Clinical Interventional Study Protocol

Protocol Version 2.0

TESTING THE FEASIBILITY OF THE INDIVIDUALIZED POSITIVE PSYCHOSOCIAL INTERVENTION (IPPI):

Pilot testing of an evidence-based program engaging 108 to 135 persons living with dementia in brief one-to-one preference-based activities

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Summary of Changes

Page/Section	Description of Change	Rationale
6, 12, 13, 14, 16, 21, 32, & 33	Update to the number of residents sites will enroll (from 15 to 20), length of time they will enroll will be extended by 1 month (from 3 to 4 months), and number of residents enrolled per month updated to 3-8 residents/month. Lastly, we have increased the number of staff participating in the emotion-focused communication training from 30 to up to 75 as we already have 50 staff and anticipate more being trained. The number of staff completing exit interviews remains unchanged.	One of our recruiting sites was sold to another company and will not be participating. Another site decided not to participate. Due to being down two recruitment locations we have asked the remaining 7 sites to enroll a few more residents to meet our enrollment targets and are giving them an additional month to complete enrollment. There has been great interest in the emotion-focused communication training and more staff than we anticipated have gone through the course.
9-10	Updating participating study sites	Two recruitment locations are not participating.
38	Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the sponsor or persons working on behalf of the sponsor (i.e. IMPACT research study staff, the DSMB and/or Safety Officer), the FDA, the NIA and its authorized representatives, and the OHRP.	New policy since my protocol was approved.

TABLE OF CONTENTS

Page

PRÉCIS

Study Title

Testing the Feasibility of the Individualized Positive Psychosocial Intervention (IPPI)

Objectives

The primary objective is to effectively deploy the IPPI program so that care providers can use the program as a part of their routine care delivery. Implementation will result in decreased expressions of behavioral distress and/or depressive symptoms for residents engaged in the program at 3-month and 6-month intervention follow-up and increased knowledge of emotion-focused communication and self-efficacy for using emotion-focused communication for care providers. Our secondary objective is to demonstrate program feasibility and fidelity as well as document barriers and facilitators in implementation.

Design and Outcomes

This study will examine the non-randomized trial of a pragmatic delivery of the IPPI program with n=108 nursing home (NH) residents to test program feasibility and impact on clinical outcomes for residents (symptoms of behavioral distress and/or depression) and up to n=75 staff (knowledge of emotion-focused communication and self-efficacy for using emotion-focused communication strategies).

Interventions and Duration

The Individualized Positive Psychosocial Intervention (IPPI) is an evidence-based program that engages PLWD in brief (i.e.,10 minute) one-to-one preference-based activities 2 times a week. To provide IPPI, care partners first complete an online course on emotion-focused communication (EFCT). This course improves care partners' emotional communication skills to be able to build stronger relationships and provide more positive care experiences for PLWD and care partners, alike. The care partners are then trained to deliver IPPI activities via short protocols to guide brief one-on-one interactions with PLWD.

Care partners will initiate implementation of the preferred IPPI activity with 3-8 residents per month upon completion of their quarterly or annual MDS 3.0 assessment (this will serve as baseline data). Initiation of engagement will be rolling, adding an estimated 3-8 residents per month for up to 4 consecutive months. The care partners will implement a minimum of 2 IPPI protocols per week with each enrolled resident for 6 months, to ensure continuous completion of the intervention through to the date of the resident's next two quarterly or annual MDS 3.0 assessments (3-month and 6-month follow-up data).

Sample Size and Population

We will partner with United Church Homes (UCH), a 106-year-old nonprofit national senior living provider to train care partners to use the IPPI program in 7 NHs in Ohio. The volunteer implementation team (e.g., approximately 3-4 staff per community, working any shift and from any department) will complete an online training and then

identify residents who have cognitive impairment and who have experienced symptoms of distress or depressive symptoms within the past 2 weeks, regardless of resident age, race, gender, or ethnicity. This study will include 105 to 110 nursing home residents (e.g., approximately 15-20 per community), and up to 30 staff will provide exit interviews about the program.

STUDY TEAM ROSTER

Principal Investigator: Katy M. Abbott, Ph.D., MGS

Scripps Gerontology Center
Miami University
367-C Upham Hall
Oxford, OH 45056
513-529-0869
abbotttkm@miamioh.edu
Main responsibilities/Key roles: Dr. Abbott will lead the project and work with leadership at the nine NH communities that UCH both owns and manages in the State of Ohio to implement the IPPI. Dr. Abbott will be responsible for the overall project including IRB approval, DSMB communications, Data Use Agreements, and oversee both qualitative and quantitative data analysis. She will be responsible for writing all final reports.

Project Manager: Molly Noble

Scripps Gerontology Center
Miami University
369B Upham Hall
Oxford, OH 45056
513-529-3605
nobleme2@miamioh.edu
Main responsibilities/Key roles: The Project Manager will assist with the virtual coaching to the NH communities who are working on the IPPI QIP. This individual will conduct the virtual orientation to the IPPI, be the point person that champions can reach out to for assistance, retrieve data from the EFCT LMS, and assist with conducting the semi-structured exit interviews with staff. These interviews will be audio recorded and the individual will transcribe the sessions, code, and analyze the qualitative data with Dr. Abbott.

Website Supervisor: Dennis Cheatham, MFA

Miami University
College of Creative Arts, Department of Art
Hiestand Hall 223
Oxford, OH 45056
513-529-7424

cheathdm@miamioh.edu
Main responsibilities/Key roles: Mr. Cheatham will ensure that all documents and training materials are usable and accessible to providers through the preferencebasedliving.com website, update security patches, and support hosting needs for the website.

Biostatistician: Alexandra Hanlon, Ph.D.

Virginia Tech
Department of Statistics
Four Riverside Circle MC-0801
Roanoke, VA 24016
540-526-2264
alhanlon@vt.edu
Main responsibilities/Key roles: Provide guidance and support on all quantitative analyses to be conducted for the project.

Statistical Consultant: Allison R. Heid, Ph.D.

2949 Oakford Road
Ardmore, PA 19003
703-727-6570
allisonrheid@gmail.com
Main responsibilities/Key roles: Dr. Heid will support data management and complete analysis for all quantitative data collected under the supervision of our biostatistician, Dr. Hanlon.

Co-Investigator: Kimberly Van Haitsma, PhD

The Pennsylvania State University,
Professor, Ross and Carol Nese College of Nursing
Director, Program for Person Centered Living Systems of Care
Adjunct Senior Research Scientist, The Polisher Research Institute at Abramson Senior Care
201 Nursing Sciences Building, University Park, PA 16802
ksv110@psu.edu
Main responsibilities/Key roles: Dr. Van Haitsma was the PI on the original IPPI RCT and will provide consultative support on the implementation of the project as well as analysis, and interpretation of study findings.

PARTICIPATING STUDY SITES

Dr. Abbott will be responsible for all of the research activities that are carried out at each site. There are no site-specific PIs. Dr. Abbott and/or the project manager Molly Noble will touch base with each site on a monthly basis as well as on an as needed basis. These meetings will serve as brief progress updates as well as trouble shooting sessions.

United Church Homes Administrative Support: Amy Kotterman

United Church Homes
170 East Center Street
Marion, OH 43302
O: 740.382.4885 | M: 614.496.7675
Email: AKotterman@uchinc.org
Main responsibilities/Key roles: Ms. Kotterman will assist with interfacing with the nine NH communities throughout the state of Ohio. Ms. Kotterman will also assist with identification of implementation co-champions, communication between their IT services and Dr. Abbott and assisting with scheduling the in-person semi-structured exit interviews.

Study Site Administrator 1: TBD

SEM Haven
225 Cleveland Ave.
Milford, OH 45150
Main responsibilities/Key roles: Oversee IPPI implementation in SEM Haven NH community.

Study Site Administrator 2: TBD

The Trinity Community at Beavercreek
3218 Indian Ripple Road
Beavercreek, OH 45440
Main responsibilities/Key roles: Oversee IPPI implementation in The Trinity Community at Beavercreek NH community.

Study Site Administrator 3: TBD

The Trinity Community at Fairborn
769 Stoneybrook Trail
Fairborn, OH 45324
Main responsibilities/Key roles: Oversee IPPI implementation in The Trinity Community at Fairborn NH community.

Study Site Administrator 46: TBD

The Parkvue Community
3800 Boardwalk Blvd.
Sandusky, OH 44870
Main responsibilities/Key roles: Oversee IPPI implementation in The Parkvue Community NH community.

Study Site Administrator 67: TBD

The Chapel Hill Community
12200 Strausser St NW.
Canal Fulton, OH 44614
Main responsibilities/Key roles: Oversee IPPI implementation in The Chapel Hill Community NH community.

Study Site Administrator 78: TBD

The Four Winds Community
215 Seth Avenue
Jackson, OH 45640
Main responsibilities/Key roles: Oversee IPPI implementation in The Four Winds Community NH community.

Study Site Administrator 89: TBD

The Harmar Place Community
401 Harmar Street
Marietta, OH 45750
Main responsibilities/Key roles: Oversee IPPI implementation in The Harmar Place Community NH community.

