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

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This 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

A table of terms, their acronyms, and definitions are provided for the protocol that follows.

Construct	Term (acronym)	Definition
Groups participating in study	Site	A Home and Community Based Services Provider under contract with the State of MI to provide MiChoice services in the Medicaid program.
	Clinician	A Home and Community Based Services provider employee who is a clinician that provides either care to beneficiaries or a supervisor who oversees clinician care and is an RN, SW, OT.
	Beneficiary	A person who is a Medicaid recipient of care and services in the Home and Community Based Services.
Components implemented in study	Community Aging in Place, Advancing Better Living for Elders (CAPABLE)	Evidence-based intervention implemented in the Home and Community Based Services program in Michigan.
	MiCAP	A package of implementation strategies that will be used to implement CAPABLE in the Home and Community Based Services in Michigan in this project.
	External facilitator (EF)	A supervisor at a Home and Community Based Services program site in Michigan where we performed our prior work and who was an early adopter of CAPABLE and will guide the work of IFs (e.g., fidelity to CAPABLE, engaging clinicians for training, understanding the benefits of CAPABLE) in one arm of the study.
	Internal facilitator (IF)	A supervisor at a Home and Community Based Services program site in Michigan who will be trained and will facilitate and lead the CAPABLE implementation, and oversee clinician training and performance of CAPABLE; and oversees the provision of usual "waiver" care.
	Interdisciplinary Coordination (IDC)	Coordination between and among the RN, OT, and SW during the performance of CAPABLE to assure the beneficiary's person-centered service plan is enacted as desired.
	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.
Organizations associated with study	Center for Information Management (CIM)	Software company that houses the electronic health record for beneficiaries in the waiver program.
	Center for Medicare and Medicaid Services (CMS)	Oversight body of all Medicaid and Medicare programs.
	Institutional Review Board (IRB)	Human Subjects oversight board.
	Grand Valley State University (GVSU)	University
	Michigan Department of Health and Human Services (MDHHS)	The oversight organization of Medicaid programs for the State of Michigan.
	National Institute on Aging (NIA)	Grant funder.
General terms used in study	Activities of daily living (ADL)	Activities such as bathing, walking, transfers that are performed to carry out daily living.
	Blackboard (Bb)	Software used to house training modules.

	Continuous Quality Assessment Review (CQAR)	Quality review process for Medicaid waiver program.
	Electronic health record (EHR)	Electronic record where beneficiaries care is documented.
	HIPAA	Health Insurance Portability and Accountability Act
	Instrumental activities of daily living (IADL)	Activities such as shopping, banking, and cleaning that are performed to carry out daily living.
	Michigan (MI)	A state.
	Person Centered Service Plan (PCSP)	Plan of care for waiver beneficiaries in the electronic health record.
	Progress Note (PN)	Notation of care in the electronic health record.
	Self-efficacy (SE)	A feeling of worth or self-esteem.
Study team at university	Primary Investigator (PI)	Investigator is the PhD trained scientist to be responsible for conducting trial and assuring all approvals, compliance requirements, and assurances are met according to NIH expectation. (Spoelstra)
	Project Manager (PM)	The PM assists the PI in performing responsibilities for conducting trial and assuring all approvals, compliance requirements, and assurances are met in accordance to NIH expectation. (Schueller)
	Research Assistant (RA)	A GVSU student (required in AREA grant funded projects) who is a research team member.
Tools used in study	EBPAS	Evidence-Based Practice Attitude Scale
	GSE	General Self-efficacy
	ILS	Implementation Leadership Scale
	MDS	Minimum Data Set for Home Care Tool
	ORCA	Organization Readiness to Change
	SIC	Stages of Implementation Completion

1.2 BACKGROUND AND SIGNIFICANCE

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 (ADLs),[3] falls and nursing home placement.[4] Consequently, implementing evidence-based models focused on aging-in-place in older adults is a public health priority. One evidence-based model is Community Aging in Place, Advancing Better Living for Elders (CAPABLE).[6-9] CAPABLE is a person-centered, delivered at home by clinicians (occupational therapist [OT] and registered nurse [RN]), 20-week intervention supported by assistive devices and home modification to improve function and factors that impact function (i.e., balance, pain, depression).

The ***goal*** of this Stage Ib project is to examine implementation of CAPABLE in Home and Community Based Service waiver program sites (N=18) in MI. The waiver supports 15,000 low-income, nursing home eligible, disabled and older adults in the community, providing 19 services (i.e., personal care, meals, etc.) and case management through home visits by 575 clinicians (RNs and social workers [SW]). This research is premised on prior work that translated[10-12] CAPABLE at one site (Hartford/CMS; 2014); and pilot tested implementation strategies (MiCAP: training, facilitation, coalition building, audit and feedback) at four sites (Hillman/CMS; 2015-17).

Building on our prior work, objectives for this project are:

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

Work at 18 program sites will include readiness assessment, training, coalition building, audit, feedback, and facilitation. Internal facilitators (IFs) and external facilitators (EFs), who were prior work adopters of CAPABLE, will facilitate.

