OFFICIAL TITLE OF STUDY:

Statewide Implementation of CAPABLE-Community Aging in Place, Advancing Better Living for Elders in the Michigan Medicaid Home and Community Based Waiver Program

NCT NUMBER: NCT03634033
Registered August 16, 2018

DOCUMENT DATE: JUNE 2, 2021

STUDY PROTOCOL

Administrative Supplement to **NIA 1 R15 AG058193-01A1S1**

Protocol Title: Statewide Implementation of CAPABLE-Community Aging in Place, Advancing Better Living for Elders in the Michigan Medicaid Home and Community Based Waiver Program

Administrative Supplement:
Funding Period: 8/1/2020 to 7/31/2021 (1-year)
IRB Determination #: 20-213-H

Parent Trial:
Funding Period: 9/1/2018 to 8/30/2021 (3-years)
IRB Determinations: GVSU 19-061; MDHHS 201811-08-EA; MSU Study00002391

ClinitalTrials.gov ID: NCT03634033 Registered August 16, 2018

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The Administrative Supplement is to the Parent Trial that is a pragmatic Dissemination & Implementation study, designed to implement and improve care delivery and beneficiary outcomes within a “real-world” complex multi-component Medicaid setting across the State of Michigan (MI).

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1.1 DEFINITIONS OF TERMS USED IN STUDY

Term	Acronym	Definition
Alzheimer's Disease	AD	Those with Alzheimer's Disease
Activities of daily living	ADL	Activities such as bathing, walking, transfers performed to carry out daily living.
Beneficiary		A person who is a Medicaid recipient of care and services in the waiver.
Caregiver		A person who is the designated caregiver of the beneficiary of care in the waiver.
Clinician		A waiver employee who is an RN, SW, or OT that provides care to beneficiaries.
Community Aging in Place, Advancing Better Living for Elders	CAPABLE	Evidence-based intervention implemented in the Home and Community Based Services program in Michigan.
External facilitator	EF	A supervisor at a waiver site in MI who was an early adopter of CAPABLE and will guide the work of IFs.
Internal facilitator	IF	A supervisor at a waiver site in MI who was trained and facilitates CAPABLE implementation, and oversee clinician training and performance of CAPABLE.
Instrumental activities of daily living	IADL	Activities such as shopping, banking, and cleaning performed to carry out daily living.
Occupational Therapist	OT	Clinician who is licensed as an OT.
Registered Nurse	RN	Clinician who is licensed as an RN.
Social Worker	SW	Clinician who is licensed as an SW.

1.2 BACKGROUND AND SIGNIFICANCE

Parent Trial

There are 39 million Americans over age 65;[1-2] and 42% of older adults report problems with function, which can lead to difficulty with activities of daily living (activities of daily living [ADL], instrumental activities of daily living [IADLs]),[3] falls, and nursing home (NH) placement.[4] The prevalence of poor function is expected to increase due to the obesity epidemic[3] and surviving longer with chronic conditions.[5] Consequently, implementing evidence-based models focused on aging-in-place in older adults is a public health priority. One such evidence-based model is Community Aging in Place, Advancing Better Living for Elders (CAPABLE).[6-9] CAPABLE is a person-centered consultative model of care delivered at home by clinicians (occupational therapist [OT] and registered nurse [RN]) 20-week intervention supported by a toolkit, assistive devices and home modification to improve function and factors that impact function (i.e., balance, pain, depression).

The ***goal*** of the Parent Trial is to examine implementation of CAPABLE in Home and Community Based Service waiver sites in Michigan. The waiver supports 15,000 disabled, low-income, NH eligible, older adults in the community, providing 19 services (i.e., personal care, meals) and case management through home visits by 623 RNs and SWs. This research is premised on prior work that translated[10-12] CAPABLE (adding SWs; Hartford, Center for Medicare Medicaid Services [CMS], 2014); and tested implementation strategies (training, facilitation, champions, coalition building, and audit and feedback; Hillman/CMS, 2015-17). ***Objectives*** for the trial are:

1. To test ***primary*** site-level outcomes of *adoption* and *sustainability* of CAPABLE after deploying implementation strategies at sites; and
2. ***Secondary*** beneficiary-level outcomes (*ADL/IADLs*, *pain*, *depression*, *falls*, *ED/hospital* use).

Implementation strategies will include readiness assessment, training, coalition building, audit, feedback, and Internal facilitators (IFs) and external facilitators (EFs) will support implementation.

Design is a 3-year community-based participatory[13] randomized Hybrid-3[14-15] mixed method[16-18] trial. Site size and quality will be used to randomize to MiCAP with internal facilitation (IF, Arm 1) or IF enhanced with external facilitation (IF+EF, Arm 2). Training of facilitators and clinicians will occur and CAPABLE will be provided to beneficiaries.

Clinician attitude and self-efficacy will be measured at baseline and 9 months; and training satisfaction upon completion. Intervention and implementation (Stages of Implementation Completion ([SIC]) fidelity data will be collected monthly for 12 months. Beneficiary pre/post-outcomes will be collected.

The **specific aims** for the Parent Trial are:

Aim 1 To test the effects of MiCAP with IF alone versus with EF on site adoption and sustainability (***primary***) and beneficiary ADL/IADLs, pain, depression, falls, ED/hospital use (***secondary***) over the next 12 months. We hypothesize that IF+EF will have improved primary and secondary outcomes compared to IF alone.
Aim 2 To determine whether the effects of EF+IF versus IF on primary outcomes are mediated by clinician attitude or self-efficacy at 9 months (Mechanism-of-action).
Aim 3 To benchmark the effects of IF and EF+IF on beneficiary outcomes pre/post-implementation.
Findings from exploratory aims will inform future work.
Aim 4 To compare the primary and secondary outcomes within 12 months, potential mediators at 9 months, and baseline leadership and readiness for sites with SIC of >50% versus sites with SIC≤50% at 6 months in each arm.
Aim 5 To explore whether baseline site leadership and readiness moderate the impact of EF+IF compared to IF on primary/secondary outcomes in 12 months to determine which sites require more intensive facilitation.
Aim 6 To evaluate clinician satisfaction, implementation cost, and policy impact for Arms 1 and 2 at 12 months.