1 STUDY OBJECTIVES

1.1 Primary Objective

The primary objective is to effectively deploy the IPPI program so that care providers can use the program as a part of their routine care delivery. We hypothesize that implementation of IPPI will result in decreased expressions of behavioral distress and/or depressive symptoms for residents engaged in the program at 3-months and 6-months following intervention initiation and increased knowledge of emotion-focused communication and self-efficacy for using emotion-focused communication for care providers delivering the intervention.

1.2 Secondary Objectives

Our secondary objective is to demonstrate program feasibility and fidelity, as well as document barriers and facilitators in implementation.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Over 75% of people living with dementia (PLWD) experience psychological and behavioral symptoms of distress. Expressions of distress can be both upsetting to the individual and care providers. Symptoms of distress can include wandering, persistent vocalizations, and resistance or refusal of care. In addition, depressive symptoms are common among NH residents living with dementia.

In the US, 59% of the long-stay NH population has dementia (National Academies of Sciences, Engineering, and Medicine, 2022). To support PLWD in the NH, Kitwood (1997) recommended person-centered care to affirm the personhood of the individual receiving care. The foundation for this care is rooted in trusted interpersonal relationships between the resident and their care team members with the goal of focusing on how a care task is completed in a way that enhances dignity. One crucial component to completing a care task with dignity is to individualize care. This means that the individual's preferences are assessed and honored throughout the care delivery process. However, easy to use processes are not in place in most NHs to support systematic delivery of preference-based, person-centered care for PLWD.

2.2 Study Rationale

The Individualized Positive Psychosocial Intervention (IPPI) is an evidence-based program designed to support care partners in engaging PLWD in positive person-centered ways that enhance well-being and reduce negative emotional and behavioral responses using non-pharmacological approaches (Van Haitsma et al., 2015). The IPPI program targets communications of distress of PLWD. IPPI provides guidance for care partners to initiate short 10-minute positive interactions with PLWD based on a resident's stated preferences. The IPPI program is built on the premise of the importance of recreational congruence. By matching recreational activities to preferences expressed by the resident, the resident's needs can be met in a way that maximizes well-being. Tailored recreational activities have been shown to improve the following outcomes among NH residents: improved depressive symptoms (Bailey et al., 2016), positive affect (Cohen-Mansfield et al., 2011), increased pleasure (Cohen-Mansfield et al., 2007), alertness (Kolanowski et

al., 2011), engagement (Van Haitsma et al., 2015), as well as reduced anxiety (Cohen-Mansfield et al., 2007) and agitation (Feliciano et al., 2009). In addition, studies have shown that a Tailored Activity Program has benefited staff and family caregivers by improving caregiver well-being (Gitlin et al., 2021), reducing upset with behavioral symptoms (Gitlin et al., 2009), and enhancing both resident and carer engagement (Gitlin et al., 2021; O'Connor et al., 2017), as well as skills such as communication and simplification (O'Connor et al., 2017).

A previous Hybrid III randomized-controlled trial of the IPPI program funded by the Alzheimer's Association with 180 PLWD in NHs found that PLWD had fewer negative emotional and behavioral responses when receiving IPPI compared to those receiving usual care interventions. They also experienced higher well-being as evidenced by more pleasure, alertness, engagement, and positive verbal behavior compared with the usual care group (Van Haitsma et al., 2015).

The goal of this project is to assess the pragmatic application of the IPPI program by UCH. A non-randomized feasibility trial will be conducted to determine if providers can independently and effectively implement the IPPI program/protocol. The IPPI program targets PLWD who are communicating distress (either behavioral distress or depressive symptoms). We will ask for staff volunteers to be a part of the site's implementation team. We anticipate the team being comprised of two co-champions (e.g., director of nursing and activities director or memory care coordinator) in addition to 2-3 care partners (e.g., CNA, activities assistants). These individuals will first complete the emotion-focused communication online training.

Next, champions will be trained to identify eligible residents following a resident's quarterly or annual MDS 3.0 assessment. If the resident triggers for cognitive impairment, as indicated by a Brief Inventory for Mental Status (BIMS; Saliba et al., 2012) score of 0-12 (a screening to identify individuals with cognitive impairment) *and* distress as reported in Section D (non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness) or Section E (non-zero response on a behavior) the resident will be enrolled in the IPPI program.

Champions will train the care partners to deliver IPPIs to each identified eligible resident. Care partners will be asked to conduct 2 IPPIs per week with each resident for 6 months. Selected residents will be engaged with the IPPI program for 6-months. IPPI enrollment will be rolling for the first 3 to 4 months of project initiation. Each time a quarterly/annual MDS 3.0 assessment is completed for a resident, if the resident triggers for both cognitive impairment and distress, the resident will be considered for IPPI enrollment. We estimate enrollment of 3-8 residents per community per month during the first 3-4 months of project initiation. The IPPI intervention will then continue to be delivered for 6-months for each enrolled resident. Intervention dosage is based on findings from our preliminary study (Van Haitsma et al., 2015).

No known risks of the intervention are anticipated. Potential risks of engaging in an IPPI activity are that the resident may become frustrated if the activity is not appropriately matched to their remaining strengths. We will work with the implementation team to understand how to use a strengths-based approach to adapt a preferred activity. For example, if a resident enjoys gardening but is not able to kneel down to the ground, a flower box placed on a table to allow the resident to plant flowers may be recommended. In addition, the staff will be trained in emotion-focused communication to identify body

language cues when a resident is in distress and unable to communicate. For example, if the resident enjoys sitting outside, but then becomes hot in the sun. The staff can recognize the change in emotion and alter the activity.

3 STUDY DESIGN

The IPPI program targets communications of distress of PLWD. IPPI provides guidance for care partners to initiate short 10-minute positive interactions with PLWD based on a resident's stated preferences. The IPPI intervention first teaches care partners strategies to better identify and manage their own feelings and those of the PLWD using an on-line, self-paced, emotion-focused communication course (EFCT). Strategies taught in the course are designed to build care partners' emotional communication skills, forge stronger relationships and provide more positive care experiences for care partners and PLWD alike. The IPPI program, designed with flexibility and feasibility in mind, is delivered in a series of simple steps including: 1) utilizing mandatory preference assessments (16 preferences collected in Section F of the MDS 3.0; e.g., being around animals such as pets, choose what clothes to wear, going outside), 2) using the care planning meeting to match a resident's important preferences with 1-2 appropriate IPPI protocols, 3) care partner delivery of one of the matched IPPI protocols with the resident, 4) real time feedback for the care partner provided by a site champion on how to follow the IPPI protocol, and 5) conducting IPPIs with a resident for approximately 10 minutes 2 days per week, at a time convenient for both the care partner and resident.

More specifically, a team of staff members who volunteer to carry out the project, making up the implementation team, will be solicited at each of the 7 sites. We expect the team to be comprised of one or two champions as well as 2-3 care partners who will be provided information about the IPPI program. Pulling from the Expert Recommendations for Implementing Change (ERIC) Project (Powell et al., 2015), we will start by documenting the organization's level of readiness for implementation and preparing the implementation team. This will include ensuring that each NH has staff members (such as director of nursing and activities professional) who can serve as champions (e.g., director of nursing and activities professional) as well as care partners (e.g., CNAs, activities professionals) who can deliver IPPI activities to residents. The implementation team will be invited to be trained for the program. Our project manager, Molly Nobel, will provide the following support: (1) guidance for the champion(s) to coach care partners in identifying an eligible resident upon completion of an annual or quarterly MDS 3.0 assessment who triggers for cognitive impairment and distress; (2) access to interactive online education materials; and (3) ongoing on-demand/as needed and scheduled (i.e., monthly) virtual consultation/facilitation for troubleshooting purposes. The implementation team will also be provided with developed informational resources that can be shared with local opinion leaders and stakeholders, such as family members.

Eligible residents will be identified by the implementation team (e.g., champion(s) upon completion of an annual or quarterly MDS 3.0 assessment. IPPI eligible residents must have a BIMS score of 0-12 and communicate distress (as reported in Section D (non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness) or Section E (non-zero response on a behavior)) on the MDS 3.0 assessment.

The implementation team will be trained with the online emotion-focused communication training (approximately 2 hours – broken up into six 15-20 min modules), complete

provided IPPI activity training videos (each 10-15 min), and be provided the IPPI manual with a checklist of steps, 60+ different IPPI protocols that address all 16 MDS 3.0 preferences in Section F, sample letters/scripts introducing the IPPI to family and staff, and communication tips sheets. Any member of the implementation team can deliver an IPPI activity. We will ask champion(s) to demonstrate an IPPI for care partners (e.g., CNAs) to watch, and then observe each care partner's initial IPPI implementation.

The champion(s) will be provided with a pragmatic data collection binder of paper forms (See Appendix A) to record these initial observations (in the form of a checklist). In addition, this binder will include a form to document staff training completion, resident preferences, and the behavior or mood item to target with the IPPI program that is most distressing to each identified eligible resident. Forms for champion(s) to document adverse events and withdraws will also be included in the binder.