Testing will occur in a 3-year community-based participatory research[13] with Hybrid-3[14-15] mixed method trial design.[16-18] With rolling enrollment, sites will be randomized to MiCAP with IF or MiCAP with IF+EF and baseline assessments of the characteristics of sites and clinicians will be completed. CAPABLE will be provided to beneficiaries. Clinicians (RNs/OTs/SWs) and IFs will be trained in CAPABLE. IFs and EFs will be trained in facilitation techniques. Post-implementation data, site Stages of Implementation Completion (SIC), and clinician satisfaction will be collected; an implementation fidelity checklist (including IF/EF fidelity) will be completed monthly. Clinician attitude and self-efficacy will be measured at baseline and 9 months. Beneficiary level data will be collected during usual care and includes assessment prior to and after CAPABLE and any assessments that occurred between the two time points.

The *significance* of this project is in the use of the evidence-based model, 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 of an evidence-based intervention to improve outcomes among older adults in a Medicaid waiver program. This natural setting approach has high generalizability for waiver sites, as we learn what intensity of implementation strategies is needed to adopt and sustain evidence, potentially transforming programs of care for our nation's most vulnerable older adults who are aging-in-place. This study is also significant as it addresses a critical barrier to implementation of evidence-based interventions to improve function in older adults living in the community to age-in-place (CAPABLE). The National Institute on Aging focuses on ways to improve function once considered an inevitable part of aging. Likewise, the American Association of Retired Persons, National Aging in Place Council, and National Association of Area Agencies on Aging have aging-in-place as a priority. Evidence suggest 90% of older adults prefer to age-in-place; yet a gap exists between their desire and ability.[29] Thus, further testing of efficacy of an intervention (CAPABLE) in a Medicaid waiver population will fill a gap in science and build evidence.

1.3 SPECIFIC AIMS

The **specific aims** are as follows.

Aim A1 To test the effects of MiCAP with IF alone versus MiCAP with IF+EF with respect to the site-level outcomes of adoption and sustainability (***primary***) and beneficiary-level outcomes of ADL/IADLs, pain, depression, falls, emergency department (ED) visits and hospitalizations (***secondary***) over the next 12 months.

Aim A2 ***Mechanism-of-action*** To determine whether the effects of EF+IF versus IF on primary outcomes are mediated by clinician attitude or self-efficacy at 9 months.

Aim A3 To benchmark the effects of IF and EF+IF on beneficiary outcomes following implementation as compared to pre-intervention.

Exploratory Aim A4 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.

Exploratory Aim A5 To explore whether baseline site leadership and readiness *moderate* the impact of EF+IF compared to IF on primary and secondary outcomes within 12 months in order to determine which sites may require facilitation that is more intensive.

Exploratory Aim A6 To evaluate clinician satisfaction at 1 month, and the cost of implementation and policy impact for IF and IF+EF at 12 months.

The National Institutes of Health (NIH) defines Implementation Science (IS) as the process of applying evidence to the treatment or prevention of human disease.[19-20] A scientific study of methods to promote uptake of evidence into routine care to improve quality and effectiveness of healthcare through the study of influences on clinician and organizational behavior.[21] This study is significant because it addresses testing of multimodal implementation strategies of an evidence-based intervention (CAPABLE) in a Medicaid setting to improve the quality and effectiveness of a waiver.

We will utilize implementation strategies[22] refined in prior work (MiCAP; Hartford/Hillman/CMS) where we trained clinicians (N=34), modified the EHR, and provided CAPABLE for beneficiaries (N=270). We extend our work and train all RNs, OTs, and SWs (N=575) in the 18 waiver sites in MI to implement the CAPABLE model of care for all Medicaid waiver beneficiaries (N=15,000). Guided by site managers, our team will select and train Internal Facilitators (IFs), who are supervisors/employees that work for the waiver site, to conduct facilitation at each site as "Champions". We will utilize waiver employees as the External Facilitators (EFs), who were early adopters of CAPABLE in our prior work, as "Super-Champions" for Arm 2.

Further, we focus on a topic of particular IS import: sustainability of implementation efforts.[23-26] In a recent scoping review of 62 trials and 41 reports in the field of knowledge translation, few studies focused on sustaining interventions.[27] Without sustainment, true practice change may not occur and healthcare outcomes may not improve. Further, we will be one of the first to examine implementation strategy (MiCAP) mechanisms of action - awareness, commitment, confidence, and trust - identified in the work of Abramowicz and colleagues in 2016,[28] while implementing a complex intervention (CAPABLE).

1.4 DESIGN

This 2-arm, 3-year randomized study that will examine implementation strategies (MiCAP) to adopt and sustain CAPABLE and improve beneficiary outcomes[14-15]. The Hybrid-3 approach was selected as we will be testing implementation intervention strategies (MiCAP) while simultaneously gathering information on the evidence-based intervention (CAPABLE) and related outcomes in a new setting, the waiver program sites.[15]

1.5 SAMPLE

The sample includes the following groups:

1. Sites: The 18 Medicaid Waiver program sites in the State of MI.
2. Clinicians: The 575 RNs/OTs/SWs employed by the site to provide care to beneficiaries.
3. Beneficiaries: The 15,000 Medicaid beneficiaries who are recipients of care in the site.

