HearCARE: Hearing for Communication and Resident Engagement

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Principal Investigator: Catherine Palmer

Sponsor: University of Pittsburgh

Study Title: HearCARE

Contract Number: HL-2019C1-16067

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CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the PCORI terms of award.

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STATEMENT OF COMPLIANCE

(1) The trial will be conducted in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the PCORI Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the University of Pittsburgh Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials have been submitted to the IRB for review and approval. The study has been approved by the University of Pittsburgh as an Exempt study. Any changes to the consent form(s) will be IRB approved.

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 09/29/2020

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1 PROTOCOL SUMMARY

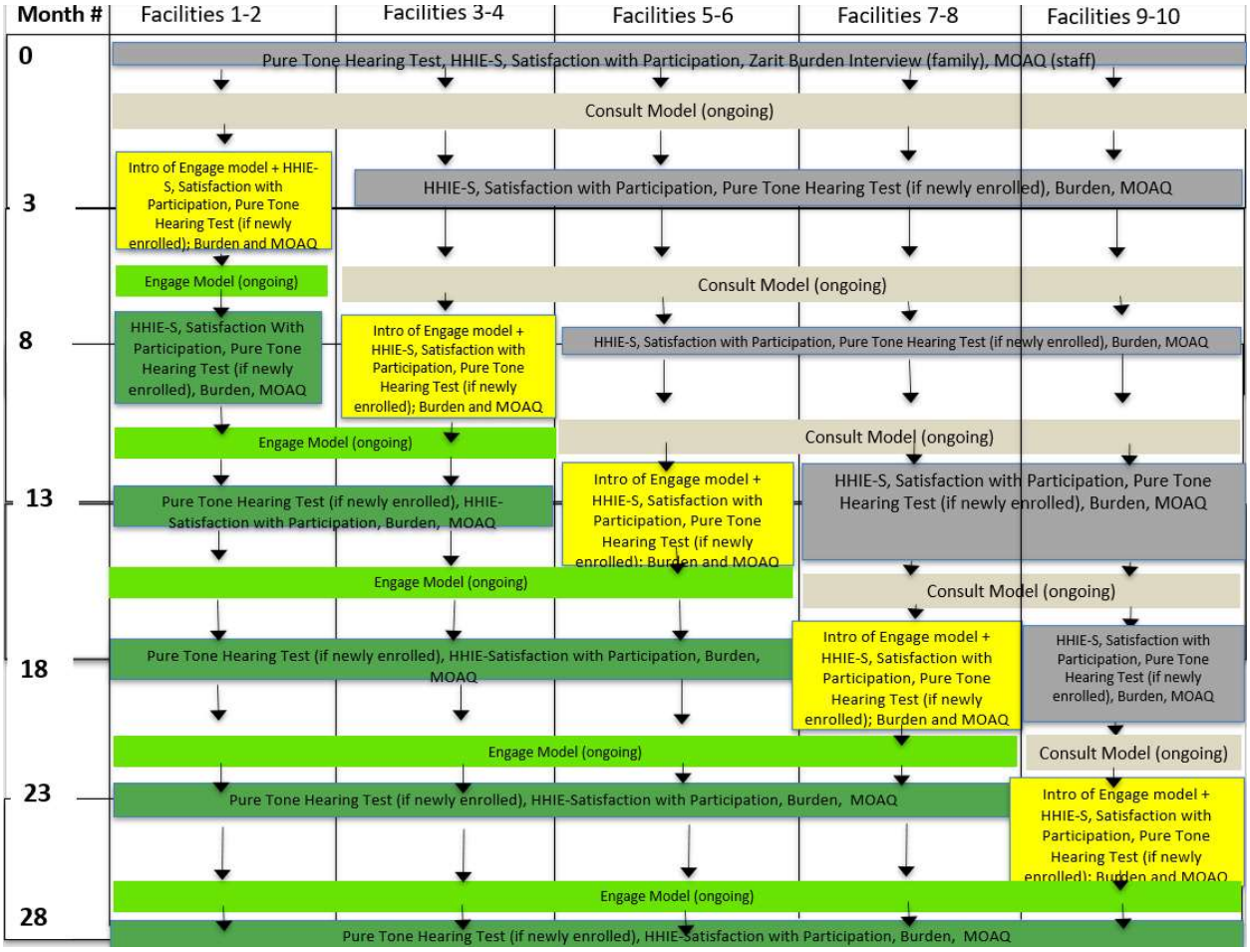
1.1 SYNOPSIS

Title:	HearCARE: Hearing for Communication and Resident Engagement
Contract Number:	**HL-2019C1-16067**
Study Description:	An open cluster cohort stepped-wedge randomized design with a phased, randomized roll out will be employed to compare the Consult Model and the Engage Model of hearing and communication care for residents in Assisted Living Facilities. The Consult Model is present in every facility and baseline data (primary outcomes: Satisfaction with Social Participation and a Hearing-Specific HRQoL measure) will be collected in each facility. Every 5 months, two new facilities will be provided with the Engage Model which will continue in the facilities until the end of the study. The primary outcomes will be measured over the course of the study. Secondary outcomes will be addressed relative to family burden and staff satisfaction. Linear mixed models will be used to test the hypothesis of improving satisfaction with social participation and hearing-specific HRQoL.