Implementation team members will align stated preferences of each eligible resident with specific IPPI protocols (i.e., important preference for reading will be matched with a reading activity IPPI protocol). While any implementation team member can deliver an IPPI activity, we will encourage care partners to take the lead in implementation of the preferred IPPI activity with each enrolled resident on a regular basis. Initiation of engagement will be rolling, adding 3-7 residents per month for 3-4 consecutive months. The care partners will implement a minimum of 2 IPPI protocols per week with each resident for 6 months, to ensure continuous completion of the intervention through to the date of the resident's next two quarterly or annual MDS 3.0 assessment (3-month and 6-month follow-up data). The project manager will provide virtual coaching to communities throughout implementation as needed. Table 1 below outlines the intervention structure and implementation strategy. In addition, we identify the implementation measure/metric we will track during the course of implementation.

Table 1. *IPPI Intervention Structure, Implementation Strategy, and Implementation Measures*

Intervention Structure	Implementation Strategy	Implementation Measure
Establish Co-champions	Assess Organizational Readiness	Organizational Readiness for Implementing Change (ORIC)[30]
Subject Identification	Identify residents who score 0-12 on the BIMS with either a non-zero score on one of 5 Section D Mood items or a non-zero score on Section E Behaviors from MDS 3.0 upon completion of a scheduled annual or quarterly MDS 3.0 assessment.	That 15-20 residents with both of these criteria are engaged during the pilot timeframe per NH community - approximately 3-8 residents per month
Implementation team identified	Recommended Activity Director and DON, and CNAs or activity personnel who care for residents identified	That 3-5 staff volunteer from each community to lead and deliver IPPI activities
Orientation to IPPI	Virtual Coaching session	Does champion/team attend orientation Yes/No measured by Project Director
Emotion-Focused Communication Training	Recommended champion(s) and care partners (e.g., CNAs/Activity personnel) complete on-line, self-paced, interactive education session prior to initiating implementation	That all of the identified implementation team completes training as identified in the learning management system
Learn how to conduct an IPPI protocol	Watch IPPI training videos, review tip sheets on considerations before, during, and ending an IPPI	Binder for champion to record if activity was completed or not
Match Resident Preferences with IPPI protocols	Review Section F of MDS 3.0 to identify resident important preferences and review IPPI Protocols on website Identify 1-2 protocols for use with resident	Completion of the Resident Preference Worksheet and EMR

Intervention Structure	Implementation Strategy	Implementation Measure
Care Conference Discussion	Identify targeted behavior to be addressed with IPPI and who will be the primary IPPI delivery care partner	Obtain a deidentified print out of the care plan and look for documentation of targeted behavior and care partner
Identify and procure IPPI supplies needed	Managing supplies – what is needed, where will they be stored, identified	Exit interview and Resident Preferences Worksheet
Assess Fidelity to IPPI protocol	Champion does one IPPI with each resident while care partner watches, then champion watches while care partner conducts one and documents if IPPI steps followed	Observation by champion is documented with the Pragmatic Checklist
Assess Adherence to IPPI protocol and participant responsiveness	Conduct two 10 min IPPIs per week over the course of 6 months (e.g., 48 sessions total)	Documentation of each of 48 IPPIs completed for each resident in EMR
Troubleshooting	Virtual Coach (Project Manager) available throughout	Number of times contacted Project Director
Communicating initiative to staff, families	Town hall meeting, letter to families	Ask in Exit interview if done yes/no
Acceptability, feasibility, and appropriateness of IPPI	Complete the Exit Interview (See Draft Appendix B)	Acceptability of Intervention (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM) in Exit interview

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

The IPPI intervention targets distress of PLWD. As a result, champion(s) will be trained to identify residents in each of the participating nine communities that have both cognitive impairment (Brief Inventory for Mental Status (BIMS) score of 0-12) and who have recently triggered for distress as reported in Section D (non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness) or Section E (non-zero response on a behavior) in the MDS 3.0.

Inclusion Criteria

Participants of any age, race, gender, or ethnicity will be eligible for enrollment if the following criteria are met:

- The individual is a long-stay resident in one of the nine participating UCH NH locations partnering with the PI for this project.
- The most recent MDS 3.0 assessment indicates a BIMS score of 0-12 *and* a non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness or Section E behavior item(s).

4.1 Exclusion Criteria

Individuals will be excluded if:

- Individual does not reside as a long-stay resident in one of the nine participating UCH NH locations partnering with the PI for this project.
- Resident does not have both a BIMS score of 0-12 *and* a non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness or Section E behavior item(s).

4.2 Study Enrollment Procedures

Seven UCH NH communities in Ohio will be invited to participate in the IPPI program. Dr. Abbott will visit in person to talk with the leadership team of each community and secure participation. The 7 sites have an average of 100 beds with approximately 50% of residents living with dementia.

Leadership Staff: The UCH staff implementation team at each site may include the Director of Nursing, Life Enrichment Director, and direct care providers (State Tested Nursing Assistants; STNAs) also known as Care Partners. These individuals will be asked to complete an exit interview for which we will seek informed verbal consent.

We will seek staff volunteers to be a part of the UCH implementation team. Dr. Abbott will meet with staff in each community, explain the IPPI project, the time commitment, and work with leadership to develop an implementation team that includes one or two champions(s) and 2-3 care partners.

Residents: UCH implementation team champion(s) will be trained to use MDS data to identify residents who are optimal for the IPPI program. Eligible residents will be indicated by a Brief Inventory for Mental Status (BIMS) score of 0-12 (a screening to identify individuals with cognitive impairment) and who have recently communicated distress as reported in Section D (non-zero response on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness) or Section E (non-zero response on a behavior) within each community.

Implementation Team: The UCH implementation team will be invited to be trained to deliver the IPPI program. They will have choice in the activity that they will do with the resident, and will be offered coaching and feedback. Trained care partners will be asked to conduct 2 IPPI activities per week with each identified resident. Selected residents will be engaged with the IPPI program on a rolling basis immediately after their quarterly MDS assessment (pre-test) over 6 months. The provider UCH utilizes a consistent staffing approach, and the idea is that the IPPI activities are integrated into routine care practices with selected residents.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

IPPIs will be conducted by trained care partners for each identified eligible resident. Enrollment will occur on a rolling basis, upon completion of an initial MDS 3.0 assessment (i.e., annual or quarterly assessment, whichever is completed at that time). Upon determination of eligibility, site champion(s) will 1) assess resident important preferences with the 16 preferences required to be collected in Section F of the MDS (e.g., being around animals such as pets, choose what clothes to wear, going outside), 2) match a resident's important preferences with 1-2 appropriate IPPI protocols, 3) invite one or more of the implementation team care partners to select one of the IPPI protocols to conduct with the resident, 4) coach the care partner(s) on how to lead the activity, 5) have the care partner(s) lead the one-to-one activity with the champion watching to give feedback, 6) have care partners conduct IPPIs with a resident for approximately 10 minutes 2 days per week, at a time convenient for both the care partner and resident.

IPPIs will continue to be offered for 6-months from date of study initiation. IPPIs will be conducted within the NH in the resident's room or a common area, or outside the NH as appropriate for meeting the preference targeted. Care partners will select from 60+ pre-created IPPI protocols and complete the interventions accordingly.

The IPPI involves minimal risk since the resident can decline and is based on his or her preference. Further, IPPI will not adversely impact the rights and welfare of residents because it will involve a meaningful and enjoyable use of time with a care partner.

Handling of Study Interventions

All participating NH communities will be provided a body of IPPI activity manuals; each IPPI activity has a corresponding toolkit with instructions and supportive conversation prompts that consist of an introduction, middle, and conclusion section. The IPPI program has been explicitly designed for PLWD who are experiencing symptoms of distress. We will assess both fidelity and adherence to the IPPI protocols during implementation.

5.2 Concomitant Interventions

5.3.1 Allowed Interventions

IPPI intervention activities will be allowed for all eligible residents.

5.3.2 Required Interventions

IPPI intervention activities will be offered to all eligible residents, but residents have the right to refuse participation prior to starting each IPPI or anytime during an IPPI activity.

5.3.3 Prohibited Interventions

No prohibited interventions are noted. All other usual care interventions for residents can continue as needed during the course of the IPPI pilot implementation process.

5.3 Adherence Assessment

Adherence to the study regimen is defined as completion of at least 80% of designated IPPI sessions per eligible/enrolled resident. Adherence to completion of two 10-minute IPPIs per week over the course of 6-months (e.g., 48 sessions total) will be tracked in the UCH EMR upon completion of each IPPI activity with each resident (see evaluations section below).

6 STUDY PROCEDURES

The Schedule of Evaluations in section 6.1 includes all study evaluations.

6.1 Schedule of Evaluations

Assessment	Pre-enrollment	Baseline, Enrollment (Day 0)	Each IPPI (2x a week for 180 days)	3-month Assessment (~Day 90)	6-month Assessment (~Day 180)	Post Intervention Trial
Organizational Readiness for Implementing Change (ORIC)	X					
MDS 3.0 data of residents BIMS scores and Section D and E Responses (*rolling*; each resident assessed for enrollment to serve as baseline assessment, 3-mon, and 6-mon)	X	X		X	X	
Identify Implementation team (Y/N)	X					
Virtual Coaching session attendance (Y/N)	X			X	X	
Emotion-Focused Communication Training (EFCT) completion (Y/N)	X					
Emotion-Focused Communication Training (EFCT) pre and post-test (knowledge, efficacy)	X					
IPPI Training (watching 2 videos) completed (Y/N)	X					
Resident Preferences Worksheet (*rolling*)		X	X	X	X	
Care Plan Documentation (Y/N)		X	X	X	X	

Fidelity Assessment with Pragmatic Checklist (*observation of 1st IPPI between each resident and implementation team member delivering IPPI*)			**X (1st IPPI only)**			
Exit Interview (communication, acceptability, feasibility, appropriateness, facilitators, and barriers)						**X**
Troubleshooting (count of contacts)	**X**	**X**	**X**	**X**	**X**	
Intervention Withdrawal form			**X**			
Adverse Events form			**X**			

6.2 Description of Evaluations

6.2.1 Pre-enrollment

These evaluations occur prior to enrollment of NH residents to the intervention.

