall risk and recovery education. Conduct home safety assessment and identify necessary repairs or modifications.	Develop work order for home repairs/modifications for handyworker.
Visit #3	As soon possible after visit #2, ideally 1-2 wks after OT #2	Brainstorm and develop action plan with participant for participant-identified goal #1 (e.g., safely bathing, going upstairs, and preparing food).	
Visit #4	As soon possible after visit #3, ideally 1-2 wks after OT #3	Review action plan #1. Brainstorm and develop action plan with participant for participant-identified goal #2. Review handyworker work and train participant on new assistive devices as able.	Issue assistive devices or medical equipment as available.
Visit #5	As soon possible after visit #4, ideally 2-4 wks after OT #4	Review action plan #2. Brainstorm and develop action plan with participant for participant-identified goal 3. Issue assistive equipment and durable medical equipment (if not already done) and train participant on new assistive devices and modifications.	
Visit #6	As soon possible after visit #5, ideally 3-4 wks after OT #5	Review OT section of the Flipbook. Help participant generalize solutions for future problems and problem-solving techniques. Review goals and participant's achievement of them. Review readiness score. Ask if participant has any final questions.	
Handyworker			
Visit #1	As soon as possible after OT #3	Visit home to assess which materials to purchase for ordered modification and repairs. **For common types of repairs and modifications involving materials on hand, begin repairing and modifying the home.**	

Visit #2	Once supplies are available	Repair and modify home based on participant goal-prioritized work order.	Notify OT when this is complete.
Registered Nurse			
Visit #1	As soon as possible after client has been admitted to Certified Home Health Agency (CHHA)	CHHA clients and RN work together to: 1) Create list of medical providers, recent or scheduled appointments, and barriers to attending appointments; RN assists clients in overcoming barriers and linking to outpatient medical services. 2) Identify key symptoms as well as questions and concerns for their medical providers; RN assists clients in communicating with medical providers. 3) Complete a comprehensive medication management assessment. Based on the assessment, RN assists the client in developing strategies to more effectively manage medications. 4) Complete a health-related social needs questionnaire[23]; based on the screener, RN completes referrals for identified health-related social needs.	If indicated: 1) Correspond with outpatient medical providers to communicate concerns or schedule an appointment. 2) Assist with referral to community-based agencies or CHHA social worker. 3) Connect with medical transportation services. 4) Communicate medication concerns to study pharmacist and/or outpatient providers.
Visit #2	As soon possible after visit #1, ideally 1-2wks after RN #1	Introduction to RN portion of *CAPABLE*. Function-focused RN assessment including pain, mood, strength, balance, medication information, and need for health care provider (e.g., PCP) advocacy/communication.	Correspondence to PCP if necessary.
Visit #3	As soon possible after visit #2, ideally 2--4 wks after RN #2	Determine goals in RN domain together. Start to brainstorm goal #1 (e.g., pain in standing, fall prevention). Demonstrate *CAPABLE* exercises. Review medication calendar. Discuss participant/PCP communication.	Correspondence to PCP if necessary.
Visit #4	As soon possible after visit #3, ideally 22-4 wks after RN #3	Complete brainstorming/problem-solving process. Develop action plans for identified goals with participant. Assess PCP response to communication of participant needs. Review, assess, and troubleshoot exercise regimen. Issue health care passport.	Correspondence to PCP if necessary.
Visit #5	As soon possible after visit #4, ideally 2--4 wks after RN #4	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. Help participant generalize brainstorming process for future health issues. Discuss participant/PCP communication. Ask if participant has any final questions.	Correspondence to PCP if necessary.

Intervention delivery characteristics: *CAPABLE Transitions* consists of an OT-led multidisciplinary team in which the study OT (≤6 visits), RN (≤5 visits), and handyworker (≤2 visits) deliver an in-home intervention over approximately three months with each OT and RN visit lasting about 60-90 minutes. The OT and RN visits are more frequent earlier in the intervention to assist older adults with the hospital or post-acute care facility-to-home transition. We gradually increase the timing interval between visits so that participants have time to practice strategies or activities following the in-home sessions. All study participants who decide to receive the full dose of the intervention will receive a total of 6 OT visits and 5 RN visits. The number of handyworker visits will depend on the modifications and repairs that are needed by the participant (e.g., if everything can be completed in 1 visit, then participants only will have 1 handyworker visit). There may be rare instances for which the handyworker visits the home more than twice (e.g., perhaps the participant has a change in functioning during the course of the intervention that would benefit from an additional home modification). Additionally, the handyworker services may be unnecessary for all participants (e.g., some participants may decline handyworker services if they already live in an age-friendly home or community). While receiving the study intervention, CHHA clients also will receive CAU from the CHHA (which may include OT services). The study OT and RN will be the same clinicians who deliver CHHA CAU. To do so, they will either lengthen the CAU visit or have a separate visit solely for the intervention. Data from the CHHA indicate that the median length of a home health episode of care is 29 days (Q1: 17 days, Q3: 47 days). For study participants who complete the *CAPABLE Transitions* intervention, we anticipate that most will complete the OT and RN sessions in approximately 90 days, and the intervention sessions will not continue past 5 months following hospital or post-acute care facility discharge (unless there is an exception noted in a Note to File document). Therefore, we expect that the majority of study participants will have CHHA CAU that temporarily overlaps with the *CAPABLE Transitions* intervention. We anticipate that there will be minimal "leakage" of the study intervention services to the CHHA CAU because the OT and RN actions for *CAPABLE Transitions* will follow a manual based on *CAPABLE* training and these actions are markedly different from their usual CHHA CAU roles.

The clinical research coordinator (CRC) will maintain a calendar to facilitate coordination of the intervention and ensure that study visits occur as detailed in the study protocol. A secure share site (UR Box) that can be remotely accessed will enhance communication between the OT, RN, and handyworker. This site also will enable study staff to monitor electronic documentation for study fidelity and to help assess study costs. The OT will have responsibility for case coordination with the CHHA staff and other interventionists and for identifying the necessary supplies to order, which include home modifications and repairs. Monthly to bimonthly meetings with the OT, RN, handyworker, CRC, and PI will ensure communication, adequate supervision, and appropriate fidelity to the intervention.

Of note, CHHA clients and dyads will determine the dose of the intervention (e.g., number of visits) and whether to participate in the various components of the intervention (e.g., types of visits such as OT, RN, and handyworker services). More specifically, after each OT or RN visit, the study participants will be asked whether they would like to continue with the intervention. The study participants can thereby determine the dose of the intervention they receive as they can discontinue participation in the intervention at any time (see Section 8 for additional detail regarding intervention discontinuation), but still continue their participation in the study assessments. Our interventionists may also terminate the study intervention if identified goals are completed (or unable to be completed) and there are no further participant-interventionist agreed-upon goals to work on.

As previously stated, the study interventionists are practicing home health clinicians that are highly experienced working with older adults who have cognitive impairment. Our study's goal is to improve home safety and functioning and the intervention is catered directly to the needs, ability, and goals of the participants – no two participants will receive the same intervention. The clinicians will not have participants perform exercises or tasks that are unsafe or beyond their ability.

The different intervention components include:

- RN care transitions home visit
- OT comprehensive assessment and development of client-prioritized functional goals
- client-OT work towards addressing functional goals
- handyworker home safety repairs
- handyworker home modifications to support patient-prioritized functional goals
- RN in-depth assessment on pain, depression, strength/balance, medication concerns, and outpatient medical provider communication and development of client-prioritized goals as they relate to these issues
- client-RN work on addressing RN domain goals

Intervention protocol, OT: This OT intervention protocol was adapted from the original *CAPABLE* intervention.[40] The OT meets with participants for up to six sessions within approximately three months of randomization.