1.6 SETTING

The setting is the MI Medicaid waiver sites.

1.7 INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria

Included are waiver sites under contract as a waiver provider in MI who use the Center for Information Management (CIM) electronic health record (EHR); clinicians employed at the site who are trained in CAPABLE; and beneficiaries who receive care from a clinician trained in CAPABLE.

Exclusion Criteria

Sites not contracted as a waiver site or those not using CIM's EHR will be excluded.

1.8 APPROVALS, DATA USE AGREEMENTS, AND CONTRACTS

The following will occur for this study.

Institutional Review Board (IRB) Approval
In compliance with GVSU and MDHHS policy, prior to data collection we will obtain IRB approval from the following.
1. GVSU
2. MDHHS

We will update the IRBs as changes occur over the course of the study.

Data Use Agreements (DUA)
In compliance with GVSU policy, we will collaborate with the Center for Scholarly and Creative Excellence to fully execute the following DUAs prior to data collection or use.
1. Between the university and MDHHS for: MDS (2017-2021), administrative (2018), Continuous Quality Assessment Review (CQAR) scores (2015-2017), and cost (2020) data
2. Between the university and the 18 sites and CIM for data from EHRs MDS, person centered service plan (PSCP), and progress notes (PNs) data (2017-21).

We will update the DUAs as changes occur over the course of the study.

Contracts to be Execute
In compliance with GVSU policy, we will collaborate with the Center for Scholarly and Creative Excellence to fully execute the following contracts prior to working with a site or data analysis by the statistician.
1. Between the university and the 18 site prior to initiating the project (role and responsibilities; training; tasks; duties; timelines; actions; and use of CAPABLE with fidelity to the intervention).
2. Between the university and the biostatistician prior to data analysis.

We will update the contracts as changes occur over the course of the study.

1.9 ORGANIZATIONS ASSOCIATED WITH THE STUDY

NIA The National Institutes of Aging funded the project (NIA 1 R15 AG058193-01A1). As such, for this study, all requirements (i.e., privacy, confidentiality, Health Insurance Portability and Accountability Act (HIPAA), IRB, budget, report, dissemination, data sharing, protocol, etc.) will be met through execution and implementation of the Notice of Award (NOA) agreement with the university.

CMS The Center for Medicare and Medicaid Services is the oversight organization of MDHHS. As such, for this study, all requirements (i.e., privacy, confidentiality, HIPAA, etc.) will be met through execution and implementation of the MDHHS IRB and DUA.

MDHHS The Michigan Department of Health and Human Services (MDHHS) is the oversight organization of all Medicaid programs for the State of Michigan, and as such, contracts with each of the waiver sites to manage, hire, or contract employees, and provide care to beneficiaries in the waiver program. As an oversight organization, MDHHS collects administrative, CQAR, and beneficiary data and has access to all current and past data of this nature. We will execute an IRB and DUA with MDHHS to perform this study.

Sites Home and Community Based Services Provider waiver program sites are under contract with State of MI MDHHS to manage, hire or contract employees, and provide care to beneficiaries in the waiver program. We will execute a contract and DUA with each site that agrees to participate to perform this study. Deployment will occur in a staged manner, with 2—4 sites each month until all are deployed.

CIM Center for Information Management (CIM) is under contract with MDHHS and 18 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 will obtain a DUA. The following will occur.

1. De-identified data on beneficiaries outcomes from care by clinicians trained in CAPABLE at sites who do not opt-out 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 (RNs/SWs/OTs) 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 (RNs/SWs/OTs) and IFs will not use the data the university (PI/PM) obtained from CIM.

1.10 EVIDENCE-BASED INTERVENTION: CAPABLE

A multi-component model of care, CAPABLE, was designed to reduce the effect of problems with physical function among low-income older adults living at home by addressing an individual's capabilities and the home environment.[11 12] CAPABLE is a 16-week structured program delivered by OTs who conduct 6 home visits and provide assistive devices, RNs who conduct 4 home visits, and a handyman who provides home alterations (i.e., installs devices, environmental modifications, and home repair).[15-19] CAPABLE is interdisciplinary team provides consultation with older adults to help them identify daily activity goals (e.g., taking a shower, walking to the bathroom), evaluate barriers to achieving those goals, and attain outcomes collaboratively.[11, 18] The OT assists older adults to carryout ADLs, instrumental activities of daily living (IADLs) and discretionary activities that are challenging at home such as functional mobility, meal preparation, bathing, and dressing. The RN targets underlying issues that influence ADLs, IADLs, and discretionary activities at home, such as pain reduction, improvement in mood, fall prevention, medication review and management, primary care physician communication, incontinence management, sexual health, and smoking cessation. The Disablement Process,[20] Life Span Theory of Control,[21] and Szanton-Gill Resilience Model[22] underpin CAPABLE. CAPABLE has demonstrated a 49% reduction in the number of ADL difficulties; and 75% of beneficiaries improved their level of ADL performance from baseline to follow-up at 5-months.[17]

Prior Work In prior work of this team, Normalization Process Theory[23] underpinned identification of six adaptations of CAPABLE to fit the waiver population and setting. This included: assigning a team leader (RN), adding SWs to address social and emotional needs, utilizing an RN to conduct medication review rather than a pharmacist, flexibility in the number and type of home visits delivered and the number of weeks (extended to 32 weeks) CAPABLE was provided, care coordinated among the RN, OT, and SW face-to-face, by phone, Skype, or email with the supervisor. A toolkit that included the 12 most common aging-in-place problems (i.e., falls, balance and strength exercises) was provided to beneficiaries; and home alterations were done when medically necessary (Medicaid rule).