Organizational Readiness

To understand each NH's organizational readiness for the intervention, each implementation team member will be asked to complete the ORIC assessment.

Identifying subjects (Screening)

UCH site champions will be trained to identify eligible residents in each community using MDS 3.0 BIMS data (score of 0 to 12) and documentation of distress as indicated by a non-zero response in Section D on PHQ-9 items of anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness or a non-zero response on a Section E behavior.

Identification of eligible residents will occur on a rolling basis, following completion of a given resident's quarterly or annual MDS 3.0. Upon review of MDS 3.0 assessments at the care planning meeting, if a resident triggers for cognitive impairment and distress, the person will be identified as eligible for the IPPI program. As a rolling process, site champion(s) and care partners will identify any newly eligible residents who have completed their quarterly or annual MDS 3.0 assessments and trigger for cognitive impairment and distress. This process will likely result in adding 3-8 residents per month for 3-4 consecutive months.

Baseline MDS 3.0 assessments (includes BIMS and Distress data) and two subsequent MDS 3.0 assessments (at approximately 3 and 6 months), along with EMR data that document the IPPIs will be provided to PI approximately half-way and at the completion of the project by the UCH corporate IT officer via a secure file transfer service. The half-way point will be when all enrolled residents are past their 3-month post IPPI initiation. The completion of the project will occur 6 months post IPPI initiation. Data for all residents will be provided and the PI will link the MDS and EMR data, extract residents engaged in the IPPI project, deidentify, and add a unique ID number for each participant prior to providing data to the Statistical Consultant, Allison Heid via a secure file transfer service.

Implementation team training

To track implementation efforts, each NH site champion(s) will be asked to record on paper forms located in a binder (see Appendix A) that assess the following yes/no questions prior to starting to implement the IPPI with residents: Did the site identify an implementation team (Y/N); Did the implementation team attend the virtual coaching session (Y/N); did the members of the implementation team complete the EFCT (Y/N); and did the implementation team complete the IPPI training (Y/N).

In addition, all implementation team members (i.e., site champion, care partners) at each NH will be asked to complete the EFCT. As a part of the online EFCT course, they will be asked to complete a pre- and post-assessment on knowledge and self-efficacy. The post-assessment will also contain questions assessing acceptability. To

assess knowledge gained from the content of the intervention, participants will respond to 16 intervention specific multiple-choice or multiple-response items prior to training (pre-assessment) and upon completion of the training (post-assessment). Items were created to specifically check learning on all key course elements. Items assess knowledge regarding ways to recognize and respond to emotions (e.g., anger, pleasure). A total count of correct answers is computed (possible range: 0 to 27; note, total exceeds 16 as some questions required more than one correct response to be selected). For self-efficacy, consistent with Bandura's (1997) initial conception of self-efficacy that it is behavior-specific, we created items modeled after Fortinsky and colleagues' (2002) and Steffen and colleagues' (2002) work with caregivers, that were tailored to the specific intervention content presented in the EFCT. By using a tailored set of items created specifically for this course, the impact of the specific intervention activities can be assessed. The scale includes 9-items asking participants how confident on a scale of 0 (*not at all confident*) to 10 (*certain you can do it*) they are completing the proposed activity. Items assess confidence in identifying one's own feelings, ability to respond effectively to those emotions, identifying emotions in others, and responding effectively to their emotions. A mean-item total score is computed (possible range: 0 to 90; $\alpha = .90$). Third, post-training program acceptability will be assessed with three metrics. Drawing upon the Implementation Research Measure for program acceptability, appropriateness and feasibility of Proctor et al. (2011) and Weiner et al. (2017), we assess Acceptability of the Intervention Measure (AIM) and Intervention Appropriateness (IAM) with two 4-item scales. Items are rated from 1 (*completely disagree*) to 5 (*completely agree*). AIM includes items such as "*The Emotion-Focused Communication Training is appealing to me*" ($\alpha = .92$; range 4 to 20). IAM includes items such as "*The Emotion-Focused Communication Training seems applicable*" ($\alpha = .94$; range 4 to 20). In addition, we assess general ratings of program satisfaction with 5-items, such as "*Overall, I was satisfied with this training*" ($\alpha = .92$; range 5 to 25).

6.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

There will be a waiver of consent for all residents enrolled in the program. Upon identification of eligibility, the implementation team uses the Resident Preferences Worksheet to identify next steps. This will be a rolling process as individuals are identified as eligible to participate. Each enrolled individual will have a Worksheet completed at their specific time of enrollment. In this Worksheet, members of the implementation team will identify the resident's important preferences and identify matching IPPI protocols that can be used. They will also identify the behavior they hope to target with the IPPI intervention. A copy of the care plan will be obtained to ensure that the targeted behavior is addressed. The PI will collect this Worksheet from champions to determine whether or not the IPPI protocols were appropriately matched to important resident preferences as a measure of implementation fidelity every three months.

Baseline Assessments

The baseline assessment for residents will be their most recent MDS 3.0 (either

annual or quarterly). The BIMS and Section D/Section E responses will be provided to the PI for each enrolled resident by the UCH IT professionals. These data will include the targeted mood or behavior selected by care partners at enrollment. The type of mood or behavior item being targeted will be different for each resident (e.g., wandering for one, verbal behavior for another).

6.2.3 Follow-up Visits

- IPPI completions 2x weekly:
  - The Fidelity Assessment with Pragmatic Checklist will be completed the first time a member of the intervention team completes an IPPI with a resident. This will be completed by the site champion when shadowing the care partner in implementation.
  - IPPIs will be documented in the UCH EMR through Point-Click-Care.
  - During implementation, troubleshooting (count of contacts of the implementation teams with the PI/Project team) will be recorded.
  - If an eligible resident is withdrawn from participation, the withdrawal date, and the reason will be documented on an Intervention Withdrawal form and provided to the project PI. This form is part of the binder that will be provided to each site champion(s).
  - Adverse Events will be reported directly to the PI if they occur as per section 7.3 below.
- 3-months (~90 days):
  - Distress data (Section E and Section D) from the next completed MDS 3.0 assessment (annual or quarterly) will be provided to the PI by the UCH IT Corporate office. The Centers for Medicare and Medicaid Services require completion of an assessment every 3-months; however, experience indicates that there is individual variability in actual completion times and therefore we will not enforce a strict allowable time window for these data. Change in each Section E/Section D item will be scored as 0 = *stayed the same as baseline* (e.g., score on MDS 3.0 baseline assessment equals score on MDS 3.0 follow-up assessment), 1 = *got better* (e.g., score on MDS 3.0 baseline assessment is better (lower) than the score on the MDS 3.0 follow-up assessment), or 2 = *got worse* (e.g., score on MDS 3.0 baseline assessment is worse (higher) than the score on MDS 3.0 follow-up assessment) for our primary, person-centered clinical outcome.
- 6-months (~180 days):
  - Distress data (Section E and Section D) from the next completed MDS 3.0 assessment (annual or quarterly ~6-months post baseline assessment) will be provided to the PI by the UCH IT Corporate office. The Centers for Medicare and Medicaid Services require completion of an assessment every 3-months; however, experience indicates that there is individual variability in actual completion times and therefore will not enforce a

strict allowable time window for these data. Change in Section E/Section D items will be scored as 0 = *stayed the same as baseline* (e.g., score on MDS 3.0 baseline assessment equals score on MDS 3.0 follow-up assessment), 1 = *got better* (e.g., score on MDS 3.0 baseline assessment is better (lower) than the score on the MDS 3.0 follow-up assessment), or 2 = *got worse* (e.g., score on MDS 3.0 baseline assessment is worse (higher) than the score on MDS 3.0 follow-up assessment) for our primary, person-centered clinical outcome.

6.2.4 Completion/Final Evaluation

Each enrolled resident will receive 6-months of the IPPI intervention. Upon completion of the intervention an Exit Interview will be completed with implementation team members at each NH site. Members of the implementation team will be invited to participate in a semi-structured intervies with researchers at the end of the project. The Exit interview (see Appendix B) will contain open-ended questions about communication and facilitators and barriers. It will also include close-ended questions on acceptability, feasibility, and appropriateness using the Implementation Research Measure for program acceptability, appropriateness, and feasibility of Proctor et al. (2011) and Weiner et al. (2017).

7 SAFETY ASSESSMENTS

Once an individual is enrolled in the study, participant safety will be monitored. Enrollment is defined as a resident identified as eligible based on most recent MDS 3.0 assessments and then having a completed Resident Preferences Worksheet.