In the 1st and 2nd OT sessions**,** the OT meets with participants and conducts a semi-structured clinical interview using the Client-Clinician Assessment Protocol (C-CAP) that has been tested for its psychometric properties for use in home-based and home modification programs.[57] The C-CAP provides a systematic approach from which to identify and prioritize performance areas that are problematic to participants. For each performance area identified, the OT observes the participant's performance and evaluates safety, efficiency, difficulty, and presence of environmental barriers and supports. The OT will provide a three-ring binder (*CAPABLE* notebook) which will contain educational materials, contact information and a calendar to integrate the sessions by the RN and handyworker interventionists. Also, in the course of this session, the OT assesses the environmental home safety (common safety and mobility risks 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 creates a list of agreed upon assistive devices and housing repairs for the handyworker.

In 3rd, 4th, and 5th OT sessions, 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 energy conservation techniques, 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 handyworker 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.

Intervention protocol, RN: This RN intervention protocol was adapted from the original *CAPABLE* intervention.[40] The RN meets with participants for up to five sessions within approximately three months of randomization.

In the 1st RN session, the RN meets with the participants and works with the CHHA client to create a list of medical providers and scheduled appointments and to identify any barriers to attending outpatient medical appointments. The RN emphasizes the importance of follow-up outpatient appointments and works with the participant to address barriers to attending appointments or any questions the participants may have for the medical providers. At this initial visit, the RN also assesses the participant's medications as well as the participant's ability to manage her own medications and tailors intervention as indicated by the assessment. Additionally, the RN will work with the participant to identify key symptoms and signs to monitor for that should prompt an urgent medical work-up. Lastly, the RN conducts a health-related social needs screener and works with the participant to make appropriate referrals to community resources as needed.

The 2nd RN session occurs approximately 2-3 weeks after the first RN session. In this session, the RN assesses the participant using the C-CAP RN developed specifically for CAPABLE in which the RN focuses on how and whether pain, depression, strength and balance, medication management, and communication with PCP impact daily function.[58] 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 the 3rd and 4th RN sessions**,** 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, and provides education and resources to address future needs (e.g., pill box for medication management).

In the final (5th) RN session**,** the RN reviews the participant's strategies and helps to generalize them to other possible challenges.

Intervention protocol, handyworker: This handyworker intervention protocol was adapted from the original *CAPABLE* intervention.[40]

The hand worker portion is contracted through handyworker services provided by a local non-profit aging services agency, Lifespan (Lifespan, Rochester, NY). Lifespan has a program entitled, "Home-Safe-Home," which has been available to the community for over 20 years.[59] The Home-Safe-Home Program provides home modifications such as grab bars, tub grips, shower seats, handheld showers, commodes, railing modifications, and other simple yet effective modifications that reduce the risk of falling. It modifies approximately 900-1000 homes a year. This program is funded in part through grants from various organizations. In an evaluation of this program, 82 (94%) of surveyed Home-Safe-Home participants reported feeling more comfortable in their home since the home modifications and 57 (65.5%) reported increased independence, most frequently with bathing (68.4%), followed by use of the bathroom and stairs (49.1%).[60] To deliver the Home-Safe-Home Program, Lifespan employs a handyworker (the current handyworker has been in this role since 2014). Upon agreeing to participate in this study and after being randomly assigned to the *CAPABLE Transitions* intervention arm, study participants will be enrolled in Lifespan's Home-Safe-Home Program. Lifespan also has liability insurance for this program and, should any participants have problems with the handyworker

modifications or installations, they can follow-up with Lifespan and the handyworker. Of note, study participants will not need to identify themselves to Lifespan as they will be enrolled in the Home-Safe-Home Program via their participation in our study. Furthermore, the handyworker, Ken Posman, is Lifespan's Home-Safe-Home Program coordinator and will be doing the handyworker modifications for all of our study participants. As such, additional study communication with Lifespan will not be needed as Lifespan will be fully aware of all of the study participants' involvement in the Home-Safe-Home Program as well as their participation in our study. We will pay Lifespan to deliver the Home-Safe-Home handyworker services to our CAPABLE Transitions participants. The handyworker will help coordinate the ordering of the assistive devices as well as the repair and modification supplies. The handyworker has extensive experience working with older adults in the area, and will make as many home visits as it takes to provide the study renovations/modifications. The budget for home repairs, home modifications, and assistive devices is $1,200 per household, similar to *CAPABLE's* $1,300,[40] an amount that was adequate for most renovations necessary for safer, more functional homes. We also have extra funds available if necessary, for unusual situations (e.g., if we need to replace or repair equipment we purchased/installed during the course of the study).

If home repairs or modifications outside the Handyworker's scope of practice are indicated (e.g., plumbing, carpentry, or electrical work), participant compensation may include additional cash payments for home repair and modification services performed through Catholic Family Center's HomeWorks Program. HomeWorks is a program that provides low-cost home maintenance/repair support to older adults. These additional cash payments of $100 would cover the expense of enrolling in HomeWorks (for 3 months) and obtaining an initial estimate of the cost of the modifications/repairs and/or the expense of minor home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by Catholic Family Center's HomeWorks contractors. Of note, HomeWorks limits the maximum service charge to $500. As many of the participants may not have funds available to pay for the costs of these services upfront, the study team will provide this compensation to the participants in cash prior to having the participants pay for these services (maximum compensation for HomeWorks services would be $500 per participant, and is included in the $1,200 budget for home repairs/modifications and assistive devices). Participants will be notified at time of informed consent that depending on the amount they are paid, they may be asked to submit a W-9 form, which includes their Social Security Number. No repairs or modifications to the participants' homes, however, will be made without the participants' permission

Similar to above, if larger home repairs or modifications outside of both Lifespan and Catholic Family Center's scope of practice are indicated (e.g., masonry, bathroom remodeling), participant compensation may include additional cash payments for home repair and modification services performed by another person (e.g., a handy worker or separate contractor) or agency (e.g., bathroom modelers) within our allowed budget. This will allow participants to complete indicated home repairs or modifications that are outside the scope of both Lifespan and CFC capabilities. We will only reimburse participants for agreed upon repairs and modifications that are consistent with the objectives of the CAPABLE Transitions intervention. Additionally, we plan to obtain an estimate of the work prior to agreeing to reimburse it. These additional cash payments would cover obtaining an initial estimate of the cost of the modifications/repairs as well as the expense of the home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by these contractors or agencies. The total cost of these and other services provided to the participant will not exceed the $1,200 budget for home

repairs/modifications and assistive devices. In unusual circumstances (e.g., much needed home safety repair), we may also be able to reimburse participants for expenses exceeding $1,200 if necessary to improve home safety or function and our budget allows. No repairs or modifications to the participants' homes, however, will be made without the participants' permission. Participants will be responsible for any costs that are associated with maintaining or replacing these items following the termination of the study.

5.2 Handling of Study Interventions

Study staff and interventionists will conduct *CAPABLE Transitions* as outlined by this protocol. This protocol has been adapted from the original *CAPABLE* intervention with several notable changes. First, the OT visits will occur more frequently in the first few weeks following the transition relative to the original *CAPABLE* intervention. Second, we will adapt *CAPABLE Transitions* so that CHHA OTs and RNs deliver the intervention within a CHHA setting. Third, our intervention will include those with moderate or severe cognitive impairment who may live alone. If they have caregivers interested and willing to participate, we may deliver the intervention to the dyad consisting of an older adult regardless of cognition and their Study Partner. Some participants with intact cognition may appreciate having a study partner available throughout the intervention. Fourth, CHHA clients and dyads will determine the dose of the intervention and whether to participate in the various components of the intervention. We will offer flexibility for the intervention visits to meet the needs of the interventionists and the participants.