Objectives:	Amplification is a well-established, evidence-based front-line treatment for those with impaired communication secondary to Age Related Hearing Loss (ARHL) . The challenge in treating ARHL is identifying a care model that effectively promotes adherence to individualized-treatment recommendations allowing the end-user to self-manage hearing loss with appropriate support. This proposal compares the two most common models of care for ARHL (defined below) provided to adults in assisted living/personal care communities. **Aim 1:** Compare the effectiveness of a Consult Model versus an Engage Model in improving satisfaction with participation in social activities for all residents. **Aim 2:** Compare the effectiveness of a Consult Model versus an Engage Model of care in increasing hearing-specific health-related quality of life (HRQoL) in residents with measured hearing loss. Secondary Aims will explore the impact of interventions on staff satisfaction and family burden as well as other stakeholder prioritized outcomes.
Endpoints:	The end point for participants is the end of the study or if they are no longer residing in the facility.
Study Population:	Residents in Assisted Living/Personal Care Senior Living Facilities
Phase or Stage:	Phase 3
Description of Sites/Facilities Enrolling Participants:	Ten Assisted Living/Personal Care Facilities will be the sites involved in the study.
Description of Study Intervention/Experimental Manipulation:	The Consult Model (i.e., usual care) is an acute care strategy, relying on a monthly Audiologist visit to the facility. The Engage Model is a chronic care approach to supportive hearing loss self-management of ARHL. Engage includes hearing screening for all residents, an individualized-communication plan for those with an identified hearing loss, provision of non-custom amplifiers, referral to audiology if needed, and ongoing support provided by trained personnel under the supervision of the audiologist. The Consult Model is ongoing in the 10 facilities. Two facilities at a time (randomized) will cross over to The Engage Model.
Study Duration:	The study duration is 28 months from start of enrollment to end of data collection.

Participant Duration: Participants will be enrolled for 28 months or the number of months from entering the facility with the study in progress to the end of the study.