1.11 IMPLEMENTATION STRATEGIES

Strategies deployed in this project to implement CAPABLE are shown in the figure; and described below.

Pre-Implementation Strategies

Relationship Building Informal relationships (collaborative work/meetings) are in place between sites and the university team from decades of prior work; and will continue to be built. Formal relationships (contracts) with MDHHS, CIM, and sites will delineate responsibilities and actions for this project.
Readiness to implement and ***leadership*** of the site and ***attitude*** of clinicians will be collected.

Champion Coalition Building IFs are clinicians with exemplary clinical practice and supervisory experience and are expected to be early adopters.

MiCAP Implementation Strategies Deployed in this Project and Domains Affected by Strategies							
DOMAIN AFFECTED BY STRATEGY	**MiCAP IMPLEMENTATION STRATEGIES DEPLOYED IN THIS PROJECT**						
	Pre-implementation		**Implementation: Education & Training**			**Centralize Oversight**	**Audit & Feedback**
	Organization readiness	***Build IF Coalition***	***IF Champions***	***Train clinicians***	***Develop clinical teams***	***EF***	***Implementation intervention outcomes***
Definition	Aspects of an organization determine readiness to implement[22]	IFs coalition to share implementation knowledge[22]	Dynamic interactive training via varying learning methods; & supervision focused on implementation[22]	Training to conduct intervention	Develop/implement teams of clinicians who meet, reflect, & share learnings[22]	Makes things easier for others: support to change attitudes, habits, skills, way of thinking & working[22].	Collect & summarize clinical performance & monitor, evaluate, modify clinician behavior[22]
Actors	Spoelstra, Schueller, waiver clinician	IF, research team	Research team for IF	IF for clinicians	IF, clinicians	EF	Spoelstra, Schueller, IF, EF
Actions	Administer tools; analyze results	Online Bb forum to build capacity; share best implementation strategies	Identify and train train-the-trainers/IF; Pre/post-test	Train clinicians; Pre/post-test; Remediate	IF leads interdisciplinary coordination; feedback on implementation/ Intervention	Assistance to IF (Arm 2)	Monitor Bb & EHR; SIC (scorecard); low adopters moved to Arm 1/2 per protocol
Target of the action	Site	IFs	IFs	Clinicians	Clinicians	IF	Clinicians
Temporality	3-months after funded		When starting implementation			1-month after implement	1 week after **CAPABLE** & ongoing
Dose	Surveys completed Baseline	1-hour discussion weekly	2-hr Bb and 2-hr training; Remediate prn	4-hr online Bb and 4-hr in person training	Meet weekly 1-hour	Weekly for 30 minutes to 1 hour until issues resolved	Weekly results to scorecard in Bb and IF reviews with clinicians; EF reviews with IF
Outcomes affected	Acceptability, readiness	Acceptability	Adoption, sustainability			Adoption, sustainability	Adoption, sustainability, outcomes

Implementation Strategies

Training Clinicians (RNs/OTs/SWs) will be trained in CAPABLE principles, approaches, techniques, and documentation (4-6 hours; pre/post-test).
Interdisciplinary coordination (RNs/OTs/SWs) will be led by IFs, focused on care coordination to promote teamwork; using brainstorming/problem solving care issues to support beneficiary goal attainment.
IFs will ***facilitate*** and EFs will provide ***centralized oversight*** for Arm 2 IFs. An IF at each site and an EF (from prior work and were trained and early adopters of CAPABLE) will be selected by the PI and will be trained (2 hours; and take a pre/post-test) in facilitation. IFs will encourage clinicians to complete CAPABLE training; and for those trained, provide feedback; facilitate fidelity to CAPABLE; and conduct remediation as needed from Month 1 through 9. EF will facilitate IF's work with clinicians trained in CAPABLE and assistance will be tailored to a site's needs.

Audit and Feedback on CAPABLE and implementation strategy fidelity data will be provided to IFs to be used to provide feedback to clinicians and develop an improvement plan as needed. The EF will use the data to facilitate IFs and develop an improvement plan as needed.

1.12 MEASURES AND TOOLS

In this study, we will measure three levels of data:

1. Site level data: Characteristics, leadership, readiness, and implementation completion.
2. Clinician level data: Characteristics, attitude toward evidence-based care, efficacy, and training knowledge and completion.
3. Beneficiary level data: Characteristics and outcomes.

We will also examine fidelity to implementation strategies and CAPABLE. Each are described and shown in the Table below.