The CRC will systematically monitor the delivery of the intervention to make sure that the study interventionists are adhering to the intervention's protocol. Additionally, to help ensure fidelity to the intervention, the interventionists will receive standardized training offered through The Johns Hopkins University School of Nursing.[61] This training will complement the content presented in the intervention's protocol. Johns Hopkins University School of Nursing *CAPABLE* Training courses include the following (of note, no person identifiers of the study participants will be shared):

- Training manuals for RNs and OTs
- OT and RN initial assessment forms
- Documentation forms for all ten home visits
- Brainstorming and action planning forms
- CAPABLE exercise book, Health Passport, medication calendar and items for participant's folders
- Tip book for participants
- Webinars for additional training and information sharing. These are offered live and recorded and archived by topic for later access
- Office hours so trained clinicians, program administrators and construction partners can ask questions, discuss challenging cases, share equipment solutions and participant successes
- Review of up to 3 work orders for each CAPABLE trained OT during office hours
- Access to Vimeo video clips of visit scenarios
- Access to other CAPABLE sites' outcomes and experiences through an online user group

We will monitor the following fidelity components: intervention adherence, intervention exposure/dose, quality of delivery, participant engagement, and differentiation between critical intervention features.[62-64] Adherence consists of the extent to which intervention components were delivered as prescribed in the study manuals. Exposure considers the number of intervention sessions and the time interventionists spent assisting participants. Quality of intervention delivery considers qualitative aspects of the delivery independent of the intervention content such as interventionist enthusiasm and global estimates of intervention effectiveness. Participant engagement is a measure of participant enthusiasm and degree of participation in the intervention. Intervention differentiation will help us identify which elements of the intervention are essential and a check to make sure that the participants in the intervention only received the plan intervention.[64] To assess these varied fidelity domains, we will use a combination of direct assessment (e.g., observation via audiotapes) and indirect measures (e.g., OT/RN self-report).[62] Similar to prior work, we also rely upon a combination of Likert and yes/no items to measure fidelity.[65] More specifically, the CRC will review the audio recorded intervention sessions and will complete the Likert and yes/no items while listening to the recording (no transcripts of the recordings will be generated). As a group, we will review the fidelity scores generated by the CRC review of the audiotapes during our regularly scheduled *CAPABLE Transitions* meetings and will use these findings to identify any potential issues that the Study OT and RN should address to improve the quality of their administration of *CAPABLE Transitions*. Tracking these fidelity metrics longitudinally should provide us with near real-time feedback to allow us to improve the delivery of the intervention as we move forward. We will use an encrypted voice recorder for this purpose. We will label these audio recordings using de-identified numbers only and will store the recordings on secure University of Rochester servers and/or the CRC and PI's computers. Access to these audio recordings will be password protected and audio recordings will be destroyed consistent with federal guidelines and the University of Rochester RSRB Policy 405.

For this pilot study, the research staff, interventionists, and participants will not be blinded to randomization assignment.

5.3 Concomitant Interventions

5.3.1 Allowed Interventions

With the exception of hospice services and active cancer treatment, participants are allowed to receive any medication, treatment, or in-home or outpatient medical services while in the study. If study participants are briefly hospitalized, we will plan to continue the intervention. Prolonged hospitalization would substantially interfere with the delivery of the intervention (i.e., 14+ days in first month of intervention, 21+ following the first month), however, and we would discontinue the intervention if prolonged hospitalization were to occur.

5.3.2 Required Interventions

The only required intervention is that study participants have to be admitted to CHHA services following discharge from a hospital or post-acute care facility.

5.3.3 Prohibited Interventions

We will exclude older adults who are receiving hospice services or active cancer treatment.

5.4 Adherence Assessment

We will ensure and monitor study adherence and fidelity through several mechanisms. First, study interventionists will complete the standardized training offered through The Johns Hopkins University School of Nursing, which will complement the study's protocol. Second, for the care transitions intervention component, the RN will participate in-person training and role-playing sessions to reinforce the procedures outlined in the study's training manual. Third, monthly to bimonthly meetings with the OT, RN, handyworker, CRC, and PI will ensure communication, adequate supervision, and appropriate fidelity to the intervention. Fourth, we will routinely audio record intervention sessions to monitor fidelity and for quality control review. These audio records will be randomly assessed and scored by a fidelity checklist that examines session content (e.g., are the main content areas covered?) and study staff and interventionist competence (e.g., greets patient, listens, shows positive regard). Fifth, we will monitor the proportion of study participants that complete each portion of the study (e.g., OT intervention, RN intervention, handyworker home repairs and modifications). Lastly, we will routinely monitor whether the after/between visit actions (e.g., communication with handyworker, completion of indicated referrals) are performed.

6 STUDY PROCEDURES

6.1 Schedule of Evaluations

Study Activities	Initial Screening (Day-28 to Day-1) All Participants	Baseline Enrollment, Assessment, and Randomization Visit (Day 0) All Participants	Intervention Arm: OT and RN Visits (≤ 11 total visits within 5 months)) AND CHHA CAU Services* (variable intensity and timeframe)	Comparator Arm: ONLY CHHA CAU Services* (variable intensity and timeframe)	2nd Assessment Visit (Day 90) All Participants	Final Assessment Visit (Day 180) All Participants
Inclusion/Exclusion Criteria	X	X	X	X		
Informed Consent (Written)		X	X	X		
Determination of Capacity for Informed Consent		X	X	X	X	X
Enrollment/Randomization		X	X	X		
Study Intervention						
Study OT Visits (≤6 Visits, Occur at 1-4 Week Intervals)			X			
Study RN Visits (≤5 Visits, Occur at 1-4 Week Intervals)			X			
Study Handyworker Visits (≤2 Visits, Occur at ~2 Week Intervals)			X			
Study Assessments						
Sociodemographics		X	X		X	
Health and Functioning		X			X	X
Mental Health and Cognitive Functioning		X			X	X
Home Environment		X			X	X
Medical and Non-Medical Services Use (Self-Reported)		X			X	X
Study Partner Questions (If Applicable)		X			X	X

Chart Extraction (e.g., Conditions, Medications, Medical Services Use, Communications)		X			X	X
Study Fidelity Measures (e.g., Participant Engagement)			X		X	X
Intervention Feedback					X	X
Adverse Events		X	X		X	X

*Both treatment groups receive CHHA CAU services (intervention arm receives *CAPABLE Transitions* and CHHA CAU; comparator arm only receives CHHA CAU). CHHA CAU services can include nursing, home health aide, medical social work, and occupational, physical, and speech therapy services. CHHA clinicians will determine the types and duration of services that CHHA clients in this group receive, which will be completely independent of the research study. The duration of CHHA can vary dramatically across CHHA clients (e.g., range from a single visit to having weekly visits for more than a year).

Table 3. Operationalization of the primary and secondary outcomes and study covariates.

Variable	Variable Type	Assessment Schedule	Data Source
Primary Outcomes			
• Participants Screened, Enrolled, and Retained	Continuous, Proportion	Monthly	Study Documentation
• Intervention Fidelity: Adherence, Dose, Quality	Continuous, Proportion	Varies	Audio Recording, Study Documentation, Self-Report
• Intervention Perceived Benefit (based on Szanton et al., 2019[40])	Likert Items, Open-Ended	3, 6 Months	Self-Report, Proxy-Report
• Data Completeness for Clinical Outcomes	Proportion	6 Months	Study Documentation
Secondary Outcomes (Primary Clinical Outcomes)			
• Home Time	Continuous	3, 6 Months	Chart Extraction, Self-Report
• Quality of Life (EQ-5D-5L, ICECAP-O[66, 67])	Variety of Variable Types	Baseline, 3 and 6 months	Self-Report
• Service Utilization: ED, Hospital, Nursing Home Use	Continuous	Baseline, 3 and 6 months	Chart Extraction, Self-Report
Sociodemographics			
• Contact Information	Address, Phone Number	Baseline, 3 and 6 Months	Self-Report
• Age, Date of Birth	Continuous, Date	Baseline	Self-Report
• Race, Ethnicity, Sex	Categorical	Baseline	Self-Report
• Formal Education, Marital Status, Living Arrangement, Income, Home Ownership and Type	Categorical	Baseline	Self-Report
• Caregiver or Receive Caregiving	Categorical	Baseline, 3 and 6 Months	Self-Report
• Children and Siblings	Continuous	Baseline	Self-Report
• Health Insurance	Categorical	Baseline	Self-Report
Health and Functioning			
• Social Needs Questionnaire[23]	Continuous	Baseline, 3 and 6 Months	Self-Report
• Self-Rated Health Status (Adapted from JHU)	Likert Items	Baseline, 3 and 6 Months	Self-Report
• Main Medical Problem, Concerns, and Goals	Open-Ended	Baseline, 6 Months	Self-Report
• Medication Adherence Measure (DOSE-Non-Adherence)[68-71]	Continuous	Baseline, 3 and 6 Months	Self-Report
• ADL (Adapted from JHU)	Continuous	Baseline, 3 and 6 Months	Self-Report
• IADL (Adapted from JHU)	Continuous	Baseline, 3 and 6 Months	Self-Report
• PROMIS* – Isolation v2.0, Mobility v2.0, Pain Interference v1.1, Ability to Participate v2.0[72]	Continuous	Baseline, 3 and 6 Months	Self-Report
• Self-Reported Falls (based on CDC's Behavioral Risk Factor Surveillance System)[73]	Variety of Variable Types	Baseline, 3 and 6 months	Self-Report
• Intervention Perceived Benefit (based on Szanton et al., 2019[40])	Likert Items, Open-Ended	3, 6 Months	Self-Report
• COVID-19 Effect Scale (modified from Impact of Event Scale-6[77]).	Likert Items, Open-Ended	Baseline, 3 and 6 Months	Self-Report
Mental Health and Cognitive Functioning			