The ***significance*** of the Parent Trial is that the use of CAPABLE in an underfunded Statewide Medicaid environment, where change is difficult to attain. This work will **impact** implementation science by testing two approaches to implementation to improve outcomes among older adults in a Medicaid waiver program. This natural setting approach has high generalizability for waivers, as we learn what intensity of implementation strategies are needed to adopt and sustain CAPABLE in a program that cares for our nation's most vulnerable older adults who are aging-in-place.

Administrative Supplement
We extend the Parent Trial in our Administrative Supplement by addressing a problem found while deploying CAPABLE with beneficiaries with Alzheimer's disease (AD) or dementia. There are 39.8 million informal caregivers in the US[19] and 16.3 million who care for someone with AD or dementia;[19, 20] and 1,500 of those are in the Michigan waiver. Most beneficiaries with those conditions did not accept CAPABLE as they were unable to receive instruction. Interventions that improve caregiver knowledge, confidence, and self-efficacy improve care they provide.[21 22] Thus, the ***goal*** of this Supplement is to extend provision of CAPABLE[6-9] to waiver beneficiaries with AD or dementia via the engagement of their informal caregivers.

This work is significant as there are 1,500 beneficiaries with AD or dementia in the waiver who could benefit from CAPABLE yet many did not, as they were to receive instructions. Consequently, a need exists to learn how to use CAPABLE with caregivers to assist beneficiaries with AD or dementia in the waiver. To date, CAPABLE has only been designed[6-9 23] to be used directly with the individuals without caregiver involvement. In the waiver, beneficiaries are required to have a designated caregiver, therefore, modifying the toolkit for use by caregivers could aid in deploying CAPABLE to beneficiaries with AD or dementia.

There is a paucity of literature on caregiver provision of assessment or direct care to individuals with AD or dementia, as most discuss burden, confidence, stress, depression, or health. In 2005, the AARP used a Delphi technique to identify caregiver competency domains of medical/nursing skills, assessment, measurement, collaborating, and communication.[24] A review of caregiver training programs found problem solving, use of community resources, and communication to be the primary focus.[25] Physical or emotional assessment, medical/nursing skills training, home exercises, medication management, or planning, like what is needed when delivering CAPABLE, appeared to be lacking in caregiver training.

Regarding toolkit usage, Powell and colleagues[26] recommend using toolkits when implementing interventions, and our parent trial uses a beneficiary toolkit. A recent review of 72 studies evaluating use of toolkits (i.e. weight management, fall prevention, vaccination, pain management, and patient safety) found 57% reported adherence to clinical procedures and toolkit effects were positive.[27] This finding supports use of a toolkit with caregivers when CAPABLE is deployed with beneficiaries with AD or dementia.

Many older adults cared for by informal caregivers have unmet needs. A 44.3% (38.2% ADL related, 14.6% IADL related) unmet need rate is common among older adults with caregivers.[28] Higher rates of unmet needs are likely in beneficiaries in the waiver as they are multi-morbid and low-income with few resources and even worse in those with AD or dementia.

1.3 SPECIFIC AIMS FOR ADMINISTRATIVE SUPPLEMENT

The **specific aims** for the Supplement are:
Aim 1 To refine the current toolkit to support caregiver's tasks and skills when using CAPABLE for a beneficiary with AD or dementia in the waiver.
Aim 2 To train clinicians (RNs, SWs, and OTs) to use the toolkit with caregivers of beneficiaries with AD or dementia in the waiver when using CAPABLE; and assess clinician satisfaction with training.
Aim 3 To determine feasibility and acceptability of and satisfaction with the toolkit by caregivers.
Aim 4 To evaluate preliminary efficacy of CAPABLE delivered via clinicians, caregivers, and the toolkit to AD or dementia beneficiaries with respect to ***secondary*** outcomes of the parent trial (beneficiary ADL/IADLs, pain, depression, falls, ED/hospital use).

A phased project over 12-months will occur, enrolling at waiver sites.
Aim 1 will be achieved through the following phases:
Phase 1.1 Consult experts to refine the toolkit for use by caregivers in the waiver to deliver CAPABLE to beneficiaries with AD or dementia. Field notes will be analyzed using thematic analysis (Month 1 to 2)
Benchmark: experts consulted, thematic analysis completed, and toolkit refined.
Phase 1.2 Consecutively enroll 5 caregivers, assess for age, sex, race, ethnicity, education, and relationship to beneficiary, provide the toolkit, and conduct phone calls using an iterative process to refine the toolkit to deliver CAPABLE to beneficiaries with AD or dementia. Field notes will be analyzed using thematic analysis. (Month 3 to 4)
Benchmark: 5 caregivers are enrolled and thematic analysis completed.
Phase 1.3 Finalize the toolkit with experts. Field notes will be analyzed using thematic analysis. (Month 5)
Benchmark: experts consulted, thematic analysis completed, and toolkit refined.

Aim 2 will be achieved through Phase 2 Prepare and provide training to clinicians in the use of the toolkit with caregivers when implementing CAPABLE for those with AD or dementia in the 18 sites; and provide the toolkit. Clinician characteristics (N=522), knowledge pre/post, and satisfaction with training on toolkit use will be summarized. (Month 6)
Benchmark: Clinicians are trained and at least 80% will be knowledgeable and satisfied with training.

Aim 3 will be achieved through Phase 3 using a mixed method pre/post-test design with a convenience sample of 60 caregivers (30 from waiver sites randomized to IF, and 30 from sites randomized to IF+EF in the parent trial) to examine acceptability, feasibility, satisfaction with delivery of CAPABLE using the toolkit with caregivers of AD or dementia beneficiaries. Feasibility will be characterized by the proportion of caregivers who are enrolled to participate in the study among those approached and proportion of those who complete the 2-month supplemental study out of those enrolled. Acceptability will be summarized by a count of toolkit use over months 2-4. After consent of caregivers and beneficiaries, caregivers will be assessed for age, sex, race, ethnicity, education, self-efficacy, and relationship to beneficiary at baseline and for usual caregiving activities over the past 1 month. Next, the toolkit and CAPABLE will be provided, and then caregivers will be assessed for toolkit use, satisfaction, and fidelity (parent trial) to CAPABLE for 3 months. At exit, assess caregiver self-efficacy, and satisfaction with the toolkit. (Month 7-11). We will also **explore** which caregivers use the toolkit when clinicians deploy CAPABLE with beneficiaries with AD or dementia.
Benchmarks: At least 80% of caregivers approached will be enrolled in the study. Of those enrolled, at least 75% will complete month 4 assessment; At least 80% of caregivers will report using the toolkit over 3 months; At least 90% of the caregivers completing month 4 will be satisfied with the toolkit.