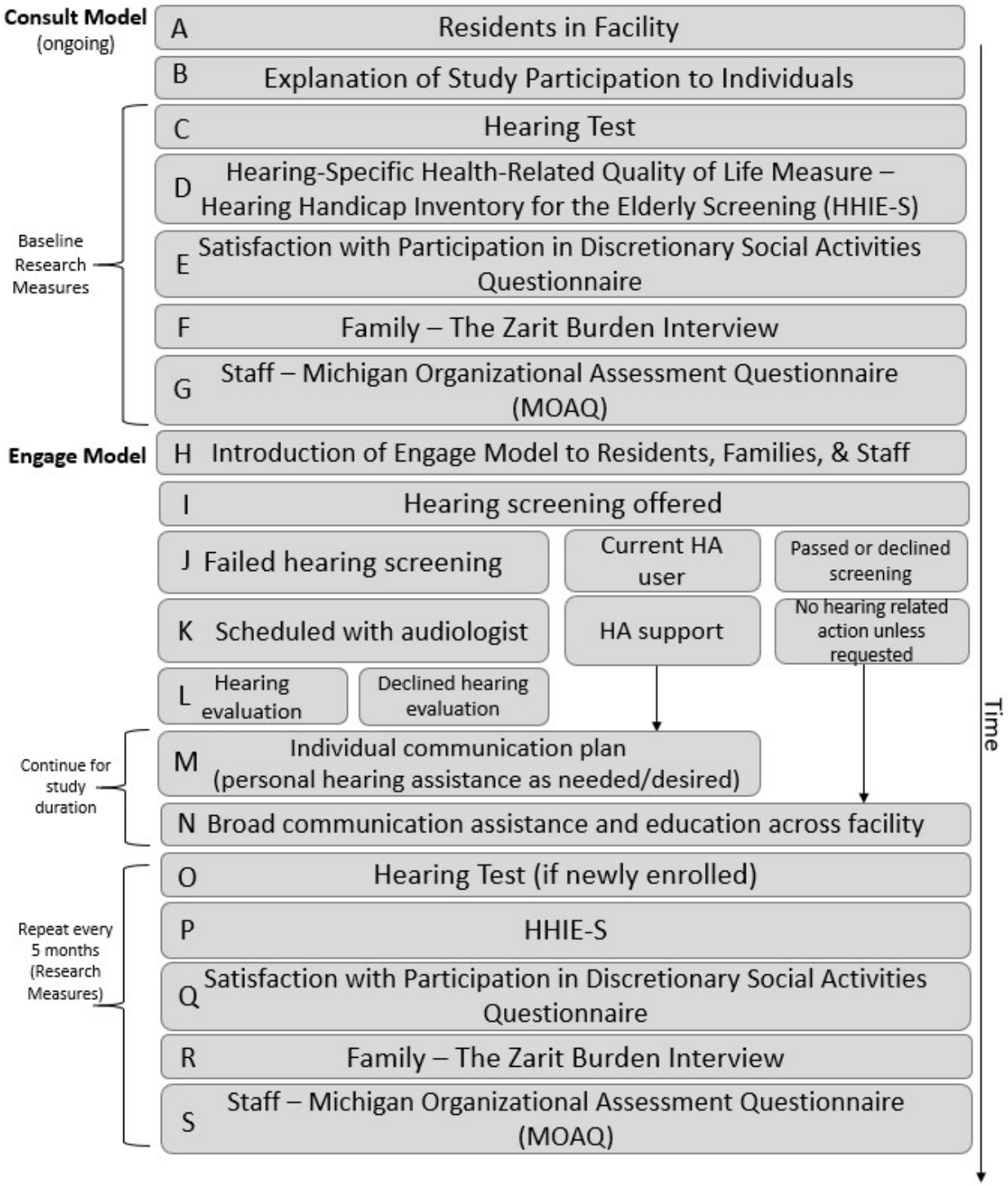
1.2 SCHEMA

The chart below provides the timeline of events for data collection and introduction of the intervention (Engage Model).



1.3 SCHEDULE OF ACTIVITIES

Please see the separate spreadsheet entitled “Schedule of Enrollment and Data Collection” for the Schedule of Events over 28 months for Residents, Family, and Staff in all facilities. Below is the schedule of activities illustrated for one block of facilities (two facilities). Blocks of facilities cross over to the Engage Intervention at different times throughout the study.



2 INTRODUCTION

2.1 STUDY RATIONALE

Amplification is a well-established, evidence-based front-line treatment for those with impaired communication secondary to Age Related Hearing Loss (ARHL) .[1] ARHL is the most prevalent cause of communication impairment among older adults.[2] The challenge in treating ARHL is identifying a care model that effectively promotes adherence to individualized-treatment recommendations allowing the end-user to self-manage hearing loss with appropriate support. This proposal compares the two most common models of care (defined below) for ARHL provided to adults in assisted living/personal care communities.