• MMSE[44, 45,86]	Continuous	Baseline	Self-Report
• PROMIS* – Anxiety v1.0, Depression v1.0, Social Isolation v2.0, Medication Management Self-Efficacy v1.0	Continuous	Baseline, 3 and 6 Months	Self-Report
Home Environment			
• Aging Gracefully Home Safety Checklist	Variety of Variable Types	Baseline, 3 and 6 Months	Interviewer Scored
• Falling Efficacy (FES-I)[74]	Continuous	Baseline, 3 and 6 Months	Self-Report
Medical and Non-Medical Services Use (Self-Reported)			
• Non-Medical Human Services Use[75]	Continuous	Baseline, 3 and 6 Months	Self-Report
• Outpatient Medical Appointments	Variety of Variable Types	Baseline, 3 and 6 Months	Self-Report
Study Partner Questions			
• Contact Information, age, sex, race/ethnicity, relationship with participant	Variety of Variable Types	Baseline, 3 and 6 Months	Proxy-Report
• Caregiver Support (Adapted from NHATS NSOC Study)[76]	Categorical, Continuous	Baseline, 3 and 6 Months	Proxy-Report
• Quality of Life (EQ-5D-5L, ICECAP-O[66, 67])	Variety of Variable Types	Baseline, 3 and 6 months	Proxy-Report
• Main Medical Problem, Concerns, and Goals	Open-Ended	Baseline, 6 Months	Proxy-Report
• ADL[40, 77, 78] Modified for Proxy Report	Continuous	Baseline, 3 and 6 Months	Proxy-Report
• IADL[40, 79]Modified for Proxy Report	Continuous	Baseline, 3 and 6 Months	Proxy-Report
• Self-Reported Falls (based on CDC's Behavioral Risk Factor Surveillance System)[73]	Variety of Variable Types	Baseline, 3 and 6 months	Proxy-Report
• Intervention Perceived Benefit (based on Szanton et al., 2019[40])	Likert Items, Open-Ended	3, 6 Months	Proxy-Report
• Modified Caregiver Strain Index[84]	Categorical	Baseline, 3 and 6 Months	Proxy-Report
• Caregiver Confidence in Medical Sign/Symptom Management[85]	Likert Items	Baseline, 3 and 6 Months	Proxy-Report
Chart Extraction			
• Number of Medical Conditions	Counts	Baseline	Chart Extraction
• Number of Medications	Counts	Baseline, 3 and 6 Months	Chart Extraction
• PCP Visits	Counts, Dates	6 Months	Chart Extraction
• Non-PCP Medical Visits	Counts, Dates	6 Months	Chart Extraction
• Participant Communication with Medical Providers	Counts, Dates, Short Narrative	6 Months	Chart Extraction
• Health Insurance Status	Open-ended	Baseline and 6 Months	Chart Extraction
Study Fidelity Measures			
• Participant and Study Partner Engagement (Adapted from Kortte et al., 2007[80])	Likert	Intervention Session, Intervention Termination	Audio Recording, Interventionist-Report
• Main Medical Problem, Concerns, and Goals	Open-ended	Intervention Session, Intervention Termination	Interventionist-Report
• Differentiation	Binary, Open-Ended	Monthly, 3 and 6 Months	Audio Recording, Self-Report

*Computerized Adaptive Testing Survey Type.

6.2 Description of Evaluations

6.2.1 Initial Screening

The initial screening will be conducted by the study RN and OT who also function as CHHA clinicians. The RN and OT will regularly screen all of their CHHA intakes to identify potential study participants (e.g., discharged from a post-acute care facility, does not have a terminal condition). The RN and study OT will ask clients passing the initial screen if they are interested in participating in our research study. For residents indicating an interest to participate in the research study, screening and study enrollment must be completed in 28 or fewer days since hospital or post-acute care facility discharge as the timing of the *CAPABLE Transitions* is an important aspect of the intervention. We will exclude CHHA clients for whom we are unable to screen and enroll in the study within this 28-day period. In addition to the URMHC interventionists recruiting participants among their new admissions, we will contact potentially eligible URMHC clients who have indicated that they are interested in participating in research when they complete the new consent process via URMHC. This new consent process is for ALL URMHC patients admitted to URMHC services in which they can "opt in" or "opt out" of being contacted by a UR researcher if there is a study they qualify for. Only participants who have consented to be contacted will be contacted by the CRC.

Study staff will regularly work with the RN and OT to review the study inclusion and exclusion criteria to consider whether any new admissions scheduled for CHHA services may qualify for the study. Unless the potentially eligible CHHA client expresses interest in participating in the study, CHHA clinicians will not share identifiable information with study staff. The RN, OT, and research coordinator will examine the following criteria:

- admitted to CHHA following a hospital or post-acute care facility discharge
- live in the Rochester, NY region
- age 65 years and older
- English-speaking
- has a terminal diagnosis or receiving active cancer treatment
- able and willing to participate in a research study

6.2.2 Baseline Assessment, Enrollment, and Randomization Visit

This evaluation must occur in 28 or fewer days of hospital or post-acute care facility discharge and will make the final determination as to whether the CCHA client is eligible for the study.

<u>Consenting Procedure</u>

Study staff will introduce the study and obtain written informed consent from the CHHA client (or from a surrogate decision maker if CHHA client is unable to provide informed consent but assents to the study). Written informed consent will occur prior to conducting the cognitive test (MMSE), which will determine if moderate or severe cognitive impairment is present.[44, 45] Following recommendations[86], we will modify the MMSE orientation questions to reflect our administration in community-dwelling older adults, rather than clinical or hospital settings. Study enrollment is stratified by cognitive impairment status, and we will prioritize recruitment of people with dementia

over those without. Additionally, if moderate or severe cognitive impairment is present, study staff will only finalize enrollment of a CHHA client into the study if they are able to provide informed consent or provide assent with the presence of a LAR. If a potential participant is unable to provide informed consent and does not have a LAR available for informed consent, study staff will terminate the interview prior to collecting any additional research information and compensate the participant $10 for completing the screening procedures

Study participants and Study Partners will sign two copies of the consent form documents. They will keep one signed copy and the study staff will keep the other signed copy. For the study staff copies of the consent form, we will upload the signed consent forms and associated documents into an electronic database (UR Box) for maintenance and long-term storage of the consent forms. We will also retain paper copies of the consent documents and all other paper source documents in the study files. No study documents will be destroyed during the RSRB required period for retention of records, though we may additionally scan and upload materials into a secure UR Box folder only accessible to study personnel, for backup purposes. Only after completing the consent process and obtaining written informed consent, will study staff commence with the screening process and baseline assessment interview.

Enrollment

CHHA clients who satisfy our inclusion and exclusion eligibility criteria will be considered enrolled in the study after they (or a surrogate decision-maker) have signed the informed consent form.