No known risks of the intervention are anticipated. The potential risks or discomfort are minimal to the organization, residents, and care partners. This intervention is focused on a positive interaction around the preference of the resident and their care partners, such as a sing-a-long activity, or going outside when the weather is good. The activities can be stopped if the resident or care partners experience distress, however that is unlikely to occur as the intervention found that residents had increased positive affect during and after the intervention. Residents can refuse to participate any time a care partner seeks to engage with them.

However, a person could become agitated during an IPPI if it is not explained well by a care partner, as with routine care. In these instances, behaviors such as wandering or becoming aggressive could occur at the same rate with which they occur during typical clinical care. Further, the population served by this intervention is by definition a vulnerable medical population experiencing dementia and often multiple other chronic illnesses. We would expect that due to the age and illness severity of the PLWD that the occurrence of falls, emergency room/hospitalizations, and death can reasonably be expected. Implementation team care partners are already trained by their specific facility in managing safety concerns and health events that may occur during typical care and they will behave the same during enrollment in the IPPI program. The care partners would act according to their facility's rules and expectations.

In the case of an adverse event occurring during study participation, an Adverse Event

form would be submitted to the PI within 3-days of the event (see procedural expectations below in 7.3). In the case of death of a resident, the site champion will be advised to call the PI to notify her of the passing.

7.1 Specification of Safety Parameters

Dr. Abbott will create a data use agreement with UCH in order to receive the MDS 3.0 and electronic health records data. Dr. Abbott will merge these data sets, add a unique identifier to the data set, and remove face identifiers such as name, SSN, HIC prior to providing it to the statistical consultant via a secure file transfer. These efforts will protect participant privacy. The Biostatistician will direct the statistical consultant on conducting the analysis, but will not have access directly to the data.

We will also provide a help line for the implementation team to contact the project manager or PI at any time if they need assistance in problem solving to modify an IPPI for a resident to their remaining strengths during the course of implementation.

We will plan for monthly check-in calls with the implementation team to see if they have any concerns and check-in on implementation progress. Residents have the ability to decline to participate in any offered IPPI activity.

All other safety parameters will be in line with safety and health regulations as set forth by the NHs themselves. Each NH is regulated by the Centers for Medicare and Medicaid Services and will be expected to follow all clinical safety and reporting guidelines during the duration of this study.

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

Safety concerns for the IPPI intervention are no more than those experienced in usual care for NH residents. NH Residents: The IPPI program will be implemented by staff as part of the nursing home resident's clinical care needs. The IPPI activities involve no more than minimal risk to the NH resident as these activities are typically done by care partners as part of standard of care. The care partner will be taught to use the good communication practices taught in the emotion-focused communication training to deliver activities that are preferred by residents. Each NH has a responsibility, as regulated by the Centers for Medicare and Medicaid Services to follow specific safety protocols and reporting guidelines. Each NH will continue to follow these protocols while delivering the IPPI intervention. The IPPI involves minimal risk since the resident can decline and is based on his or her preference, would not adversely impact the rights and welfare of residents because it would involve a meaningful and enjoyable use of time with a care partner, the legally authorized representative would be informed about the new clinical activity being tried with their loved one/client as is the case with any new clinical activity being implemented with individuals, and deidentified data will be provided from the provider organization.

7.3 Adverse Events and Serious Adverse Events

Adverse and serious adverse events for this study are defined as follows:

Adverse Event (AE): Any unfavorable medical or behavioral outcome in a clinical research study participant, including but not limited to expression of extreme distress (defined as a person specific change in behavior that is uncharacteristic of the individual

whereby the individual is visibly upset and/or inconsolable), an illness event (i.e., a heart attack, stroke), or a fall temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

Serious Adverse Event (SAE): Any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Is another condition which investigators judge to represent significant hazards

Unanticipated Problem (UP) Definition: Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected, in terms of nature, severity, or frequency, given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the study population;
- Related or possibly related to participation in the research;
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Adverse events are not anticipated to occur in response to the intervention beyond the routine experience of events in clinical care. We expect no SAEs to occur as a result of an IPPI activity because they are meant to be short, enjoyable activities. We would expect that due to the age and illness severity of the people living with dementia that the possibility of falls, emergency room/hospitalizations, and death can reasonably be expected. During our monthly check-in calls with the implementation team, we will ask if any adverse events have occurred, "*Have there been any unexpected changes in resident behaviors or health while participating in the study?*"

NHs will otherwise follow their regulated health and safety protocols and responses.

7.3.1 Reporting Procedures

In the occurrence of an AE or SAE, during an IPPI, the implementation team will be instructed to complete the column in the provided binder on the final column of the resident preferences worksheet, providing a description of the event, the timing of the event, and the anticipated clinical response. If warranted, the team will be instructed to complete the IMPACT Serious Adverse Event (SAE) Report Form.

If an AE or SAE becomes apparent during a monthly call, the PI will request a completion of an Adverse Events or IMPACT Serious Adverse Event (SAE) Report Form, as applicable.

In the case of death, the site champion will also be instructed to call the PI to relay this information.

Following typical clinical safety protocols of the specific NH, a determination of continuation in the IPPI program will be determined by the NH clinical implementation team based on severity of event and relationship to the study. The decision for care alteration or necessary withdrawal from the study will be communicated with the PI through the Adverse Events form and/or if necessary, the second to last column of the Resident Preferences Worksheet. That column asks if the resident completed the IPPI program and if no, why not. For reporting, the decision of relatedness, expectedness. and severity of events will be defined as follows:

Severity of Event

All AEs will be assessed by a qualified medical professional on the NH implementation team using a protocol defined grading system to describe severity.

• Mild – Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

• Moderate – Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning.

• Severe – Events interrupt a participant's usual daily activity and may require systemic treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

Expectedness

• Unexpected - Nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.

• Expected - Event is known to be associated with the intervention or condition under study.

Relationship To Study Intervention

In the case of an AE, a qualified clinical professional on the implementation team at the resident's NH will help judge the relationship of the AE to the study intervention. In light of the medical status of the resident participating in the study, the qualified clinical professional, will evaluate the degree to which the event was related to underlying disease/concurrent illness or study-related procedures, accidents, and other external factors. The clinician will indicate "Yes" in the final column of the Resident Preferences Worksheet and complete the Serious Adverse Even Report Form Template:

• Definitely Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event occurs in a plausible time relationship to the IPPI intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure, and that could not be reasonably explained by the known characteristics of the subject's clinical state. Depending upon severity of AE, the clinician may judge the event to warrant withdrawal from the study.

• Possibly Related – There is some evidence to suggest a causal relationship (e.g., the event occurred within a reasonable time after an IPPI happened or follows a known or expected response pattern to the suspected intervention). However, other factors may have contributed to the event (e.g., the participant's clinical condition, other concomitant events). An AE rated as "possibly related" soon after discovery, can be flagged as requiring more information and later be upgraded to definitely related", as appropriate.

• Not Related – The AE is clearly not related and completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. For example, another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically implausible

All adverse events that are serious (SAE) and unexpected (i.e., have not been previously reported for the study's intervention) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory Safety Officer within 48 hours of the study's knowledge of SAE.

- Only those adverse events that are serious (SAE), unexpected, and related to the intervention must also be reported to Advarra IRB. Unexpected and unrelated SAEs will be reported to Advarra IRB on a case-by-case basis if requested by the IMPACT Collaboratory Safety Officer or NIA IMPACT Collaboratory PO.

All deaths will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory Safety Officer within 24 hours of study's knowledge of death.

- Advarra IRB does not require the specific reporting of death outside of the SAE reporting requirement above, but they will be notified on a case-by-case basis if requested by the IMPACT Collaboratory Safety Officer or NIA IMPACT Collaboratory PO.

All unanticipated problems (UPs) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Dr. Julie Lima), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory Safety Officer within 48 hours of the study's knowledge of the event.

The summaries of all previously reported unexpected and related SAEs, deaths, and UPs, as well as all other SAEs and AEs will be reported to IMPACT Collaboratory Regulatory and Data Team Lead (Dr. Julie Lima), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharyya), and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) at a minimum every 6 months, or at a frequency requested by the IMPACT Collaboratory Safety Officer or NIA IMPACT Collaboratory PO.

7.3.2 Follow-up for Adverse Events

NH implementation teams will follow all existing health and safety protocols in their NHs for procedures following a safety-related or health-related event until the AE or SAE is resolved or the person is considered stable.

Upon resolution of the event, the site champion will provide additional information to the PI to indicate the timing of resolution/stabilization of the event. All AEs occurring while in the study will be documented appropriately regardless of relationship to the intervention. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition significantly deteriorates at any time during the study, it will be recorded as an AE.

The site champions will record all reportable events with start dates occurring any time after participant enrollment for 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation.

During each monthly check-in the PI will inquire about the occurrence of AE/SAEs since the last call. Events will be followed for outcome information until resolution or stabilization.

7.4 Safety Monitoring

The IPPI program does not entail risks to the NH resident or staff member. Each involved individual can refuse to participate at any time. The IPPI program is based on a preferred activity leading to a meaningful and enjoyable use of time between the resident and care partner.

The NIA IMPACT Collaboratory Safety Officer will oversee all data and safety monitoring activities for this study to evaluate the progress of the study, and to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. Advarra IRB will conduct the ethical review required for the protection of human subjects.