Aim 4 will be achieved through identifying 60 (30 each Arm 1 and 2) beneficiaries who received care from caregivers in Aim 3 for Phase 4 Preliminary efficacy will be tested based on the beneficiary outcomes (parent trial). Effect sizes for the toolkit will be estimated from statistical tests comparing beneficiary outcomes pre/post-implementation. Arm differences will be examined. (Month 12)
Benchmarks: Effect sizes for beneficiary outcomes from pre- to post and by parent trial arm are estimated.

This supplement is innovative in that we extend our NIA trial in response to NOT-AG-20-008, filling a gap in deploying CAPABLE to address the unmet needs of with beneficiaries with AD or dementia[19-22, 30] in the waiver.

We innovate by using a toolkit to build the knowledge and skills of caregivers.[25-27] Thus, extending our trial to provide CAPABLE to beneficiaries with AD or dementia in the waiver.

1.4 DESIGN
Design for each phase of the supplement follows.
Phase 1.1 of the project will have a 2-month qualitative design with data collected in field notes by study staff.
Phase 1.2 of the project will include a 2-month consecutive enrollment of five caregivers to refine the toolkit. This design has proven to be effective in practice-based research, which has been used since 1945 in drug therapy, internal medicine, cardiology, and nutrition,[29-33] and for research questions driven by crucial clinical problems, such as care of those with AD or dementia. Recruiters at the sites will identify and obtain permission from caregivers to release their name to study staff who will mail the consent form, contact via phone, conduct informed consent and after form is received conduct baseline interview, mail the toolkit, and discuss modifications as needed. After each interaction, the toolkit will be refined prior to the next interaction until all interactions are complete and the toolkit is refined.
Phase 1.3 of the project will have a 1-month qualitative design with data collected in field notes by study staff.
Phase 2 of the project will have a 1-month mixed methods descriptive and open question design with data collected by study staff pre/post-training.
Phase 3 of the study will have a mixed method pre/post-test pilot design. We will enroll 60 caregivers. Recruiters at the sites will identify and obtain permission from caregivers to enroll in the study. Study staff will conduct informed consent from beneficiary and the caregiver and the baseline data and mail the toolkit. Then clinicians will conduct care for 3 months. Study staff will conduct a monthly assessment for 3 months and at exit interview with the caregivers.
Phase 4 will include the analysis of data from beneficiaries and examination of preliminary efficacy.

1.5 SAMPLE A convenience sample of 522 clinicians in Phase 2, 65 caregivers (5 in Phase 1.2 and 60 in Phase 3), and 60 beneficiaries in Phase 3 will be used.

1.6 SETTING The setting is the MI Medicaid waiver sites in the Parent Trial.

1.7 INCLUSION AND EXCLUSION CRITERIA
Caregivers (Phase 1.2)
Included are caregivers (new) of beneficiaries diagnosed with Alzheimer's Disease or Dementia, and who are 18 years of age or older, and speak English in the waiver.
Excluded are caregivers of beneficiaries without AD or dementia in the waiver.

Clinicians (Phase 2)
Included are clinicians employed in the waiver (parent trial).
Excluded are clinicians not employed in the waiver.

Caregivers (Phase 3)
Included are caregivers (new) of beneficiaries that are the Legal Authorized Representative (LAR) or Durable Power of Attorney (DPOA) that are activated for healthcare decision making of the beneficiary diagnosed with AD or Dementia, and who are 18 years of age or older, and speak English in the waiver.
Excluded are caregivers of beneficiaries and those who do not have an activated LAR or DPOA for healthcare decision making for a beneficiary with AD or dementia; or without AD or dementia in the waiver.

Beneficiaries (Phase 3)
Included are beneficiaries enrolled in the waiver who are diagnosed with AD or dementia (sub-set of parent trial) who are be 18 years of age or older, speak English, who have a LAR or DPOA that are activated for healthcare decision making. This includes those with all phases of the disease of AD or dementia, those who are non-communicative or who are bed bound as they may benefit from elements of CAPABLE, such as medication management.

Excluded are beneficiaries without AD or dementia; or those without an activated LAR or DPOA for healthcare decision making in the waiver.

1.8 APPROVALS AND CONTRACTS

Prior to data collection:
Institutional Review Board (IRB) Approval will be obtained.
Contracts we will modified to include screening (beneficiary/caregiver), training and use of toolkit (clinician), and executed with sites.
Data Use Agreements are in place (Parent Trial) between with MDHHS and CIM to obtain beneficiary data.

1.9 ORGANIZATIONS ASSOCIATED WITH THE STUDY

MDHHS The Michigan Department of Health and Human Services (MDHHS).
Sites Home and Community Based Services Provider waiver program sites are under contract with State of MI MDHHS to manage, hire employees, and provide care to beneficiaries in the waiver program.
CIM Center for Information Management (CIM) is under contract with MDHHS and sites (20 years) to house and manage the EHR and billing software for the State of MI Medicaid waiver program. This platform contains beneficiary level data for all Medicaid beneficiaries in the waiver program where our study will occur. The website (www.ciminc.com/) provides a description of CIM's mission and purpose; and contains a statement of HIPAA compliance, required by CMS and MDHSS. We have a Fully Executed DUA; and a modified contract to include new beneficiary MDS data. The following will occur.

1. Data on beneficiary outcomes from care by clinicians trained in CAPABLE at sites who consent will be obtained from CIM.
2. Data transfer to the university (PI/PM) will be electronic through a CIM data secure encrypted portal as the data will be de-identified.
3. Data would be downloaded by PI/PM on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door that is locked at all times and only accessed by faculty approved to use the room. Only the PI/PM have access to the locked files cabinet.
4. Clinicians and IFs, who are also the supervisors of the clinicians at the sites, already have access to all identifiable CIM data in the EHR (Medicaid beneficiary data) to provide usual care.
5. Clinicians and IFs will not use the data the university (PI/PM) obtained from CIM.