Characteristic Measures

Characteristics of site, clinician, and beneficiaries will be collected at baseline. Site level data includes size, CQAR scores, number of supervisors/clinicians, number of beneficiaries, and years contracted in waiver. Clinician level data (RN/OT/SW/IF) includes age, race, gender, discipline, and years working in waiver program site. Beneficiary level data includes age, gender, and race.

Tools

Implementation Leadership Scale (ILS) will be collected at baseline from clinicians to examine organizational leader behavior and actions that actively support implementation of evidence-based practice.[77-78] ILS has 12 items with sub-scales (Cronbach's alpha): proactive leadership (.94); knowledgeable leadership (.97); supportive leadership (.93); and perseverant leadership (.94), each with 3-items. Items are scored on a 5-point scale indicating the degree to which a leader performs specific behavior.

Organizational Readiness to Change Assessment (ORCA) will be collected at baseline from clinicians (Cronbach's alpha .88) and used to examine site readiness to implement evidence-based practice.[79] There are 115 items in the manager tool and 124 in the clinician tool and each has 3-open ended questions regarding readiness. In systematic review of organizational assessments, the TCU-ORC ranked highest for reliability and validity of those available to date.[79] Scoring for each scale are obtained by summing responses among each scale; then divide by the number of items; and then multiply the mean by 10. Sub-scales include needs (clinician, program, training); pressure for change; resources (offices, clinician, training, equipment, internet, supervision); and attributes (growth, efficacy, influence, adaptability, satisfaction, and orientation).

Evidence-Based Practice Attitude Scale (EBPAS) and General Self-efficacy (GSE) will be collected from clinicians at baseline and 9 months. EBPAS is a 50-item tool with 12 sub-scales that measures four constructs: openness; appeals of the new intervention (appeal); willingness to using required interventions (requirements); and conflict between clinical experience and research results (divergence).[80] Questions are on a 5-point scale. GSE is a 10-item tool (Cronbach's alpha .79-.90) with items rated on a 4-point scale summed to produce a score ranging from 10 to 40.

MDS-HC Data on demographic characteristics (age, race, and gender), health status (I/ADLs, pain, depression, and falls), ED visits, and hospitalizations collected on the Minimum Data Set-Home Care (MDS-HC) ***collected in*** the EHR as part of usual care will be obtained. The MDS-HC is a self-reported, person-centered assessment for the collection of minimum essential nursing data, developed by InterRai, with reliability and validity, and used in the waiver since 1993.

Stages of Implementation (SIC) is an 8-stage tool examining implementation with 3 phases (pre-implementation, implementation [adoption], sustainability). Items delineate the date a site completes activities, yielding an assessment of duration (time to complete a stage), proportion (stage activities completed), and a general measure of how far a site moved in the process.[81] [82]Three scores will be derived:

1. *Number of stages completed* is a simple count of progression through stages; the score is the last stage in which at least one activity was performed.
2. *Time spent in each stage* is calculated by taking the difference between the date of completion of the first activity in the stage and the date of completion of the last activity in the same stage. Skipped activities are not included. If a site skips the last activity in a stage and completes an activity in a subsequent stage, they automatically move to the subsequent stage. However, if they later complete the skipped activity, the duration score is adjusted for the original (earlier) stage to include the activity.
3. *Completed all 8 stages*: the completion date is logged in stage 8. For sites that chose to discontinue implementation at any point in the process, the date is logged in the furthest stage that the site enters. In the case where data are summarized before the stage is complete but a site has not discontinued implementation, the site data are treated as being censored, just as it would in a standard time-to-event or survival analysis.[83] *Proportion of activities completed* is calculated as the number of activities completed divided by the number of possible activities in each stage. Activities in each stage are ordered based on their logical progression up to the last activity the site completes in the stage or completion of the final activity in the stage. Achievement of either activity indicates completion of that stage.

Measures						
DOMAIN	**CONSTRUCT**	**CONCEPT(S)**	**Aims***	**Who Measured**	**How Measured**	**Collected by**
Inner Setting	Readiness for Implementation	Leadership Engagement	A5	Sites	ILS	PM
		Readiness to implement			ORCA	
		Size of WA Agency			Admin Data 18	-
		CQAR Scores			CQAR 2016-18	
Individual: Site and/or person	Demographics	Site # employees/ beneficiary#, CQAR, cost	-	Sites	Admin Data	
		Clinician: age/race/ethnicity/sex/discipline/ degree/year experience/in WA		Clinician	Survey	PM
		Age, sex, race, ethnicity, comorbidities		Beneficiary/patient	MDS	-
	Clinician: engagement	1. Attitude 2. Self-efficacy	A2	Clinician	1. EBPAS 2. GSE	PM
	Beneficiary/patient outcomes	I/ADLs, falls, pain, depression/ED/hospital	A3 & A4	Beneficiary/patient	MDS	-
Process	Training	Knowledge with CAPABLE	A2	Clinician	Survey	PM
		Knowledge with IF/EF		IF/EF		
	Team Building	Interdisciplinary coordination		Beneficiary/patient	PNs in EHR	-
	Coalition Building	Occurrence/type		IF	Data tool	
Inner Setting	Adoption	Fidelity to training	A1 & A2	Clinician	Type/date/# done	PM
		Fidelity to IF/EF		IF/EF	IF Data tool	RAs
		Fidelity to CAPABLE		Beneficiary/patient	PSCP in EHR	-
	Sustainability	Fidelity to change		Sites	SIC	RAs
	Acceptability	Satisfaction with training	A6	Clinician IF EF	Survey	PM
	Cost	$	A6	Clinician IF EF beneficiary/patient	Wages, benefits	PM
Outer Setting	Policy	Payment for incentive	A6	CMS Contract	Contract 10/1	PM