In addition, all activities for this intervention will abide by expected Centers for Medicare and Medicaid Services Health and Safety care requirements within the NHs.

8 INTERVENTION DISCONTINUATION

Participating in the IPPI intervention is optional for residents. Residents can refuse participation at any time. The staff can choose to discontinue the IPPI with any participant based upon their clinical judgement and the individual may be withdrawn from the study.

Withdrawal can also follow a significant health change or hospitalization that makes the participant unable to continue to participate in the IPPI intervention activities. Implementation team clinical staff will make a judgement call.

Participants may also be withdrawn due to death. Residents living with dementia in a NH are a vulnerable population, health events are common and anticipated (i.e. falls).

Participants may also be withdrawn from the study if the individual leaves the NH to move to another NH. The resident must continue to reside in the same NH for the 6-months of the study period to be engaged in the intervention.

For all reasons of withdrawal, the implementation team for a given resident will communicate the withdrawal to the PI with the second to last column on the Resident Preferences Worksheet stating the date and the reason.

While there is no formal plan for replacement of subjects, due the rolling nature of enrollment, additional eligible residents may be added to the study to accommodate a withdrawal if it occurs within the first 3 consecutive months of the study.

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

The primary objective is to effectively deploy the IPPI program so that care providers can use the program as a part of their routine care delivery. We hypothesize that implementation will result in decreased expressions of behavioral distress and/or depressive symptoms for residents engaged in the program at 3-month and 6-month intervention follow-up and increased knowledge of emotion-focused communication and self-efficacy for using emotion-focused communication for care providers.

Our secondary objective is to demonstrate program feasibility and fidelity as well as document barriers and facilitators in implementation.

For this pilot study, we will have a non-randomized, within-person design, examining how individual levels of distress change from baseline to 3-months to 6-months. We will report rates of overall sample change versus stability. No randomization will occur for this trial, as the primary purpose is to establish pragmatic feasibility of the intervention.

The primary clinical outcome will be reports of distress as rated in the residents' MDS 3.0 annual or quarterly assessments in Section E and Section D (Saliba & Buchanan, 2009). These items will also be rated by the implementation team care partner delivering the intervention. These data will be collected at baseline (to determine eligibility) and at 3-months and 6-months post-intervention enrollment. The items in Section D and Section E are validated standardized items used to assess all NH residents in the United States receiving funding from the Centers for Medicare and Medicaid Services. Section D depression item responses are drawn from the widely used and validated PHQ-9 (Kroenke et al., 2001; anhedonia, sad mood, poor self-esteem, poor appetite, or restlessness). The items ask "*Over the past 2 weeks, have you been bothered by any of the following problems*?" and then if the resident responds "*yes*" they are asked "*About how often have you been bothered by this*?". Item level scores are 0 (*did not occur*), 1 (*2-6 days*), 2 (*7-11 days*), or 3 (*12-14 days*). The Section E behavior items have been used as a valid indicator of behavioral distress (Saliba & Buchanan, 2009). Items include the presence of verbal, physical or other behavior symptoms directed toward others, rejection of care, and wandering. For section E, each behavior is rated with a 0 (*did not occur in the past week*), 1 (*occurred 1-3 days in the past week*), 2 (*occurred 4-6 days*) or 3 (*occurred daily*). For each resident care partners will have designated a targeted mood or behavior item selected for improvement and assessed via MDS data. The targeted mood or behavior selected by the care partner at baseline will be reassessed at 3-months and 6-months and recorded as 0 = *stayed the same as baseline* (e.g., score on MDS 3.0 baseline assessment equals score on MDS 3.0 follow-up assessment), 1 = *got better* (e.g., score on

MDS 3.0 baseline assessment is better (lower) than the score on the MDS 3.0 follow-up assessment), or 2 = *got worse* (e.g., score on MDS 3.0 baseline assessment is worse (higher) than the score on MDS 3.0 follow-up assessment) for our primary, person-centered clinical outcome. The type of mood or behavior item being tracked will be different for each resident (e.g., wandering for one, verbal behavior for another)

The secondary clinical outcomes will be knowledge and self-efficacy pre-and post-EFCT data for all implementation team members. To assess knowledge gained from the content of the intervention, participants will respond to 16 intervention specific multiple-choice or multiple-response items prior to training (pre-test) and upon completion of the training (post-test). Items were created to specifically check learning on all key course elements. Items assess knowledge regarding ways to recognize and respond to emotions (e.g., anger, pleasure). A total count of correct answers is computed (possible range: 0 to 27; note, total exceeds 16 as some questions required more than one correct response to be selected). For self-efficacy, consistent with Bandura's (1997) initial conception of self-efficacy that it is behavior-specific, we created items modeled after Fortinsky and colleagues' (2002) and Steffen and colleagues' (2002) work with caregivers, that were tailored to the specific intervention content presented in the EFCT. By using a tailored set of items created specifically for this course, the impact of the specific intervention activities can be tested. The scale includes 9-items asking participants how confident on a scale of 0 (not at all confident) to 10 (certain you can do it) they are completing the proposed activity. Items assess confidence in identifying one's own feelings, ability to respond effectively to those emotions, identifying emotions in others, and responding effectively to their emotions. A mean-item total score is computed (possible range: 0 to 90) and internal consistency ratings are high ($\alpha = .90$).

To assess feasibility and fidelity as a component of our second objective, we will track the number of residents each NH is able to engage in the program via data collected from the Resident Preferences Worksheet. This worksheet also tracks alignment of important preferences with activities; we will review for appropriateness. We will track how many implementation team members complete the EFCT based on data from the EFCT LMS. We will also provide a standardized Pragmatic Checklist that site champion(s) will use to observe an IPPI session by each care partner to establish implementation fidelity. This short checklist incorporates learning from the online trainings into a Yes/No format to ensure that good communication practices are utilized. Each checklist item is equal to one point and a total number of points will be calculated to assess the fidelity to the intervention process. Each care partner delivering the IPPI will be observed once with each resident by an implementation team member. Care partners will record the date and how long the IPPI session lasted in the EMR. This documentation will be used to report on the amount, frequency, and duration of IPPI delivery to determine if the recommended 2 sessions per week over the course of 6 months were implemented. Further, participant responsiveness to the IPPI protocol will be measured through the question "*Would you like to do this activity again*?" posed to residents upon completion of an IPPI activity and recorded in the EMR. Finally, acceptability, feasibility, and appropriateness will be calculated by staff in both the EFCT post-test and the exit interview (Weiner et al., 2017; AIM, IAM, and FIM measures). Qualitative data will be collected to determine facilitators and barriers in the Exit interview with participating implementation team members.

9.2 Sample Size and Randomization

Nine NHs will be invited to participate in this pragmatic implementation feasibility study. Care partners will initiate implementation of the preferred IPPI activity with 3-7 residents per month upon completion of their quarterly or annual MDS 3.0 assessment (this will serve as baseline data) in each NH. Initiation of engagement will be rolling, adding an estimated 3-8 residents per month for 3-4 consecutive months. This study will include between 105-1110 residents and between 30-75 staff members from the implementation teams. Findings from this study will guide any needed adaptions to the implementation, approach, and power needed for a full-scale Stage IV effectiveness ePCT study.

9.2.1 Treatment Assignment Procedures

For this pragmatic implementation feasibility study, subjects will not be randomized. Individuals will be enrolled in any of the 7 NHs per the proposed eligibility/enrollment plan.

9.3 Interim analyses and Stopping Rules

No interim analyses are planned since the study is mostly focused on the feasibility of implementing the IPPI program. However, the study PI will monitor indicators of project feasibility and fidelity and offer virtual coaching as required to ensure implementation is being completed (i.e., ensure an implementation team is set up, ensure training with the EFCT and the IPPI are completed).

While not anticipated, in the event of repeat SAE/AEs linked with the study protocols, a safety review will be conducted by the PI in concert with the assigned Safety Officer to do determine whether study efforts should be discontinued. We will submit an interim and final Data Safety Monitoring (DSM) submitted for review by the IMPACT NIA Safety Officer.

9.4 Outcomes

Outcomes data will be analyzed descriptively.

9.4.1 Primary outcome

The primary clinical outcome will be reports of distress as rated in the residents' MDS 3.0 annual or quarterly assessments in Section E and Section D (Saliba & Buchanan, 2009). These items will also be rated by the implementation team care partner delivering the intervention. These data will be collected at baseline (to determine eligibility) and at 3-months and 6-months post-intervention enrollment. For each resident, a targeted mood or behavior item selected for improvement and assessed via MDS data will be used as the primary outcome. The targeted mood or behavior will be recorded as 0 = *stayed the same as baseline* (e.g., score on MDS 3.0 baseline assessment equals score on MDS 3.0 follow-up assessment), 1 = *got better* (e.g., score on MDS 3.0 baseline assessment is better (lower) than the score on the MDS 3.0 follow-up assessment), or 2 = *got worse* (e.g., score on MDS 3.0 baseline assessment is worse (higher) than the score on MDS 3.0 follow-up assessment) for our primary, person-centered clinical outcome at 3-months and 6-months post

intervention enrollment. The type of mood or behavior item being tracked will be different for each resident (e.g., wandering for one, verbal behavior for another).