Baseline Assessments

For participants who have been successfully screened for eligibility and are enrolled into the study, baseline assessments are performed against which to measure the study's intermediate and primary outcomes as well as to account for pertinent covariate data. The baseline assessment will examine the following domains (see Section 6.1 for detailed description of measurements):

- Sociodemographics
- Health and Functioning
- Mental Health and Cognitive Functioning
- Home Environment
- Medical Services Use (Self-Reported)
- Study Partner Questions (If Applicable)
- Chart Extraction regardless of PCP affiliation (e.g., Medical Conditions, Medications, and Medical Services Use, Communication)

Randomization

Immediately following termination of the baseline assessment interview, study staff will randomly assign participants via a stratified random permuted block method.[1] Randomization will be stratified based on cognitive impairment status (moderate/severe cognitive impairment present: MMSE score $\leq$ 20; moderate/severe cognitive impairment absent: MMSE $\geq$ 21).[44, 45,86] Block randomization will then occur

within each strata to ensure appropriate allocation to the treatment and CAU groupings. REDCap[56] will track the randomization groupings. The study intervention will commence as soon as possible following randomization.

Compensation

Of note, in addition to receiving compensation for their time participating in the research assessment interviews, participant compensation may include additional cash payments to cover the expense of home repairs and modifications that are recommended and agreed upon by our study interventionists and performed by Catholic Family Center's HomeWorks contractors (up to a maximum of $500 per participant).

6.2.3 Intervention Visits (≤11 total visits)

The intervention will proceed as outlined in the *CAPABLE Transitions'* protocol. In addition to delivering the intervention, the study OT and RN will assess the engagement of the study participant or dyad with the intervention. The study OT and RN also will monitor for the presence of study-related adverse events at each visit.

6.2.4 Follow-Up and Final Assessment Visit

Including the baseline assessment visit (on day 0), study staff will conduct the follow-up and final assessment visits at approximately 90 days (+/- 15 days) and 180 days (+/- 30 days), respectively. Of note, many participants likely still will be receiving the intervention at the 90 day assessment. At the 180 day assessment, however, no participants will be receiving the intervention. These assessment visits will examine the same domains that the baseline assessment examines, but also will include questions to obtain information on intervention feedback. The follow-up assessments will examine the following domains:

- Sociodemographics
- Health and Functioning
- Mental Health and Cognitive Functioning
- Home Environment
- Medical Services Use (Self-Reported)
- Study Partner Questions (If Applicable)
- Chart Extraction regardless of PCP affiliation (e.g., Medical Conditions, Medications, and Medical Services Use, Communication)
- Study Fidelity
- Intervention Feedback (intervention arm only)

The CRC or research assistant also will perform the determination of capacity for informed consent at these 3- and 6-month intervals to screen for whether participants who initially demonstrated capacity for informed consent may have lost the ability to provide informed consent. If they are unable to demonstrate capacity for informed consent, we will go through the entire consent process again, and those unable to demonstrate informed consent only will be able to continue with study participation if they have a legally authorized representative (LAR; see Section 7.3.1 for definition of LAR) who also will need to demonstrate capacity to provide informed consent prior to signing the informed consent document. If the older adult is unable to provide informed

consent and does not have a LAR able to provide informed consent, they will not be able to continue with the study and the in-person assessments and interventions sessions will cease.

Additionally, for participants who discontinue the study intervention, unless the participants refuse to participate in the study assessments, the CRC or research assistant will continue to conduct assessments per the assessment schedule. Assessment for adverse events will terminate when in-home assessment visits are concluded at approximately 180 days following hospital or post-acute care facility discharge, which also marks the period for when participation in the study terminates. Of note, this last assessment visit will occur after the OT and RN intervention sessions have been completed (for many participants, the last assessment visit will occur approximately 2 months following the termination of the intervention). Possible reasons for early termination of the study intervention include participants are no longer willing to participate in the intervention or that participants have moved, transitioned to a nursing home for long-term care, or died (see Section 8 below for a detailed list of intervention discontinuation procedures).

7 RISK/BENEFIT ASSESSMENT

7.1 Risk Category/Potential Risk

Minimal risks to study participants are expected. For the assessment interviews, the primary risk is invasion of privacy, breach of confidentiality (if safety issues such as elder abuse are detected), or mild reactions of distress or fatigue. Given that assessments are conducted in the participant's homes, others could be present, which risks revealing the participant's involvement in the study. Participants will have full discretion in having others present. Assessment measures and procedures have been safely used in previous research with older adults; no sustained negative effects from assessments are expected, but negative outcomes cannot be ruled out.

Similarly, with regard to the intervention sessions, some participants may experience some discomfort, or fatigue in having study staff in their homes for the intervention sessions. Additionally, as the intervention sessions may include exercises to enhance function and reduce the risk of falls, some patients may be physically fatigued at the end of these sessions (in particular, the OT sessions can include physical activities such as simplifying tasks and the environment, using assistive devices, and balance and fall recovery techniques to decrease fear of falling). The original *CAPABLE* was well received and tolerated by older adult participants, however, who uniformly reported that the intervention benefited them.[81, 82] Additionally, as *CAPABLE Transitions* likewise aims to improve home safety by reducing the presence of environmental hazards (home hazards is an intermediate outcome), we expect that those participating in our intervention will be at less risk of experiencing adverse events such as falls.

If a participant's cognition declines such that she is unable to work towards her study goals, our interventionists will work with the participant to identify new goals to work on. If the capability of a participant changes (for worse or better) such that there are no further identified feasible goals to work on, we will end the intervention. Our intervention is multifaceted (e.g., handyworker, OT, and RN), meaning that only those components for which there are no clear objectives or workable goals may terminate. This also could occur if a participant achieves their goals quickly, thereby only requiring a few of the interventionist sessions rather than all of the possible sessions.

We will train both the study interviewers and interventionists to handle these minimal discomforts if they occur (e.g., if a participant is becoming fatigued, can change activities or terminate the session) and will conduct assessments regarding intervention safety at every in-home visit. During these assessments, study staff will regularly query for the occurrence of adverse events. Although we do not anticipate there to be any serious adverse events related to our intervention, staff will systematically monitor for these events during the intervention and follow-up periods and report them should they occur (consistent with RSRB policy 801, "Reporting Research Events").

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

At each intervention session, study staff will inquire about the occurrence of adverse events and significant adverse events since the last visit (timing of intervention sessions shown in Table 2). This schedule of assessments is such that, as the intensity of the intervention is the greatest, so will we monitor for the occurrence of adverse events most intensely, which will help us identify the presence of any study-related adverse events.

7.3 Protection Against Risks

This section provides information on how risks to participants in the study will be mediated and specifies events that would preclude a participant from continuing with the intervention. This section also includes the informed consent procedures and measures to protect participants against risk during the study.

7.3.1 Informed Consent Process

This section explains the informed consent process and how it is used to protect participants.