Fidelity Measures

Implementation Strategies Data on implementation strategy fidelity (monthly for 12-months) includes readiness assessment (yes/no by manager/clinician), training (#CAPABLE certification), IF/EF (#/type), and audit and feedback (# reports viewed/# actions). Actions coded will include training, coaching, consultation, supervision, modeling, problem solving, and providing feedback, supporting, instructing, demonstrating, and assisting with evaluation.

Acceptability of training by clinicians, IFs, and EFs will be evaluated by number completing training and via conduction of pre-/post- tests devised in our prior work.

Costs of implementation will be estimated based on the time spent in Bb, training, and meetings.

Measure of policy impact will be examined in the waiver contract.

CAPABLE An EHR assessment (OT [baseline assessment]/SW [mood]/RN [medication review), PSCP (presence of desire of beneficiary), and PN (documentation of brainstorming, problem solving, role modeling) review will provide data of use of CAPABLE as a measure of fidelity comparing pre/post CAPABLE.

1.13 DATA COLLECTION, MANAGEMENT, SAFETY, AND STORAGE

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 beneficiary, clinician, and IF names and IF phone number. The names will be used by the PI/PM in the key to assign a study number and will be used to track progression. All data (Excel sheets) will use the study number (not the name). Only the PI/PM have access to the study key. The Research Assistants will call the internal facilitator's using the provided phone number. No other PHI will be collected for the study.

Data Collection and Management for this study will include site, clinician, beneficiary, and fidelity data.

1. Site data will be collected from MDHHS (administrative data) at baseline; and clinicians' leadership and readiness from electronic survey in Qualtrics.
2. Clinician data collection (characteristics, attitude toward evidence-based care, efficacy) will be from an electronic survey in Qualtrics and from the Bb platform (training knowledge and completion).
3. Beneficiary outcome data (de-identified) will be from CIM (characteristics and outcomes).
4. Fidelity data on:
    a. Implementation completion (SIC) will be collected from telephone survey conducted by RAs at the university.
    b. Implementation strategy use (IF/EF Data Tool) will be collected from telephone survey conducted by RAs at the university.
    c. 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.).

MDHHS

Per the DUA, MDHHS will provide administrative data via a data transfer to the university (PI/PM). 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.

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 the Qualtrics platform where surveys will be deployed for this study.
    - Only the PI/PM will have access to the Qualtrics platform identifiable data for this study.
    - RAs conducting the telephone surveys of IFs will complete a survey in Qualtrics.
- 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.
- Data for the study would not be available to the site, clinicians, or supervisors.

Bb

Blackboard (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 (RN/OT/SW) and IF/EF 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 (RN/OT/SW) and IF/EF 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.

Month obtained	DATA COLLECTION: Obtained from and What Obtained				
	MDHHS	**Clinicians (RN/OT/SW)**	**IFs**	**EFs**	**CIM**
0	#beneficiaries #staff #supervisors #years MiChoice CQAR 2015-17	Consent Demographics ILS ORCA	Consent Demographics ILS ORCA	Consent Demographics ILS ORCA	MDS in EHR
1		Consent Demographics EBPAS GSE Train: CAPABLE pre/post/satisfaction	Consent Demographics EBPAS GSE Train: CAPABLE pre/post/satisfaction Train: Facilitation pre/post/satisfaction	Consent Demographics EBPAS GSE Train: CAPABLE pre/post/satisfaction Train: Facilitation pre/post/satisfaction	
2			SIC; IF/EF Data Tool		PSCP & PNs in EHR
3			SIC; IF/EF Data Tool		PSCP & PNs in EHR
4			SIC; IF/EF Data Tool		PSCP & PNs in EHR
5			SIC; IF/EF Data Tool		PSCP & PNs in EHR
6			SIC; IF/EF Data Tool		PSCP & PNs in EHR
7			SIC; IF/EF Data Tool		PSCP & PNs in EHR
8			SIC; IF/EF Data Tool		PSCP & PNs in EHR
9		EBPAS GSE	EBPAS GSE SIC; IF/EF Data Tool	EBPAS GSE	PSCP & PNs in EHR
10			SIC; IF/EF Data Tool		PSCP & PNs in EHR
11			SIC; IF/EF Data Tool		PSCP & PNs in EHR
12	Cost		SIC; IF/EF Data Tool		MDS, PSCP, PNs in EHR
	Policy	Review of CMS Contract			

The above table depicted deployment of data collection activities by month, where the data will be collected from, from whom the data source is (site, clinician, IF, beneficiary), and which measures (characteristics/tool) and tools (SIC, GSE, EBPAS, etc.) are used to collect the data.

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.