1.10 EVIDENCE-BASED INTERVENTION: CAPABLE

As stated, CAPABLE was designed[6-9 23] for use by individuals[23] without caregiver involvement. In the waiver, caregivers of beneficiaries with AD or dementia could assist clinicians in providing CAPABLE by helping identify daily activity goals (e.g. taking a shower, walking to the bathroom), evaluating barriers to achieving those goals, and supporting attainment of outcomes. Caregivers could assist:

1. OTs by directing the beneficiary's functional mobility, meal preparation, bathing, and dressing.
2. RNs by assessing pain and providing strategies and medications as needed, improving mood with activities, fall prevention through exercise or home modification, medication management through pill set-up and administration, primary care physician communication by attending appointments and making phone calls, and/or incontinence management by toileting or using incontinence underwear.
3. SWs by assessing mood, identifying community resource needs, and communication.

Caregivers will use the toolkit to assist clinicians to deploy CAPABLE with beneficiaries in the waiver.

We expect the modified toolkit to include:

1. Information on caring for those with AD and dementia.
2. Algorithm-based assessment tools to examine common symptoms of those with AD or dementia, and instructions to identify conditions that need input from a clinician or provider.
3. Self-management strategies for caregivers to use when caring for those with AD and dementia.
4. Other items identified by experts or caregivers during the project.

Consultants added to our team include: Dr. Diana Sturdevant and Ms. Teri Round from the University of Oklahoma, who are content experts in care of individuals with AD or dementia and their caregivers.

1.11 IMPLEMENTATION STRATEGIES

We continue strategies deployed in the Parent Trial to implement CAPABLE: 1) Relationship Building. 2) Readiness to implement. 3) Coalition Building. 4) Training Clinicians. 5) Interdisciplinary coordination. 6) Facilitation and centralized oversight. 7) Audit and Feedback.

We extend our work in the supplement to include use of the toolkit with caregivers.

1.12 MEASURES AND TOOLS

Measures are based on Consolidated Framework for Implementation Research (CFIR) as listed in the Table.

CFIR Domains, Constructs, and Concepts and How, Who, and When Measured

	CONSTRUCT	CONCEPT(S)	MEASUREMENT		
			How	Who	When
Inner Setting	Implementation	Acceptability	1-Phone survey 2-Blackboard audit	1-Caregiver 2-Clinician	1-Monthly x3 & exit 2-Exit: training
		Feasibility	1-Screening form 2-Blackboard use	1-Caregiver 2-Clinician	1-When recruited 2-When trained
	Fidelity (Parent Trial)	Fidelity to CAPABLE	Audit in EHR	Beneficiary	Monthly for 3 months, exit
Individual	Clinician characteristics, training, and satisfaction	1-Age, gender, race, ethnicity, discipline, years worked in waiver 2-Training knowledge uptake 3-Satisfaction	Survey	Clinician	1-Before training 2-Pre/post-training 3-Post training
	Caregiver characteristics, care, perception of beneficiary outcomes, and satisfaction	1-Age, gender, race, ethnicity, education, self-efficacy, relationship to beneficiary 2-Toolkit use, self-efficacy 3-Satisfaction	1-Survey via phone call 2 & 3-Phone call	Caregiver	1- Phase 1.2 & 3 Baseline Phase 3: 2-Monthly for 3 months, exit 3-Monthly for 3 months, exit
	Beneficiary (Parent Trial)	Age, gender, race, ethnicity, ADL/IADLs, pain, depression, falls, ED/hospital use	MDS: pre- in usual care; post via phone survey	Beneficiary	Pre- in usual care Post-assessment at exit

4A Characteristics Clinician and caregiver characteristics will be collected at baseline; and beneficiary as in parent trial.

4B General Self-efficacy (GSE) of caregivers will be collected at baseline and exit.

4C Beneficiary outcomes will be collected as in the parent trial for the baseline and will be collected via phone call with the caregiver during the exit survey.

4D Fidelity Measures in the Parent Trial include an EHR assessment (OT [baseline assessment]/SW [mood]/RN [medication review), Care Plan (presence of desire of beneficiary), and Progress Note (documentation of brainstorming, problem solving, role modeling) review will provide data of use of CAPABLE as a measure of fidelity comparing pre/post CAPABLE.

4E Other measures: Data from experts and caregivers in field notes will be collected in notebooks. Data on recruitment of caregivers and beneficiaries will be collected on the Screening Form and in blackboard for clinicians. Use of the toolkit by caregivers, training of clinicians in pre/post-tests, and satisfaction with toolkit of caregivers will be examined using surveys designed in prior work.

4F Respondent Burden will be minimal**.**

4Fi for clinicians, it is expected that data collection will take less than 15 minutes; and training will take 1-hour (Phase 2).

4Fii for caregivers in Phase 1.2, it is expected that review of the toolkit will take 60 minutes for each interaction; and for caregivers/beneficiaries in Phase 3 and 4 it is expected that data collection will take less than 15 minutes for each of the surveys.

In prior work, no clinicians, caregivers, or beneficiaries refused to participate because of interview length.

1.13 PARTICIPANT COMPENSATION, DATA COLLECTION, MANAGEMENT, SAFETY, AND STORAGE

Participant Compensation

Caregivers will be compensated for time to participate:
Phase 1.2 (N=5) $250 upon completion of data collection; prorated at $50 for each of the five phone calls.
Phase 3 (N=60) $250, prorated at $50 for each of the baseline, 3-monthly assessments, and exit surveys after completed.

This pragmatic, real-world setting study utilizes employees who are either a supervisor (IF), who is a clinician that oversees the provision of care, or a clinician, who conducts usual waiver care and/or CAPABLE. Both supervisors and clinicians have access to the electronic health records of all their beneficiaries at their site.

- Clinicians and IFs have access to beneficiary data where employed.
- IFs have access to which clinicians are trained in CAPABLE.
- EFs will not have access to beneficiary data at a site where they are not employed.
- Clinician, IF, or EF will not have access to study data.