- The consent process informs a volunteer about the study, indicates the participation is voluntary, and states that the volunteer has the right to stop at any time. Risks are delineated in the informed consent form and described orally during the consent process.
- Individuals will provide written informed consent prior to the start of the in-person screening activities or the baseline interview. Consent forms only will be used if they have a current IRB approval stamp. The informed consent process will be conducted in a manner to facilitate questions from potential study subjects. If a study team member is unable to answer a question, an investigator will be contacted. All questions from potential subjects will be answered prior to obtaining a signature. The PI, a Co-I, or an IRB-approved consent designee must be present when a subject signs the informed consent form. That member of the study team must sign the informed consent form at the same time and in the presence of the subject. The consent form must be signed and dated by the subject and the consent designee. No subjects will be involved in research activities unless an investigator or a designated study staff has obtained documentation of legally effective informed consent of the subject. The collection of protected health information and questionnaires are considered to be research activities requiring prior documentation of informed consent.
- The study RN will regularly screen all of her CHHA intakes to identify potential study participants (e.g., discharged from a post-acute care facility, does not have a terminal condition). The study RN will ask clients passing the initial screen if they are interested in participating in our research study. For residents indicating an

interest to participate in the research study and agree to have a study staff member visit them to provide more information, the study RN and CRC will work together to schedule an in-person screening visit that is convenient to the potential participant. Consent only will be sought under circumstances that provide the prospective subject sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or representative shall be in language understandable to the subject. Potential study subjects will be given ample time to read and consider the consent form. All subjects will be reminded of the voluntary nature of study participation. Using the consent form to structure discussion, research personnel will explain the study, its potential benefits and risks, and alternatives, and document the consent process by signature of the subject and the person obtaining consent. During informed consent procedures, individuals will be told about possible risks and benefits of participation. This will include information that questions asked may cause them to feel uncomfortable or upset. Subjects will be informed that they may withdraw from an assessment at any time for any reason and receive full reimbursement for that assessment, and that they may withdraw from the research study at any time without negative consequences. Subjects are further informed that research staff will perform an immediate evaluation of their safety should safety concerns arise during assessments or intervention sessions. For non-acute medical or psychological concerns research staff identify, we will recommend that subjects follow-up with their primary care physicians. Research staff will assess the subject's capacity with an RSRB-approved Determination of Consent Capacity Form that has been successfully implemented in other studies of older adults and consists of open-ended questions that will address the potential subject's knowledge and understanding of the study's objectives, general procedures, voluntary nature of participation (ability to withdraw), and possible risks and benefits of participation. For individuals who have difficulty in one or more of these areas, further review of the relevant elements of the study will be provided in order to improve their knowledge and understanding to a level that enables them to make a meaningful choice about participation. Those who demonstrate adequate capacity to consent will be invited to sign the informed consent form to enroll as a research subject. The consent will be an ongoing process during the study. Explanations of the study and verbal consent will be conducted at each data collection. Subjects will be reminded that their participation is voluntary and that they can withdraw at any time for any reasons.

- For potential subjects who lack the capacity to provide informed consent, study staff will only proceed with the research study if the potential subject assents to the study and a **legally authorized representative (LAR)** is willing to: 1) enroll the participant in the research study, 2) demonstrates capacity for consent, and 3) signs the consent form. A LAR is an individual authorized to consent on behalf of a prospective research participant. Of note, failure to object is not assent and resistance to a research procedure in a non-verbal subject is an indication of dissent for that procedure. Federal regulations (45 CFR 46.116 and 21 CFR 50.20) defer to state law for persons authorized to provide such consent. Consistent with RSRB policy and congruent with New York State Public Health Law, Article 29-C and Article 29-CC (Family Health Care Decision Act), the persons listed below in order of authority, may act as a LAR to give consent to research participation for persons with decisional impairment. If a person listed is not reasonably available, or is unwilling or incompetent to make a decision regarding research participation

on behalf of the subject, the authority falls to the person of next highest priority.

1. A health care agent properly designated on a health care proxy form;
2. A court-appointed guardian under the New York Mental Hygiene Law Article 81;
3. A research proxy (individual designated by the research subject, while retaining the decisional capacity to do so), to make decisions for her/him regarding participation in research;
4. A family member or friend (in the priority listed below) pursuant to the New York State Family Health Care Decisions Act (Public Health Law Article 29-CC):
    a. A spouse or domestic partner;
    b. An adult son or daughter;
    c. A parent;
    d. An adult brother or sister; or
    e. A close friend, who is an adult (18 years or older) and has a close personal relationship with the subject, provided that the individual 1) provides a signed written statement, in a format approved by the RSRB, to the PI that he/she is a close friend of the subject, 2) that he/she has maintained such regular contact with the patient as to be familiar with the patient's activities, health, religious or moral beliefs, and 3) stating the facts and circumstances that demonstrate such familiarity.

7.3.2 Protection Against Risks

This section describes measures to protect participants against study specific risks, as well as plans for notifying participants of trial results during and after the conclusion of the trial and providing the participants' health providers with the appropriate information from the trial, as needed, concerning individual participants. Study procedures, both assessments and interventions, pose minimal risk to participants. Below we describe potential risks and study procedures to protect against these risks.

The PI (Dr. Simning) will be responsible for prompt reporting of new information and other study-related safety information such as study-related or unexpected adverse events and protocol deviations that involve a safety issue to the RSRB, sponsor, federal agencies, and other required entities. Expected, non-study-related adverse events also will be tracked and reported on in the RSRB continuing reviews. The study will be modified to address safety issues or even put on hold if necessary. The PI will review the data periodically to identify any problems and potential risks.

- In order to protect the **confidentiality of subject information**, we will take a number of precautions. These include training research interviewers in confidentiality procedures; entry and storage of data using coded identification labels; maintenance of project computers in secure locations with restricted access by enforced password protection; and use of Health Insurance Portability and Accountability Act (HIPAA) compliant data management software (e.g., REDCap, Box). Back-ups of study files will be made daily to allow for recovery of data due to disk failure. All data, including assessment measures, will be obtained

with the written consent of the patient. Information pertaining to individual participants will be released with the patient's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the participant or others. All data will be identified by a uniquely coded study number assigned to each participant. Access to the master list of study numbers will be restricted to the PI and CRC. Confidentiality will be further maintained by the storage of "hard copy" data in locked files in a locked office. Access to computerized data is restricted and subject to review by the PI. Publications or presentations will report only cumulative data or descriptions certain to maintain participants' anonymity. All data collection involving human subjects will be HIPAA compliant. All data involving human subjects will be stripped of any identifiers; the data will be stored in secure programs called REDCAP and Box, which manage protected health information in a HIPAA compliant manner. Audio recordings will occur on encrypted devices, will be password protected, and will be destroyed in accordance with local and federal guidelines to protect the security and confidentiality of identifiable information.

- In order to protect subjects' **privacy**, audio recordings of intervention session only will be made with subjects' written consent; subjects will be free to refuse to answer any questions they would prefer to not answer; and interviews will be conducted in private settings.
- Risks associated with **emotional distress or fatigue** will be minimized by employment of research personnel and interventionists with appropriate backgrounds and work experience with older adult subjects. The baseline research interview will last approximately two hours in total. Given the length of time involved for this assessment, and concerns regarding subject health and well-being, subjects will be reminded that if they become fatigued, they may terminate the interview at any time, and that the interview can be conducted over multiple sessions as needed. Research personnel will be trained to recognize potential signs of fatigue among older adult subjects, and to actively suggest alternative data collection strategies (e.g., telephone-based and mail-in interviews), in order to reduce the possibility of overwhelming study subjects and to ensure completeness of data collection. These strategies have been employed effectively in the PI's past research involving older adult populations.
    - During the course of assessment interviews, research staff will monitor subjects' reactions for signs of distress or fatigue. If necessary, subjects may take breaks from the interview, or complete the interview over several sessions if fatigue becomes a concern.
    - If a subject's level of emotional distress becomes a concern, the research staff member will evaluate the subject's emotional state and safety and will briefly attempt to de-escalate the patient's distress. If these measures do not effectively reduce the subject's distress within 10-15 minutes and, depending on the severity of the subject's distress, research staff will call Dr. Simning (or the person covering for him), who will maintain a cell phone for this purpose.
    - The study subjects will consist of a population of functionally impaired older adults with a recent acute medical illness. Research staff therefore will be trained in the study's safety protocols for managing acute medical events (e.g., chest pain, loss of consciousness), suicide risk, and elder abuse. Subjects will be informed that study staff will perform an immediate evaluation of their safety

should concerns arise during assessments or treatment sessions. Subjects also will be informed that their confidentiality may be breached should concerns arise about their safety (e.g., if emergency medical services are needed). Finally, they will be informed that suspected child abuse will be reported, as mandated by law, as well suspected elder abuse. Any subject who endorses death or suicidal ideation will be asked additional questions to assess her/his safety. Any endorsements of active suicidal ideation will involve notifying Dr. Simning for review of risk and protective factors and consideration of emergency psychiatric services. Dr. Simning is a board-certified geriatric psychiatrist with expertise in suicide evaluation and management and regularly provides clinical care to older adults who are distressed and at risk for suicide. While it is expected (based on prior research) that only a small minority of subjects for the current study will report significant distress (and even fewer suicide ideation or elder abuse), research staff will be trained in the study's safety protocol and data from each assessment will be reviewed with Dr. Simning weekly, or more often if needed. A small minority of participants may experience elder abuse. In the case of suspected elder abuse, subjects will be given an immediate referral to appropriate community-based resources (e.g., Adult Protective Services, the Elder Abuse Prevention Program of Rochester), which provide crisis intervention services, and the primary care provider will be contacted via a letter and/or a phone call. Any suspected cases of elder abuse will be immediately reviewed with the PI before research staff sends the assessment. Situations involving potential imminent safety concerns may involve the use of emergency services and law enforcement authorities. A similar safety protocol has been used successfully in Dr. Simning's prior studies as well as other University of Rochester studies involving older adults.