1.14 DATA ANALYSIS

Preliminary analysis

The distributions of outcomes, mediators, and potential covariates will be assessed, outliers will be investigated by inspecting the residuals, and models described below will be fit with and without outliers to examine their influence on the results. Analyses will be implemented in SAS 9.4 as follows:

Aim A1 To test the effects of MiCAP with IF alone versus MiCAP with IF+EF with respect to the site-level outcomes of adoption and sustainability (***primary***) and beneficiary-level outcomes of ADL/IADLs, pain, depression, falls, emergency department (ED) visits and hospitalizations (***secondary***) over the next 12 months. Primary outcomes will be analyzed using a linear mixed effects model with repeated measures: 11 monthly measures of the SIC, 11 monthly summary records of clinician's actions based on EHR documentation, and monthly for 9 months measures from IF tools (statistical model #1). Covariates will include trial arm, variables used in randomization (site's size and CQAR score), and time entered as a class variable to model potentially non-linear patterns. In addition, we will use general liner model to analyze clinicians' fidelity training data. Log-rank test and Cox proportional hazard modeling will be employed to analyze time spent in each stage (treated as censored if a site does not complete a given implementation stage). The test of significance of the coefficient of the trial arm variable will yield the formal test of hypothesis associated with this aim for the main (time-averaged) effect of IF+EF v. IF alone. The analysis of secondary beneficiary-level outcomes will employ use generalized linear model with appropriately distributed errors and the random effect of site added to account for nesting of individuals within sites. For counts of falls and health service use, Poisson error distribution will be specified. Alternatively, as a zero-inflated Poisson or negative Binomial model based on the distribution of the counts will be fit. The explanatory variables including trial arm will be evaluated as predictors of zero inflation (whether or not the count is zero), and as predictors of the magnitude of the count when it is not zero. Pre-intervention MDS assessment will be used to obtain baseline version of each outcome, which will be included as a covariate to explain the variation in post-intervention outcomes.

Aim A2 ***Mechanism-of-action*** To determine whether the effects of EF+IF versus IF on primary outcomes are mediated by clinician attitude or self-efficacy at 9 months. In addition to statistical model #1, statistical model #2 will be fit at the clinician level with site as a random effect to account for nesting of clinicians within sites. To test for mediation, trial arm will be treated as the independent variable; each of the potential mediators (one at a time) will be tested for their effect on the outcome variable. We will use a bias corrected bootstrapping analytic strategy[86-87] based on 5000 bootstrap samples to estimate confidence intervals around the indirect effect of the trial arm on the outcome variable, through the mediator. To establish mediation, the 95% confidence interval around the indirect must not include 0.

Aim A3 To benchmark the effects of IF and EF+IF on beneficiary outcomes following implementation as compared to pre-intervention. The analysis of this aim will use 2 repeated measures of beneficiary outcomes: at the start of this study (pre-intervention) and in the following 12 months. Time by trial arm interaction will be included. The least square (LS) means according to the interaction term will be output from this model, and differences from pre-to-post CAPABLE will be evaluated for each arm to gauge the magnitude and practical meaning of improvements.

Exploratory Aim A4 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. General or generalized linear models (as appropriate based on outcome or potential mediator distribution) will include the binary indicator of whether SIC at 6 months is >50% or <50% in interaction with the trial arm variable. Differences between LS means according to SIC level will be tested within each arm. Because these analyses are exploratory, in addition to formal tests of significance, the effect sizes will be estimated.

Exploratory Aim A5 To explore whether baseline site leadership and readiness *moderate* the impact of EF+IF compared to IF on primary and secondary outcomes within 12 months in order to determine which sites may

require facilitation that is more intensive. To address this aim, statistical models described under analysis for Aim 1 will be modified to include trial arm by potential moderator interaction. The effect sizes that correspond to the interaction term will be estimated.

Exploratory Aim A6 To evaluate clinician satisfaction at 1 month, and the cost of implementation and policy impact for IF and IF+EF at 12 months. We will use descriptive statistics to summarize clinician satisfaction with training and the cost of implementation. We will use qualitative thematic analysis to analyze all qualitative data on survey tools. We will report on the policy impact as evidenced in the State Contract for the Medicaid Waiver program.

1.15 SAMPLE SIZE AND POWER CONSIDERATION

Aim 1: The sample size considerations for this study are based on the number of available sites given the project scope and timeline: N=18 sites will participate. With N=9 randomized to each condition, correlation of 0.7 between pairs of 11 repeated measures, the detectable adjusted effect size for the site-level outcomes is approximately 1.2, expressed as Cohen's d, difference between trial arm means in the standard deviation units. If the observed differences are smaller than 1.2 of the standard deviation, statistical significance will not be reached, then the estimate of the effect size will be obtained and used to formally power a subsequent R01-size study that will be proposed based on the results obtained in this R15 project. For the beneficiary-level outcomes, we assumed an average N=750 beneficiaries analyzed per site and conservative intraclass correlation coefficient of 0.01 for planning purposes to obtain the design effect factor DEFF=8.49. In the comparison of the trial arms for the beneficiary-level outcomes, the sample size adjusted for the design is 795 per trial arm, and it allows to detect the effect size as small as 0.14 Larger effects were seen in the preliminary studies for the beneficiary-level data, and 1/3 of the standard deviation or larger is often used as a threshold for clinical significance.[88-89] Since even small effects could be detected as statistically significant, the study is well powered to detect any meaningful differences between IF and IF+EF in beneficiary outcomes. The tests of mediation effects in Aim 2 will have an even greater power because of further reduction in error variance due to controlling for the mediator. Aim 3 benchmarks the outcomes against the pre-intervention period and has no associated hypotheses. Thus, power considerations are not applicable. Similarly, exploratory aims 4-6 have no associated hypotheses; thus, the results will be used for generation of hypotheses for the future R01-scope trial.