Protected Health Information

For this study we will collect the clinician, beneficiary, and caregiver names and beneficiary and caregiver phone numbers and addresses. The names will be used by the PI/PM in the key to assign a study number and will be used to track progression. The phone numbers will be used for consent and data collection. The addresses will be used to mail study material to the beneficiaries and caregivers. Only the PI/PM have access to the study key. Research Assistants will call caregiver using the phone number when assigned. No other PHI will be collected for the study.

Data Collection and Management this study includes clinician, caregiver, beneficiary, and fidelity data.

1. Clinician data collection (characteristics, knowledge) will be from an electronic survey in Qualtrics and from the Bb platform (training knowledge and satisfaction).
2. Caregiver data collection (characteristics, use of toolkit, and satisfaction) will be from phone calls, and surveys.
3. Beneficiary outcome data (de-identified) will be from surveys via phone calls and CIM (characteristics, outcomes).
4. Fidelity data on: CAPABLE will be collected from the PI/PM examination of the EHR (assessment, PCSP, and PNs).

The only study members that will have access to identifiable data are the PI and PM. The PM will assign study numbers and keep a key with site and clinician identifiers, separate from any data Excel sheets, so that all Excel data sheets remain de-identified (no name, address, phone, Medicaid#, etc.).

CIM

Per the DUA, CIM will provide de-identified beneficiary outcome data via a data transfer to the university (PI/PM) at the end of the site's project time period.

- This will occur electronically through a CIM data secure encrypted portal.
- Data would be downloaded by PI/PM on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door that is locked at all times and only accessed by faculty approved to use the room.
    - Only the PI/PM have access to the locked files cabinet.
- Data for the study would not be available to the site, clinicians, or supervisors.

Qualtrics

Qualtrics is a web-based survey creation, collection, and analysis software tool that can be used for the creation of open surveys, targeted (panel) surveys, and open polling. Qualtrics provides secure, intuitive, web-based interfaces for users to enter data, and users with approved permissions/passwords can access the system with an Internet connection. Qualtrics servers are hosted in world-class data centers with all the necessary physical security controls (e.g., 24/7 monitoring, cameras, visitor logs, entry requirements.).

Qualtrics has Transport Layer Security (TLS) enabled to encrypt respondent traffic. Communications are sent over TLS connections, which protects communications by using both server authentication and data encryption. This ensures that data in transit is safe, secure, and available only to intended recipients. Qualtrics software is available to all university faculty and staff as a site license, centrally funded. Qualtrics survey data is protected, and only available to the survey designers.

- For this project, the PI/PM will construct all electronic and phone surveys in a Qualtrics platform. Surveys were designed so each question on the survey will be voluntary and may be skipped. Only the PI/PM will have access to Qualtrics or identifiable data for this study.
- After completion of a survey, the data will be downloaded in an Excel format by the PI/PM on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door locked at all times and only accessed by faculty approved to use the room. Only the PI/PM have access to the locked files cabinet.
- Data will be de-identified by the PI/PM prior to use of the data by RAs or statistician. De-identified data would be stored on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door that is locked at all times and only accessed by faculty approved to use the room.

Blackboard (Bb)

Bb is a virtual learning environment and course management system developed by Blackboard Inc. Bb is Web-based server software features course management, customizable open architecture, and scalable design that allows integration with information systems and authentication protocol. For this study, we will deploy clinician training in Bb.

- The Bb training course's identifiable data will be solely available to designers (PI/PM) and not available to other project or site staff at any time.
- Data collection on clinician training knowledge (pre/post-test) and completion (finished training) will be collected from Bb by the PI/PM.
- Data from Bb would be downloaded by PI/PM on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door that is locked at all times and only accessed by faculty approved to use the room. Only the PI/PM have access to the locked files cabinet.
- Data will be de-identified by the PI/PM prior to use of the data by RAs or statistician. De-identified data would be stored on encrypted jump drives; and stored in a locked file cabinet in GVSU CHS Room 323 (Research Center) with a door that is locked at all times and only accessed by faculty approved to use the room.
- Data for the study would not be available to the site, clinicians, or supervisors.

Data Security

Data storage and security will be assured as per GVSU policies and placed in secure password-protected platforms and is described in detail in the Data Safety Monitoring Plan (DSMP) and overseen by the Data Safety Monitoring Board (DSMB) as stated in the DSMP Charter for the Parent Trial.

1.14 DATA ANALYSIS

Analysis of each of the aims is as follows

Aim 1 Field notes will be analyzed using thematic analysis.

Aim 2 Clinician's satisfaction with training will be summarized using the descriptive statistics, including the portions of those satisfied or highly satisfied with training.

Aim 3 To evaluate feasibility, the proportion of consenting caregivers and beneficiaries out of eligible and approached will be summarized using point estimators and 95% confidence intervals (Cis). We will also estimate the proportion of caregivers who completed month 4 assessment out of those who consented.

To evaluate acceptability, counts of toolkit use as reported by caregivers over months 2-4 will be summarized using point estimates and 95% CIs. Caregiver self-efficacy at enrollment will be compared to that at month 4 using paired t-tests. To account for the parent trial design, we will also fit a constrained longitudinal model for two repeated measures of caregiver self-efficacy (enrollment and month 4). The predictors will be time

(enrollment or month 4), parent trial arm, and their interaction, with a constraint of equality of trial arm means at enrollment due to randomization.[37] This model will be fit as linear mixed effects model if the outcome distributions are normal or can be normalized with transformations or as a generalized linear mixed effects models if transformations are not successful. With these techniques, all 60 caregivers will be included in analysis under missing at random assumption. The effect sizes will be expressed as Cohen's d of differences between least square (adjusted) means in the standard deviation units. The threshold for clinical significance of the differences corresponds to 1/3 to ½ of the standard deviation (d=0.33 to 0.5).[38 39] If clinically significant differences by trial arm at month 4 are found, pre- to post-changes will be estimated from this model (point estimates, CIs, and effect sizes) separately for IF and IF+EF arms. Otherwise pre-to post-changes will be estimated based on the entire sample of 60 caregivers.