- The study PI (Dr. Simning) will provide weekly (and as needed) supervision to research staff. In addition, Dr. Simning is a licensed geriatric psychiatrist and is experienced in working with older adults, including those experiencing emotional distress and will available as needed.

- To ensure appropriate safety precautions when conducting in-person study procedures, the process for conducting in-person visits outlined in the Guidance for Human Subject Research will be followed to mitigate risk for COVID-19. When/if a participant or a caregiver develops COVID or there is a suspicion of COVID, we will reschedule/postpone visits accordingly.

8 INTERVENTION AND STUDY DISCONTINUATION

There are several ways this intervention and/or study can terminate for study participants:

1) Intervention discontinuation by the study participant: Study participants may withdraw voluntarily from participation in the study at any time and for any reason. If the participant withdraws from participating in the intervention, with the permission of the participant, we will continue with the follow-up assessment interviews (at three and six months) to monitor their response to the intervention via intention-to-treat principles and to help capture study-related AE and SAEs. If a participant were to experience an AE, we also would ask their permission to follow them until the AE has resolved (even if this extends past the study period). Of note, there are two subgroups within this category. The first subgroup consists of those who are satisfied with the intervention (e.g., perceive that they have benefited from the intervention), but no longer want to receive it (e.g., they want a smaller "dose" of

the intervention). The second subgroup consists of those who elect to discontinue to the intervention because they are not satisfied with the intervention (e.g., do not perceive that they have benefited from the intervention), and therefore no longer want to receive it.

2) Study withdrawal by the study participant: Study participants may withdraw voluntarily from participation in the study at any time and for any reason. This category will be for participants who decide to withdraw participation from any additional study activities including the intervention and study assessments.

3) Intervention discontinuation by the study team: We will discontinue the intervention in the situations outlined below. Of note, if the participant is agreeable and able, we will continue to conduct the study assessments after the intervention is discontinued.

- Death (many of the participants will have severe, chronic medical comorbidities and we anticipate that some may die during the course of the study)
- Changing residences (including transitioning to nursing home long-term care)
- Prolonged hospitalization that substantially interferes with the delivery of the intervention (i.e., 14+ days in first month of intervention, 21+ days following the first month)

We will not replace participants who withdraw from the study.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

This study is a randomized, CAU-comparator, unblinded, 60-subject clinical trial of an OT-led in-home intervention designed to help older adults successfully transition to their homes following a hospital or post-acute care facility discharge. This research project is designed to be an iterative pilot study whose primary objective is to examine the feasibility of the *CAPABLE Transitions* intervention and the assessment of the study's intermediate and primary outcomes. Guided by research staff experiences, feedback from the study interventionists and participants, and our treatment fidelity data, we will continually seek to enhance and optimize the study protocol and procedures to improve recruitment. Such modifications could include adjustments to the intervention schedule or content or updates to our recruitment and retention process.

Given the focus on feasibility rather than hypothesis testing, this study is not blinded. This lack of blinding will enable the study CRC, research assistant, and/or PI to work closely with the study interventionists and treatment group participants to identify ways to enhance the study and its procedures.

Our analyses will largely consist of univariate statistics to examine the proportions and means and variance of the primary and secondary outcomes listed below and in Table 3.

Primary outcomes:

- screening, enrollment, and retention of study participants
- fidelity to and perceived benefit of the intervention
- data completeness with regard to our intermediate and primary outcomes

Secondary outcomes (at three and six months following hospital or post-acute care facility discharge):

- home time
- quality of life
- health care utilization

9.2 Sample Size and Randomization

The total sample size of 60 is consistent with a prior pilot study of the original *CAPABLE* intervention, which had 40 participants.[81] This sample size is not powered to test hypotheses or to compare differences across the care-as-usual and treatment groups.

9.2.1 Treatment Assignment Procedures

Study staff will randomly assign participants via a stratified random permuted block method.[1] Randomization will be stratified based on cognitive impairment status (moderate/severe cognitive impairment present: MMSE score $\leq$ 20; moderate/severe cognitive impairment absent: MMSE $\geq$ 21).[44, 45,86] We will conduct block randomization to ensure that there is appropriate allocation to the treatment and CAU groups across moderate/severe cognitive impairment strata. REDCap[56] will track the randomization groupings. In total, 60 participants will enroll in this study. We will prioritize the recruitment of people with dementia over those without, but aim to increase our recruitment of non-cognitively impaired patients as well. Because the goal of this pilot study is to focus on feasibility, the bias that may be introduced by having unblinded research staff is of minimal concern at this stage.

9.3 Interim analyses and Stopping Rules

As the primary objective is to examine *CAPABLE Transitions'* feasibility rather than clinical effect, we are not planning to conduct interim analyses with associated stopping rules.

9.4 Outcomes

9.4.1 Primary Outcomes

The primary study outcomes consist of the feasibility measures listed below.

1) Screening, enrollment, and retention of study participants: We will conduct univariate analyses to evaluate how many CHHA participants we screened, how many enrolled, and how many successfully finished the study.
2) Fidelity to and perceived benefit of the intervention (at three and six months):
    a. To assess fidelity to the intervention, study staff will examine audio recordings of the intervention sessions and in-between session procedures (e.g., handyworker work order completed) and score whether the OT/RN completed the critical components associated with the intervention session. We will score completion of the critical components as "yes" or "no" and will then conduct univariate analyses to examine OT/RN adherence to the study protocol for the intervention sessions.
    b. To evaluate perceived benefit of the intervention, study staff will conduct interviews at three and six months to obtain survey responses to Likert item scales on *CAPABLE Transitions* perceived benefit and burdensomeness to study participants. We will analyze these Likert item responses with univariate statistics. For narrative feedback, we will examine individual participant quotes and reported concerns for which we will not conduct

statistical analyses.

3) Data completeness with regard to our primary and intermediate outcomes at three and six months: We will use univariate statistics to examine the proportion of the CAU and intervention group participants who have information on our primary (i.e., home time, quality of life, health care utilization) and intermediate (e.g., timing and frequency of medical appointments, frequency of communication with medical providers, medication adherence, anxiety and depressive symptoms, physical functioning, home hazards, fear of falling, mobility, self-efficacy, pain) outcomes.

9.4.2 Secondary Outcomes

This study's secondary objectives are to obtain preliminary data on home time, quality of life, and health care utilization at three and six months following hospital or post-acute care facility discharge. Univariate analyses will provide the means and standard deviations for these outcomes.