9.4.2 Secondary outcomes

The secondary clinical outcomes will be knowledge and self-efficacy pre-and post-EFCT data for all implementation team members. Items will be completed prior to the start of the EFCT for each team member and after the completion of the EFCT.

To assess feasibility and fidelity as a component of our second objective, we will track the following:

- Number of residents each NH is able to engage in the program via data collected from the Resident Preferences Worksheet.
- Alignment of important preferences with activities on the Resident Preferences Worksheet; we will review for appropriateness.
- How many implementation team members complete the EFCT based on data from the EFCT LMS.
- Implementation fidelity with a standardized Pragmatic Checklist that a site champion will use to observe an IPPI session by each care partner
- Response to the intervention by the resident for each IPPI, care partners will record when an IPPI was conducted in the EMR.
- Amount, frequency, and duration of IPPI delivery to determine if the recommended 2 sessions per week over the course of 6 months were implemented with the EMR.
- Acceptability, feasibility, and appropriateness of the intervention will be calculated for staff in both the EFCT post-test and the exit interview (Weiner et al., 2017; AIM, IAM, and FIM measures).
- Facilitators and barriers to implementation in the Exit interview with participating implementation team members.

9.5 Data Analyses

Analysis of data will be descriptive. To address our first objective of clinical impact for residents, we will code a change score for each enrolled resident's targeted behaviors (e.g., improved, stayed same, worsened) in two ways. We will use the MDS 3.0 data between baseline and 6 months. We will report aggregate percentages of improved, stayed same, and worsened from the MDS 3.0 data. For implementation team members, the outcomes of knowledge and self-efficacy will be analyzed through paired samples t-tests of pre- and post-EFCT test measures.

For our second objective of feasibility and fidelity, we will calculate the number of residents each NH is able to engage as a percentage of the goal (e.g., 15 residents minimum) via data collected from the Resident Preferences Worksheet. We will also calculate the percentage of the implementation team that completed the EFCT based on data from the EFCT LMS. Finally, we will calculate the average number of IPPIs completed (via the EMR). Acceptability, feasibility, and appropriateness will be calculated according to responses from the exit interview (Weiner et al., 2017; AIM, IAM, and FIM measures). Qualitative data collected by the semi-structured exit interview

will be audio recorded, transcribed verbatim, and coded for facilitators and barriers in Dedoose.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

The primary clinical outcome for residents is found in the nursing home's routinely collected MDS assessments in their electronic medical record (EMR). Data will be extracted from the EMR by UCH IT and provided to Dr. Abbott for merging, extracting participating residents and deidentifying the data.

The secondary clinical outcome (for implementation team members) will be completed within the EFCT LMS system that directly transmits the data to the PI.

Feasibility and fidelity measures will be documented as follows:

- The Resident Preferences Worksheet will be completed by the implementation team care partner delivering the IPPIs to a given resident.
- The standardized Pragmatic Checklist will be completed by the site champion for each care partner when they are conducting their first IPPI.
- Documentation of IPPIs will be completed by the implementation team care partner delivering the IPPIs to a given resident in the EMR.
- Measures of acceptability, feasibility, and appropriateness of the intervention will be collected from the implementation team members in both the EFCT LMS post-test and at the exit interview. A questionnaire will be distributed to participating implementation team members at the time of the exit interview.
- Open-ended qualitative interviews will be audio-recorded by the PI to document facilitators and barriers to implementation during the exit interview.

Each enrolled participant and implementation team member will be assigned a unique ID number to protect resident privacy. All data analysis will be with deidentified data and not include any participant's name or identifying information.

10.2 Data Management

MDS 3.0 data for all residents will be provided to the PI by UCH IT Professionals. Dr. Abbott will identify participating/enrolled residents and extract distress (Section D and Section E) MDS 3.0 data at 3-months and 6-months post enrollment date and transmit data with face identifiers such as name, SSN, and HIC removed prior to statistical consultant via a secure file transfer.

Data collection forms will be provided to the site champion(s) for completion in a binder including the a) Implementation team training documentation, b) Resident Preferences Worksheet, and the c) Pragmatic Observation Checklist. For the resident preferences worksheet, site champion(s) will maintain a password protected list of the name of each resident that is enrolled into the IPPI program along with a unique ID# that is determined by the champion(s). This password protected file will be shared with the PI who will then

link the data from this worksheet to the electronic medical record data prior to deidentifying.

The statistical consultant on the project will receive de-identified data from the PI via a secure file electronic transfer.

Staff completing the EFCT will be prompted to answer questions within the EFCT LMS before and after completion of the training. These data will be extracted from Qualtrics, de-identified by the PI, and provided to the statistical consultant.

At the Exit Interviews, the PI and Project Manager will conduct a primarily qualitative interview that will help to answer secondary objectives.

Qualitative interviews will be audio-recorded, transcribed in otter.ai, and then uploaded into Dedoose, a qualitative data analysis software, and provided to the statistical consultant for coding.

10.3 Quality Assurance

10.3.1 Training

None of the NH staff serving on the implementation teams will receive human subjects research training. However, all NH staff serving on the implementation team at each of the 9 NHs will receive a series of trainings in the IPPI program before conducting the IPPI intervention. First, implementation team members will be provided information about the IPPI program. The implementation team will first complete an online training with the EFCT course. The EFCT (Emotion-focused communication training) course is a self-paced course set up through a Learning Management Service (LMS) to teach individuals strategies to better identify and manage their own feelings and those of PLWDs. Strategies taught in the course are designed to build individuals' emotional communication skills, forge stronger relationships and provide more positive care experiences for care partners and PLWD alike. Second, the implementation team will complete the provided IPPI activity training videos. These training videos demonstrate less effective and more effective dementia communication skills and staff to the use of simple, "plug and play" resources to deliver the IPPI activities during their normal daily workflow. Care partners will also be provided a body of IPPI activity manuals with checklist of steps, 60+ different IPPI protocols that address all 16 MDS preferences in Section F, sample letters/scripts introducing the IPPI to family and staff, and communication tips sheets. Each IPPI activity has a corresponding toolkit with instructions and supportive conversation prompts that consist of an introduction, middle, and conclusion section. The IPPI program has been explicitly designed for PLWD who are experiencing symptoms of distress.

Each care partner that is trained will first observe the site champion completing an IPPI with a resident and then will be shadowed by the site champion upon implementation of their first IPPI. Feedback will be provided to ensure protocols are being followed.

In addition, the project manager will provide virtual coaching throughout the pilot grant period through monthly calls and as needed.

10.3.2 Quality Control Committee

A formal quality control committee will not be assembled, however monthly check-in calls with the site champions with the participating NHs will serve as an opportunity to monitor quality and address concerns in implementation. The Project Manager will lead these meetings and ask participants to provide an update on implementation at each meeting to ensure the project is moving forward as anticipated.

10.3.3 Metrics

The MDS 3.0 data will serve as our primary outcome measure. NH providers have dedicated MDS nurses who have been trained how to correctly input the MDS data as it also provides the algorithm for reimbursement. Data from our secondary outcome will be provided by the implementation team before and after they engage with the emotion-focused communication training. The Qualtrics questionnaire has been set so individuals cannot skip any question. There is a "prefer not to answer" option offered for every question to ensure all questions are reviewed and that participants can skip any question.

10.3.4 Protocol Deviations

During the monthly calls the PI will take notes of any ongoing project barriers or facilitators which will be explored in the Exit Interviews as well, with this any deviations from the protocol for a given NH will be documented. These documented deviations will be shared with the project data manager/statistical consultant to determine impact on analyses and inclusion of data. All deviations will also be compiled to report as lessons learned from the pilot project to inform submission of a future full-scale Stage IV effectiveness ePCT study.

10.3.5 Monitoring

Monthly check-in calls with the nine participating NH site champions will serve as a monitoring function for this pilot grant. The Project Manager will check-in with each site during these calls to ensure each is following the agreed upon protocol for enrollment, training, shadowing, and implementation. Data collection forms will also be reviewed every 3 months by the Project Manager, to support project implementation.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and waiver for consent and any subsequent modifications will be reviewed and approved by Advarra, Inc.

11.2 Informed Consent Forms

Consent:

Nursing Home Residents: There will be no randomization process for this feasibility trial.

We are requesting a waiver of consent for resident participation in the study. This includes not only those that are exposed to the IPPI program itself, but for the release of EHR data for all NH residents in the study sites, regardless of participation/eligibility. The latter is because would be challenging for the UCH IT staff to create a cohort-specific data extract for the project. We believe the waiver of informed consent is justified for the follow reasons.

First, the research involves no more than minimal risk to subjects. Prior research has indicated there is minimal risk because this is a preference-based activity for the resident and should be a positive experience. The types of activities we are asking staff to engage residents in are usually done as part of standard care, but in a group setting.

Second, the research could not be practicably carried out without the requested waiver. It would not be practicable for care partners to seek informed consent from either the NH resident living with dementia or their legally authorized representative because the IPPI is a clinical process implemented to address a clinical need. For example, the moment a resident starts to be physically or verbally abusive to a staff member during care they need to have the ability to immediately start an IPPI activity. The IPPI activities would be integrated into the care process to address a clinical need. We do not think that residents or their legally authorized representative would object if they knew of the waiver and its intent in facilitating the research. We believe that most people would prefer to engage in activities they find meaningful and enjoyable on a one-to-one basis.