Aim 4 To evaluate preliminary efficacy of CAPABLE delivered via the toolkit to AD or dementia beneficiaries, constrained longitudinal model with 2 repeated measures (pre-CAPABLE and post-CAPABLE) will be fit for each beneficiary outcome of the parent trial (beneficiary ADL/IADLs, pain, depression, falls, ED/hospital use). The covariates will be time, trial arm, and trial arm by time interaction, with the constraint of equality of trial arm means pre-CAPABLE because of randomization. From this model, we will output the least-square means by trial pre- and post-CAPABLE, and estimate the effect sizes for between-arm differences and for the differences from pre- to post-CAPABLE in each arm and overall if effect sizes for trial arm differences are below 0.33.

1.15 SAMPLE SIZE AND POWER CONSIDERATION

The sample size of 60 caregivers for this project was selected based on the timeline, available caregivers and resources. The effect sizes estimated in this supplemental study will be used to inform a larger study that can be formally powered using these estimates. **For Aim 3,** in the estimation of proportion of consented caregivers, assuming that 90 caregivers are approached and 60 consented, the margin of error of the 95% CI for consent rate will not exceed ±9%. For the attrition rate, assuming 48 of 60 caregivers complete the study, the margin of error of the 95% CI for retention rate will not exceed ±10%. **For Aim 4,** assuming correlation of 0.4 between two repeated measures based on past work,[23] statistical significance for the tests of IF versus IF+EF differences at .05 level in two-sided tests and power of .80 or greater will be reached if these differences correspond to adjusted d=0.62 or greater. For the tests of pre- to post differences, the detectable effect size is 0.68 within each arm (n=30), and 0.47 for the entire sample (n=60). If the effect sizes turn out to be smaller, statistical significance will not be reached in this supplemental study, but estimates of the effect sizes will be used to formally power a larger study with AD or dementia beneficiaries and their caregivers.

1.16 RANDOMIZATION

Randomization occurred in the Parent Trial at the site level to **Arm 1** (MiCAP with IF) or **Arm 2** (MiCAP with IF+EF). The PM maintains a confidential file documenting study Arm by site. Only the PI/PM will know Arm assignment by site.

1.17 STUDY PARTICIPATION

Voluntary study participation from clinicians, caregivers, and beneficiaries will occur and is noted in each recruitment brochure and within informed consent form.

Clinician surveys were designed so each question on the survey will be voluntary and may be skipped.

Caregivers and Beneficiaries Study staff will review verbally on phone calls (Phase 1.2, 3) the voluntary nature of study participation.

Characteristics of Clinicians In total, an estimated 522 clinicians are employed in the waiver and 522 clinicians could be enrolled in this study. A survey was conducted in 2011 to collect general characteristics of clinicians and we expect to experience a similar rate of inclusion: 97% female; 95% Caucasian, 3% African American, 3% Hispanic, 1% American Indian, and less than 1% Asian/Pacific Islander (some respondents answered with more than one response); and 42% were 50 years old or older, 26% 40-49, 22% 30-39, and 10% were less than 30 years old.

Characteristics of Caregivers In total, 65 caregivers will be enrolled in this study. A convenience sample of caregivers will be enrolled at the participating waiver program sites in Michigan. We expect to experience a

similar rate of inclusion: 60% female; 80% Caucasian, 18% African American, 3% Hispanic, and 2% other; and 42% were 50 years old or older, 26% 40-49, 22% 30-39, and 10% were less than 30 years old that mirrors beneficiaries as most caregivers are family member, with some children who are younger.

Characteristics of Beneficiaries In total, an estimated 15,000 waiver beneficiaries are in the waiver and about 13,500 waiver beneficiaries at the 18 participating waiver sites. From our current study, we expect to experience a similar rate of inclusion: 78% female; 72% Caucasian, 24% African American, 3% Hispanic, and 1% American Indian; and the average enrolled beneficiary age is 67.07 years (SD 13.22; range 25-96). In our previous translation study, we found the participants had extensive comorbid conditions with a mean of 5.1 (SD 1.97; range 2-8) and with a mean summed score of 13.7 (SD 11.2; range 3-21).

1.18 SCREENING, RECRUITMENT and INFORMED CONSENT

Caregivers (Phase 1.2)

Screening Prior to recruitment, Supervisors employed by the site, who have access to medical records, will identify caregivers of beneficiaries with AD or dementia, and complete the Screening Form (#8), and request permission to release their name, address, and phone number to the study staff. The supervisor will notify study staff of those willing to be contacted to have study explained by sending the Screening Form via encrypted fax.

Recruitment Study staff will mail the study brochure, consent wait 1-week, and call the caregiver via phone.

Informed Consent The study staff will review the study brochure, IC, mailed previously, explain the study and answer any questions.

Clinicians (Phase 2)

Screening Contracts with the sites provide the PI the email address of clinicians.

Recruitment The PI will distribute a recruitment brochure via email to clinicians inviting them to participate.

Informed Consent If interested in participating, the clinician can click on a link to the informed consent in the email. The consent will be located in Qualtrics, and electronically signed by the clinician prior to data collection or training.

Caregivers and Beneficiaries (Phase 3)

Screening Prior to recruitment, Supervisors employed by the site, who have access to medical records, will identify caregivers of and those beneficiaries with AD or dementia who are the Legal Authorized Representative (LAR) or Durable Power of Attorney (DPOA) that is activated for health care for that beneficiary, and complete the Screening Form (#9), and request permission to release their names, and phone number to the study staff. The LAR or DPOA is a person legally authorized to make medical decisions for the participant. We utilize LARs and DPOAs, as beneficiaries with AD or Dementia who do not have the capacity to understand informed consent, a representative to act on behalf of the beneficiary; which is common practice in AD trials.[34-36] The supervisor will notify study staff of those willing to be contacted to have study explained by sending the Screening Form via encrypted email to the study staff.

Recruitment Study staff will mail the study brochure, consent (Caregiver and Beneficiary ICs) and HIPAA (Beneficiary) form to the caregiver and/or LAR/DPOA, wait 1-week, and call the caregiver via phone.

Informed Consent

The study staff will review the study brochure, ICs (Caregiver and Beneficiary) and HIPAA (Beneficiary) Forms, mailed previously, explain the study and answer any questions.

As it is likely the beneficiaries with AD or Dementia will not have the capacity to understand IC, a representative may act on behalf of the beneficiary; which is common practice in AD trials.34-36 The LAR or DPOA, a person legally authorized to make medical decisions for the beneficiary, may be used. (GVSU Human Research Review Policy 813, Research involving participants with questionable consent capacity and/or legally authorized representatives).