1.16 RANDOMIZATION

Randomization for this study occurs at the site level. Sites will be randomized by the PM, to **Arm 1** (MiCAP with IF) or **Arm 2** (MiCAP with IF+EF) using the following steps.

Step 1: Data on site size (number of beneficiaries [patients]) and Clinical Quality Assessment Review (CQAR) scores will be obtained.

Step 2: We will block sites in pairs with similar size and CQAR scores, and flip a coin to determine A**rm 1** or **Arm 2** assignment for study.

The PM will maintain 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 sites, clinicians (RNs/OTs/SWs/IFs), and beneficiaries will occur.

Sites and clinicians will be informed of the benefits of CAPABLE from prior work; beneficiaries who received CAPABLE had improved ADL/IADLs, fewer falls and hospitalizations as well as being highly satisfied; and clinicians with increased knowledge in CAPABLE improved those beneficiaries outcomes.

Sites: PI/PM will contact a site via phone to confirm intent to participate; then provide the contract for review. Sites who sign a contract agree to be a part of the study.
Clinicians: PI will ask clinicians (RN, OT, and SW, IFs) to complete CAPABLE training using a flyer/email. Clinicians who sign the consent, agree to be a part of the study.
Beneficiaries: The state and sites will provide the Opt-out Consent document to the beneficiaries, which includes an option to opt out of the study by calling the PI, if desired.

1.18 INFORMED CONSENT AND HIPAA COMPLIANCE

Clinician Informed Consent Clinician (RN/OT/SW/IF) informed consent will be conducted and an electronic signature obtained on the consent form approved by IRB prior to data collection and CAPABLE training. The consent form will be modified and approved by the IRBs, if changes are necessary, prior to use.
Beneficiary Opt-out Consent and **HIPAA (Health Insurance Portability and Accountability Act) Authorization** Alteration via a waiver of documentation of informed consent for the Medicaid beneficiaries will occur via two modes.

- For current Waiver beneficiaries: the State or sites will mail the Opt-out Consent document or the sites will hand deliver opt-out consent form to the beneficiary during the next home visit.
- For new Waiver beneficiaries: sites will include Opt-out Consent document in enrollment packets, which will be hand delivered to the beneficiary during their initial home visit in the Mi Choice program.

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 WITHDRAWL OR DISCONTINUATION

A site, clinician, 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. Withdrawal and discontinuation are included in the contracts. Decisions to participate or not will not affect their current or future employment or status as a Medicaid program in the State. 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

Sites, clinicians 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 sites, and individual clinicians and beneficiaries.

Benefits of Participation

Sites There may or may not be direct benefits for the sites. Sites may gain knowledge from this study will help determine ways to assist waivers caring for disabled individuals living in the community, may improve retention of clinicians, and may save costs. Findings may help future waiver sites, clinicians, and beneficiaries.
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.
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 home visits. 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

Sites can agree or not agree to participate in the study. A contract will be obtained prior to data collection.
Clinicians Clinicians can agree or not agree to participate in the study. Clinicians (RNs/OTs/SWs/IFs) employed by the sites will participate in this study. A consent will be obtained from a clinician prior to completing surveys. 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 CAPABLE training: The IF who is also a supervisor at the site where the clinician is employed and performs "usual" Waiver care will have access to "all" beneficiary electronic health records, and be informed of CAPABLE trained fidelity performance/non-performance by a clinician and/or be informed by PI/PM of need a for a clinicians to have remediation for fidelity to CAPABLE. To minimize the risk, IFs will be trained in how to motivate and conduct remediation. Will include in the contract with sites that need for clinician remediation would not impact a clinicians employee status if consent to participate in the study.
Beneficiaries Beneficiaries have the option to opt out of the study if desired; and will to receive "usual" waiver care regardless of decision to participate or not participate in the study.
Protecting Confidentiality Identifying information (name, address, date of birth, Social Security or Medicare numbers) 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.
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 3-years. 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. 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.

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 2019.
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 18 sites:

1. Annual written report of clinical trial progress will be written and submitted each September (2019, 2020)
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 sand 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

Number	Attachment
A1	NIA Application (resubmission)
A2	Study Protocol V4 10-31-2018
A3	Consent Form (clinicians [RN/OR/SW/IF])
A4	Measures (administrative data, characteristics)
A5	ILS
A6	EBPAS
A7	GSE
A8	SIC
A9	IF/EF Tool
A10	Email/flyer for clinician training participation

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