Third, we need to use identifiable private information and the research could not practicably be carried out without using such information in an indefinable format. Because we will need to link individual level data from multiple data sources (e.g., MDS and EMR) we will work with UCH IT to send the PI a crude dump of their system and the PI will link, deidentify the data and send to the statistical consultant.

Fourth, we do not think the waiver has the potential to cause adverse consequences as it involves engagement with a care partner in a preferred important activity. We are not allowing for the opportunity to obtain clinical consent but relying upon the staff clinical judgement to identify when the resident would benefit from an IPPI activity.

Fifth, the resident's legally authorized representative will be provided with information about the IPPI program upon enrollment via phone call or email and told that their loved one/client is involved in the IPPI program to remediate the communication of distress. We can and plan to share information about the findings of the study with each UCH site.

Implementation Team as Study Subjects:

We will explain the IPPI program to staff at each UCH location and seek volunteers to be a part of the implementation team who will roll out the program (they will not be consented as study subjects). We will invite them to be trained in delivering the IPPI and support them as needed during the duration of the project.

We will seek to consent staff to complete a semi-structed group exit interview at the end of the study. We request a waiver of documentation of consent for this activity. This will be sought by either the project manager or PI conducting the interview because we will be conducting the interviews via telephone or Zoom. There is minimal risk as we will be asking implementation team members to tell us about the implementation facilitators and barriers they experienced.

11.3 Participant Confidentiality

We are requesting a full HIPAA waiver in order to utilize PHI for both recruitment and outcome data. Staff need to access the MDS data to identify eligible residents and the PI plans to receive an identifiable data dump from UCH. The use of identifiable data involves no more than minimal risk to the privacy of individuals for the following reasons. First, UCH IT will send the PI the data through a secure file transfer that is password protected. Second, once the PI is able to link the data sets, identifiers will be destroyed prior to sending to the statistical consultant via a secure file transfer that is password protected. Third, PHI will not be used or disclosed to a third parted except as required by law. Fourth, the research could not be practicably conducted without the full HIPAA waiver because UCH staff could not be able to identify eligible residents without the waiver. Fifth, the research could not be practicable conducted without the ability to link individual data from multiple data sets (e.g., MDS 3.0 and EMR).

We will plan for an individualized report to each NH community with results based on their staff and residents. In addition, we will offer to present aggregated findings at town hall sessions, resident council, and family council meetings. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the sponsor or persons working on behalf of the sponsor (i.e. IMPACT research study staff, the DSMB and/or Safety Officer), the FDA, the NIA and its authorized representatives, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the IMPACT Collaboratory, the OHRP, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

All study procedures and protocols will be pre-approved by the Advarra, Inc. and will meet all ethical requirements for Human Subjects Research.

13 COMMITTEES

N/A

14 PUBLICATION OF RESEARCH FINDINGS

Publication of the results of this trial will be governed by the policies and procedures developed by the Steering Committee. Any presentation, abstract, or manuscript will be made available for review by the IMPACT Collaboratory prior to submission. Publication of the results of this pilot study will be governed by the policies and procedures developed by the IMPACT Collaboratory.

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16 SUPPLEMENTS/APPENDICES

While any member of the implementation team can complete these forms, we anticipate the champion(s) being primarily responsible. We will ask that the champion(s) submit data to the research team in batches with the 3 month and 6 month electronic data. These forms can be scanned and emailed or faxed to the project manager, Molly Noble via encrypted email at nobleme2@miamioh.edu or private fax at 513-529-3605.

Appendix A. Binder Forms

Site:_____

Implementation Team Details

Staff Name	Position	Did individual complete EFCT?	Email address*	Did individual watch both IPPI training videos?	Did individual review 3 tip sheets (Considerations before, during and ending the IPPI)?

***email address will be used to identify if individual completed the Emotion Focused Communication Training**

IPPI Program – Resident Preferences Worksheet

Site champion(s) will maintain a password protected list of the name of each resident that is enrolled into the IPPI program along with a unique ID# that is determined by the champion(s). This password protected file will be shared with the PI who will then link the data from this worksheet to the electronic medical record data prior to deidentifying.

After completing a resident's preference assessment, identify and record their most important preferences in the column "Important Preferences." Next, review the list of IPPI protocols then record the protocols that match the resident's important preferences in the "Matching IPPIs" column. Review the list of matching IPPIs with the implementation team member(s) that will be facilitating the activity with the resident and let them chose which IPPI activities (1-2) they are most comfortable doing. After they've chosen the IPPI activities, record their selection in the "IPPIs Selected" column. Identify one or more resident behaviors that are the target outcome for the intervention as indicated on the MDS Section E. Finally, note if the resident completed the project and if there were any adverse events.

Resident Unique ID#	**Important Preferences**	**Matching IPPIs**	**IPPIs Selected by implementation team**	**Supplies Needed Location**	**Which targeted behavior(s) do you hope the IPPI will remediate? Check all that apply**	**Did the resident complete the IPPI Project?** Yes No If no, why did the individual not complete the project?	**Did the resident have any adverse events?** Yes No If Yes, complete *Serious Adverse Event Report Form*
	•	•	•	○	○ Physical behavioral symptom ○ Verbal behavioral symptom ○ Other behavioral symptom ○ Rejection of Care ○ Wandering ○ Depressive Mood Symptoms	○	○

Observation Checklist of Fidelity to IPPI Protocol conducted by Champion

Did the person delivering the IPPI do any of the following?

1. Yes No N/A Introduce self to resident
2. Yes No N/A Introduce IPPI activity to resident
3. Yes No N/A Consider possible distractions (background noise, visual/tactile)
4. Yes No N/A Check that individual could hear or was wearing hearing aids if applicable
5. Yes No N/A Interrupt resident in the middle of a visit (reverse coded)
6. Yes No N/A Give the resident a choice of two items/topics
7. Yes No N/A Ask open-ended questions
8. Yes No N/A Allow the resident time to respond to a question or complete a task
9. Yes No N/A Notice responsive behaviors (eye contact, facial expressions, gestures)
10. Yes No N/A Validate the resident's thoughts and feelings (echo words or gestures)
11. Yes No N/A Encourage the resident to do as much as possible independently
12. Yes No N/A Is the activity a positive emotional experience for the resident?
13. Yes No N/A Adapt to situation – if resident does not want to continue – change subject
14. Yes No N/A If resident becomes agitated, tries to calm them down
15. Yes No N/A Communicate that the session is over
16. Yes No N/A Thank the resident for participating
17. Yes No N/A Explain what is happening next

Serious Adverse Event Report Form Template

Protocol Title: Click or tap here to enter text.

Project ID: Click or tap here to enter text.

PI Name: Click or tap here to enter text.

Encrypted Site ID (e.g., site01, site02)**:** Click or tap here to enter text.

Encrypted Subject ID (e.g., ptID001, ptID002)**:** Click or tap here to enter text.

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1. **SAE Onset Timeframe** (Two-month timeframe anytime within which the event occurred)**:**
   Click or tap to enter a date. **To** Click or tap to enter a date.

2. **Duration of SAE** (Number of days):
   Click or tap here to enter text.

3. **Location of adverse event:**
   - ☐ Emergency Department
   - ☐ Hospital
   - ☐ Outpatient visit

☐ Nursing Home/Skilled Nursing Facility
☐ Home
☐ Other, Specify: Click or tap here to enter text.
☐ Unknown

4. **Was this an unexpected adverse event?** ☐ Yes ☐ No

5. **Brief description of participant:**

   Sex: Choose an item.

   Age: Choose an item.

6. **Adverse Event Term:** Click or tap here to enter text.

7. **Brief description of the nature of the serious adverse event** (attach additional page if more space is needed.)**:** Click or tap here to enter text.

8. **Category of the serious adverse event:**

   ☐ death
   ☐ life-threatening
   ☐ hospitalization - initial or prolonged
   ☐ disability / incapacity
   ☐ required intervention to prevent permanent impairment (Devices Only)
   ☐ important medical event

9. **Intervention type:**

   ☐ Behavioral/Life Style, Specify: Click or tap here to enter text.
   ☐ Device, Specify: Click or tap here to enter text.
   ☐ Education, Specify: Click or tap here to enter text.
   ☐ Medication Deprescribing, Specify: Click or tap here to enter text.
   ☐ Other, Specify: Click or tap here to enter text.

10. **Intervention target:**

    ☐ Clinicians/staff
    ☒ Person living with dementia
    ☐ Care partner
    ☐ Other, Specify: Click or tap here to enter text.

11. Relationship of event to intervention:

☐ Not related (clearly not related to the intervention)
☐ Possible (may be related to the intervention)
☐ Definite (clearly related to the intervention)

12. Was study intervention discontinued due to event? ☐ Yes ☐ No

13. What steps were taken to treat serious adverse event? If none, state so.
Click or tap here to enter text.

14. List any relevant tests, laboratory data, history, including preexisting medical conditions (do not include dates or identifiable locations)**:**
Click or tap here to enter text.

15. Type of report: ☐ Initial ☐ Follow-up ☐ Final

Signature of Principal Investigator _____ Date: _____