Verbal Assent will be obtained from the beneficiary, if possible, using an Assent Script and Form for Individuals without Consent Capacity by study staff during enrollment. Staff will document if the beneficiary provides a verbal assent by stating “yes”, or if the beneficiary does not respond on the form.

If the caregiver is interested in participating for themselves and as LAR/DPOA for the beneficiary, the caregiver and/or LAR or DPOA, will be asked to sign the Caregiver and Beneficiary ICs and Beneficiary HIPAA Forms and return one copy of each to the study staff via the enclosed envelope, prior to any data collection.

1.19 PRIVACY AND CONFIDENTIALITY ISSUES

Any information about the individuals in the study, including identity and answers to questions are confidential and will not be shared with others. In addition, the responses will be combined with those of all others in the study. All study team members are Human Subjects and HIPAA trained and follow all privacy and confidentiality requirements.

1.20 STUDY WITHDRAWAL OR DISCONTINUATION

Withdrawal.

A clinician, caregiver, and/or a beneficiary may withdraw and/or discontinue their participation at any point in the project by notification of the internal facilitator and/or PI/PM via email, phone call, or in writing.

Clinicians. Withdrawal and discontinuation are included in the contracts. Decisions to participate or not will not affect clinician current or future employment; or beneficiary or caregiver status as a Medicaid program recipient in the State.

Caregiver. The caregiver will also be told that they are free to withdraw at any time during the study. The instructions for the study, including their right to withdraw at any time, will be repeated to the individuals during each interaction.

Beneficiary. The beneficiary will also be told that they are free to withdraw at any time during the study. The instructions for the study, including their right to withdraw at any time, will be repeated to the individuals during each interaction. For beneficiaries with cognitive impairment, they may indicate withdrawal from the study by verbally stating no desire to receive CAPABLE, not accepting all or part of the CAPABLE intervention, or by not allowing the clinician and/or caregiver to assist with components of the intervention.

Discontinuation. Three attempts at data collection will occur and if no response, no further contact will be attempted, and be considered a discontinuation.

1.21 POTENTIAL RISKS AND BENEFITS TO PARTICIPATION

Clinicians, caregivers, and beneficiaries will be assured of the confidentiality of all information given and be protected in the following manner: 1) use of identification numbers rather than names with computerized data entry; 2) release of data in aggregate form only; and 3) omission of identifiers in all reports and presentations. Therefore, risk/benefit ratio is heavily weighted in favor of benefit for individual clinicians, caregivers, and beneficiaries.

Benefits of Participation

Clinicians. There may or may not be direct benefits for the clinicians. Clinicians will not be placed at increased physical, financial, or legal risk as a result of taking part in this study. Clinicians will learn new knowledge and skills that may or may not benefit ability to perform their duties when employed as a clinician. It may take some time and effort for clinicians to complete the training and to answer questions.

Caregivers. There may or may not be direct benefits for the who are the care providers for beneficiaries, as above in the beneficiary section.

Beneficiaries. There may or may not be direct benefits for the beneficiaries. Beneficiaries may experience improvement in activities of daily living, instrumental activities of daily living, pain, falls, depression, hospital and ED visits. Beneficiaries will not be placed at increased physical, financial, or legal risk as a result of taking part in the study. It may take some time and effort for beneficiaries to answer questions and adapt to the extra care. Beneficiaries will continue to receive care under the direction of their waiver clinicians, even if the beneficiaries choose not to take part in this study.

Protection against Study Risks
Clinicians can agree or not agree to participate in the study. A consent will be obtained from a clinician prior to data collection. Clinicians will be informed that completing a survey is voluntary and their responses will be kept confidential. Any report of this research will not include their name or any other information by which they could be identified. For those clinicians who consent and complete training: Included in contracts with sites that non-participation would not impact a clinician's employee status.

Caregivers can agree or not agree to participate in the study and their beneficiary will to receive "usual" waiver care regardless of decision to participate or not participate in the study.

Beneficiaries have the option to consent for the study if desired; and will receive "usual" waiver care regardless of decision to participate or not participate in the study. There may or may not be direct benefits for the beneficiaries. Beneficiaries may experience improvement in activities of daily living, instrumental activities of daily living, pain, falls, depression, hospital and ED visits. Beneficiaries will not be placed at increased physical, financial, or legal risk as a result of taking part in the study. It may take some time and effort for beneficiaries to answer questions and adapt to the extra care. Beneficiaries will continue to receive care under the direction of their waiver clinicians, even if the beneficiaries choose not to take part in this study.

Protecting Confidentiality Identifying information (name, address, date of birth, etc.) are not used to identify those who participate in the study. Those who participate will be assigned an identification number which will become the identifier of records for all who participate. This number will be given to study personnel to enter into the study database. Only the PI/PM will link the identification number with the data to the central location for review.

1.22 ADVERSE EVENTS AND PROTECTION AGAINST STUDY RISKS

Adverse Events This study is "low risk" and no adverse events are anticipated. A Serious Adverse Event (SAE) is defined as a breach of confidentiality; whereas a Non-Serious Adverse Event (NSAE) is defined as data storage or security without breach of confidentiality. Tracking of events will occur by the PI/PM who will enter all SAE/NSAE into an Excel database compiled for reporting. Reporting of an SAE to PI will occur within 24 hours. If PI evaluates SAE to be moderate or serious, will convene the Data Safety Monitoring Board (DSMB). All events determined by DSMB to be an SAE will be reported to the GVSU IRB and NIA Project Official within 48 hours. NSAE events will be reported to PI within 7-days. If PI evaluates NSAE to be of nature needing further reporting, will report to the IRB, DSMB, and NIA as appropriate. We do not anticipate any SAEs or NSAEs.