9.5 Data Analyses

Data analyses will consist of univariate analytic approaches. For this pilot study, we have no plans to perform across groups comparisons or to test hypotheses. Although our sample size is too small to facilitate across group comparisons or hypotheses testing, the 24 CHHA CAU participants will provide precision and variance estimates for our primary clinical outcomes among the comparator group, which subsequently will be used to inform sample size calculations for the large-scale clinical trial to follow.[83]

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

Study staff (e.g., CRC, research assistant) will collect and obtain study data directly from the participants (via in-person interviews) as well as from the participant's medical records. The collection, transfer and storage of data will be conducted in compliance with HIPAA and structured to minimize risk of protected health information disclosure. All records related to a participant's research will be stored in locked filing cabinets or on computers protected with passwords. Furthermore, study staff will record data directly into data collection forms that are present in REDCap and all web-based information transmission is encrypted. We also will rely on UR Box to store electronic information, which is HIPAA compliant. The database servers are housed in secure institutional data center facilities at University of Rochester. Additionally, audio recordings of intervention sessions will monitor fidelity and assist with quality control review. These audio recordings will be labeled using de-identified numbers only and will be stored on secure University of Rochester servers and/or the CRC and PI's computers. We will also use an encrypted voice recorder to protect participants' protected health information. Access to these audio recordings will be password protected and audio recordings will be in accordance with local and federal guidelines. The protocol includes a list of the study survey measures (Table 3). During the RN and OT intervention sessions, the RN and OT may decide to skip certain questions/items to focus on issues that are most relevant to each participant. Consequently, study interventionists can, at their discretion, skip or not complete questions in these assessments that they feel are less relevant to the participants they are working with for the study intervention visits. For fields/questions we believe are critical to the study, we will make sure that they require a response in REDCap and cannot be skipped, such as Adverse Event assessments.

10.2 Quality Assurance

10.3.1 Training

To ensure appropriate human research knowledge, all study personnel with access to subject research data will have completed mandatory training in the protection of human research participants per guidelines issued by the U.S. Department of Health and Human Services, Office for Human Research Protections (https://www.hhs.gov/ohrp/) and per guidelines of University of Rochester Medical Center (URMC). Any additional personnel will complete this training before having access to the study databases. Consistent with University of Rochester Medical Center RSRB policy, all investigators and research staff will complete certification by the RSRB, which requires completion of a course that contains topics such as “History and Ethical Principles,” “Privacy and Confidentiality,” “Informed Consent,” and “The Federal Regulations.” This course provides a substantial resource to the investigators for understanding the ethics and regulations governing research with human subjects. Research staff also will be trained to assess, de-escalate, and activate appropriate levels of care for those experiencing emotional distress

10.3.2 Quality Control Committee

Not applicable.

10.3.3 Metrics

Audiotaping of intervention sessions will be routinely conducted for fidelity and quality control review. OT/RN adherence to the intervention also will be quantified. Additionally, the PI and *CRC* will regularly monitor the database to ensure that data are appropriately recorded and complete.

10.3.4 Protocol Deviations

Study staff must not deviate from the protocol, except to protect the life and physical well-being of a participant in an emergency. All deviations from the protocol, with the reason for the deviation and the date of occurrence, will be documented using the Protocol Deviation Tracking Log Form. Protocol deviations will be reviewed and evaluated on an ongoing basis and, as necessary, appropriate corrective and preventive actions will be instituted.

10.3.5 Monitoring

The principal investigator will be responsible for monitoring the study. Routine monitoring will occur to verify that:

- participant enrollment is being achieved
- the inclusion/exclusion criteria has been met at enrollment
- the correct version of the informed consent has been signed by the subject
- AEs and SAEs have been captured and properly reported
- verify that the data are accurate and complete

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

The University of Rochester Medical Center's RSRB will review and approve this study's protocol and its informed consent document and any subsequent modifications.

11.2 Informed Consent Forms

We will obtain signed consent forms from each participant. As many of our participants may have cognitive impairment that could affect their ability to provide informed consent, we will systematically evaluate their capacity for informed consent. To do so, the CRC or research assistant will read the consent form to participants, who will be encouraged to ask questions throughout the process. To determine capacity for informed consent, at the conclusion of the consent process and prior to signing the consent form, study staff will ask all participants the following questions:

- Could you please tell me what this study is about?
- What are the potential risks to you of participating in this study?
- What are the benefits for participating in this study?
- Do you understand that your participation in this study is voluntary and that you may stop at any time or not answer any questions that you feel uncomfortable answering?
- Do you have any questions about the interview?

If in answering these questions the participant is unable to demonstrate an understanding or appreciation of the issues, research staff and the participant will further review the consent form and repeat the pertinent questions. Participants who achieve a demonstrated understanding of the study will be determined to have capacity to provide informed consent. For those who do not, research staff will attempt to identify a legally authorized representative (LAR; see Section 7.3.1 for definition of LAR) who also will need to demonstrate capacity to provide informed consent prior to signing the informed consent document. If the older adult is unable to provide informed consent and does not have a LAR able to provide informed consent, we will thank them for their time with $10 for completing the screening and procedures and inform them that they are not eligible for the study. Participants' answers are tracked on a Determination of Consent Capacity Form that is kept with the research record as documentation of the consent process. For participants/LARs unable to provide informed consent, however, we will document the reason for study ineligibility on the Determination of Consent Capacity Forms. On these forms, we will not include any personal identifiers, but rather will use a screening ID number to track completion of these forms for participants and, if applicable, LARs. For participants and LARs unable to provide informed consent and who are not enrolled in the study, the screening ID number will not be linked to any personal identifiers. For enrolled participants who thereby demonstrate and provide informed consent or who have an LAR that provides informed consent, however, we will link these screening ID numbers with an assigned study-specific ID number that can be linked to identifiers we are collecting for the study. We will not keep any identifiable information for older adults/LARs who do not or are unable to sign consent to participate in our study. Rather, we will only keep basic demographic information such as age, sex, and race and ethnicity to allow us to track those who do and do not participate in our study; those older than 89 will be grouped in a 90+ age category.

11.3 Participant Confidentiality

All participant data, including assessment measures, will be obtained with the written consent of the participant or surrogate decision-maker. All data collection will be HIPAA compliant, and a uniquely coded study number assigned to each participant will identify participant data (i.e., a participant ID number). To protect the confidentiality of participant information, we will take a number of precautions:

- use research personnel trained in confidentiality procedures
- enter and store data on highly secure servers
- maintain project computers in secure locations (e.g., locked offices)
- restrict access to study data to study personnel on a needed to know basis that is enforced with password protection
- minimal reliance on paper documents
- publications or presentations will report only cumulative data or descriptions certain to maintain participants' anonymity

In particular, we will rely on URMC's REDCap servers housed in a local data center at the University of Rochester (all web-based information transmission is encrypted). REDCap was developed in a manner consistent with HIPAA security requirements and is recommended to University of Rochester researchers by the URMC Research Privacy Officer and Office for Human Subject Protection. Access to computerized data is restricted and subject to review by the PI. In accordance with local and federal guidelines, we will keep study data for a minimum of three years following submissions of the final reports to NIA.

Furthermore, information pertaining to individual participants will be released with the participant's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the participant or others. If necessary, information also may be released without written permission of the participant for monitoring by the RSRB, NIA, OHRP, or other governmental agency.

11.4 Study Discontinuation

The study may be discontinued at any time by the RSRB, the NIA, the Office for Human Research Protections, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

This research study will be conducted only after receiving approval from University of Rochester Medical Center's Research Subjects Review Board. Human research at University of Rochester is grounded in foundational ethical principles. These guiding ethical principles are embodied in the Nuremberg Code of 1947, the Declaration of Helsinki of 1964 and its subsequent revisions (World Medical Association), and particularly in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The Belmont Report principles of respect for persons, beneficence and justice are accepted as critical for the ethical conduct of human subject research. Additionally, this study will adhere to the principles of NIH's Good Clinical Practice designed to help assure the safety, integrity, and quality of

clinical trials and address elements related to the design, conduct, and reporting of clinical trials.

13 COMMITTEES

Given that *CAPABLE Transitions* is a minimal risk study, a data and safety monitoring board is not warranted. Instead, this study will have a research mentorship committee that will provide broad oversight of the study. This committee will include mentors on the K23 award and will have broad oversight on all aspects of the study and will provide expert feedback as needed should the study experience difficulties in its operationalization and implementation.

14 PUBLICATION OF RESEARCH FINDINGS

Although this pilot study is neither designed nor powered to test a hypothesis, we nonetheless plan to publish and/or present on the intervention's protocol, development, and preliminary findings.

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