1.23 ROLES, RESPONSIBILTIES, AND TRAINING

Study Personnel
PI is a PhD, NIH trained experienced "trial" scientist, having completed over 40 trials, able to carry out the role and responsibilities to carry out the study, as approved by NIA.
Co-I is a PhD, NIH trained experienced "trial" scientist, having completed over 200 trials, able to carry out the role and responsibilities to carry out the study, as approved by NIA.
PM is BS prepared individual, and experienced PM with over 10 projects completed with this PI; and able to carry out the role and responsibilities to carry out the study, as approved by NIA.
RAs the following training will occur for all students (undergraduate and graduate) who will act as "research assistants" in this study.
Role and Responsibilities Training Each RA prior to interacting with any site, IF, clinicians, or beneficiaries or with collecting data will complete online, reading, and in-person orientation and training:

1. Complete CITI training and submit certificate to the PM the first week working on the project, and prior to interacting with study clinicians, IFs, or beneficiaries or data.
2. Receive a job description, and review, understand, and sign, which includes the role and responsibilities entailed within the position.
3. Receive a position manual, and review, understand, and deploy in their role.

4. Review and understand the DSMP and DSMP Charter, Study Protocol, measures, literature supporting project evidence and approach; and the quality assurance-monitoring plan.
5. Report directly to PM with weekly schedule, activities, needs, requests, problems, or any other issues that may arise.
6. Review, attend, and participate in team meetings when not in class.
7. Conduct DUMMY data collection in a HIPAA and confidentially protected manner and accept feedback from PM until conducted correctly.
8. Complete the orientation checklist as defined in position manual.

If needed, remediation will occur on any deficit area by the PM, until all areas are satisfactory.

1.24 FOLLOW-UP AND RECORD RETENTION

The duration of the study is 1-year. Subjects identifying information will be linked to the data (in keys on available to the PI/PM) for the duration of data collection and until analysis is completed and verified. Once results are verified, the keys linking data to subjects will be destroyed.

The method for destruction of written records will occur via shredding using a HIPAA compliant provider; and only archiving of de-identified information will occur. The method for destruction of electronic records will occur via burning of drives using a HIPAA compliant provided; and only archiving of de-identified information will occur.

Record retention will be maintained in a locked file cabinet in the university in a locked office and kept 7-years after the completion of the study.

1.25 DISSEMINATION PLAN

The following dissemination activities will occur as a result of this NIA funded clinical trial.

ClinicalTrials.gov

1. The clinical trial under this award will be registered within 21-days of initiation of data collection.
2. The clinical trial results information will be submitted to ClinicalTrials.gov within 11 months after the trial's primary completion date.
3. Informed consent documents for this clinical trial will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
4. GVSU has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements

Peer Reviewed Publication

1. The protocol for this trial will be written into a manuscript and submitted to Implementation Science for publication in early 2021.
2. The results of this trial will be written into a manuscript and submitted to Implementation Science for publication in 2021.

Peer Reviewed Presentations

1. The results of this trial will be written into an abstract and submitted to the Academy of Health Dissemination and Implementation Science annual conference for presentation in 2021.
2. The results of this trial will be written into an abstract and submitted to the Gerontological Society of America annual conference for presentation in 2021.

Formal Reports to MDHHS and sites:

1. Annual written report of clinical trial progress will be written and submitted each September (2020, 2021)
2. A final report of clinical trial progress will be written and submitted in September 2021.

Other dissemination activities will occur as opportunities arise.

1.26 DATA RESOURCE AND SHARING PLAN

The activities will occur as a result of this clinical trial.

Data Sharing GVSU will share de-identified data from this clinical trial in the following manner:
1. ScholarWorks@GVSU is an open-access repository maintained by the GVSU Libraries that displays and maintains works by GVSU Research Scientists.
2. PI will prepare de-identified and labeled data set(s) from this trial in excel format and attach a codebook.
3. PI will provide dataset to the GVSU Library for publication on ScholarWorks platform.
4. GVSU Library will set up notice of clinical trial data availability in ScholarWorks.
5. GVSU Library will accepts requests for the clinical trial data in ScholarWorks, which is an Open Access platform accessible worldwide.
6. GVSU will provide the required data release form to those requesting the data from this clinical trial.
7. Upon receipt of the complete data release form the individual requesting the data, the GVSU Library will provide data to requester.
8. GVSU Library will notify Principal Investigator (Spoelstra) of data sharing.
9. GVSU Library will compile a list of all data sharing and provide to NIA, the PI, or others as appropriate as requested.

Resource Sharing GVSU will share resources, to include the SAS code used to process and analyze the data in this trial and the codebook used to prepare data for analysis from this clinical trial in the following manner:
1. ScholarWorks@GVSU is an open-access repository maintained by the GVSU Libraries that displays and maintains works by GVSU Research Scientists.
2. PI will prepare SAS analytic codes used to process, analyze trial data in WORD format, and attach an EXCEL format codebook.
3. PI will provide SAS analytic codes and the Codebook to the GVSU Library for publication on ScholarWorks platform.
4. GVSU Library will set up notice of clinical trial SAS analytic codes and Codebook availability in ScholarWorks.
5. GVSU Library will accepts requests for the SAS analytic codes and Codebook in ScholarWorks, which is an Open Access platform accessible worldwide.
6. GVSU will provide the required data release form to those requesting the SAS analytic codes and Codebook from this clinical trial.
7. Upon receipt of the complete data release form the individual requesting the SAS analytic codes and Codebook, the GVSU Library will provide data to requester.
8. GVSU Library will notify PI of data resources sharing.
9. GVSU Library will compile a list of all data resources sharing and provide to NIA, the PI, or others as appropriate as requested.

1.27 LIST OF ATTACHMENTS

	Attachments
1	
2	Tool: GSE
3	Tool: MDS
4	Measures: Toolkit Use, Caregiver Satisfaction, Clinician Pre/post-test
5	Recruitment Brochure: Clinician (Phase 2)
6	Recruitment Brochure: Caregiver (Phase 1.2)
7	Recruitment Brochure: Caregiver & Beneficiary (Phase 3)
8	Screening Form: Caregiver (Phase 1.2)
9	Screening Form: Caregiver & Beneficiary (Phase 3)
10	IC: Clinician (Phase 2)
11	IC: Caregiver (Phase 1.2)
12	IC: Caregiver (Phase 3)
13	IC: Beneficiary (Phase 3)
14	Protocol
15	Data Safety Monitoring Plan (DSMP)
16	Data Safety Monitoring Board (DSMB)

17	NOA R15 NIH 1R15AG058193-01A1 Funded Grant
18	References
19	HIPAA Form: Beneficiary
20	Assent Script-Form for Beneficiaries

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