The Consult Model (i.e., usual care) is an acute care strategy, relying on a monthly Audiologist visit to the facility.[3–6]

The Engage Model is a chronic care approach to supportive hearing loss self-management of ARHL.[7–13] Engage includes (a) hearing screening for all residents, (b) an individualized communication plan for those with an identified hearing loss (e.g., one-to-one, group, telephone, television plans, hearing aid trouble shooting, communication strategies, etc.), (c) provision of simple, non-custom amplifiers, (d) referral to audiology if needed, and (e) ongoing support provided by trained personnel (Communication Facilitator) under the supervision of the audiologist.

Aim 1: Compare the effectiveness of a Consult Model versus an Engage Model in improving satisfaction with participation in social activities for all residents.

Aim 2: Compare the effectiveness of a Consult Model versus an Engage Model in increasing hearing-specific health-related quality of life (HRQoL) in residents with measured hearing loss.

Secondary Aims will explore the impact of interventions on staff satisfaction and family burden as well as other stakeholder prioritized outcomes.

2.2 BACKGROUND

Untreated ARHL is associated with a variety of poor health outcomes including increased frailty,[14,15] falls,[16,17] cognitive decline,[18–20] depression,[20] anxiety,[21] and social isolation.[22,23] The multiple health and social outcomes impacted by untreated hearing loss contribute to decreased quality of life (QoL).[24] Importantly, treating hearing loss in older adults is associated with positive health and social outcomes including reduced risk of falling,[25] hospitalization,[26,27] incidence of depression,[13,28,29] and anxiety[30]. Conversely, treatment also fosters increased social participation.[31] Social participation is "a person's involvement in activities that provide interaction with others in society or the community"[32]. Social participation is a critical determinant of healthy aging.[33–36]

The audiology consult (i.e., acute-care) model is the most common approach to hearing care in Senior Living Facilities.[3–6] This ***Consult Model*** increases physical accessibility by bringing the clinic to the facility on a monthly basis. Yet, this approach does not address the chronic nature of ARHL or the need for

ongoing support to manage technology and the communication environment. An alternative strategy (***Engage Model***) that has shown promise in Senior Living Communities[7–10,12] consists of this same access to an audiologist but is supplemented by a trained Communication Facilitator (CF) who is available weekly to assist the residents and staff. Assistance provided by the CF may include supporting hearing aids use, troubleshooting technology, dispensing non-custom amplifiers, fostering group communication, and addressing environmental manipulations (**RQ-5**). The Baltimore HEARS study provided a prospective randomized-controlled trial (RCT) designed to assess the feasibility, acceptability, and preliminary efficacy of a hearing intervention including simple amplifiers and ongoing support by CFs in a community-based environment. Although the study included a small number of participants, results indicated that the program was acceptable, 93% benefited, and 100% would recommend the program to others.[13] An RCT evaluating the Active Communication Education (ACE) program, a chronic care approach, for ARHL found improved hearing-specific HRQoL and increased social participation.[12] Researchers also have focused on other health conditions in RCTs examining the use of support personnel in order to promote ongoing management of chronic conditions and have found reduced disability and improved HRQoL related to the implementation of care assistants.[37,38] Although encouraging, these results leave a gap in the evidence base that would resolve the dilemma that persists in designing hearing care for ARHL. An intervention study comparing the Consult and Engage Model of hearing health care would assist the resident, family, staff, and organization in decision making related to desired hearing care (**RQ-3**).

Ferguson et al's Cochrane Database Systematic Review confirmed that amplification is the evidence-based treatment for those seeking hearing help.[1] The dilemma lies in which model of care will identify those individuals in need of help and provide the needed support to promote successful adherence to individualized-treatment recommendations allowing the end-user to participate in self-management of the chronic condition of ARHL. The American Speech-Language-Hearing Association's Ad Hoc Committee on Audiology Service Delivery in Home Care and Institutional Settings provides guidance for hearing care supplemented by ongoing support in residential settings and the American Academy of Audiology provides guidelines related to audiology support personnel who might provide this ongoing care. The Assisted Living Guidelines in the State of Pennsylvania (consistent with other states) indicate that hearing status should be documented (*section 2800.252, 2800.224*) as part of resident intake, that the need for communication support services should be identified (*section 2800.4, 2800.130*), and that self-management of communication issues should be promoted (*section 2800.201*). Currently, there are no data available to inform an individual managing an Assisted Living Facility as to what intervention would be effective and bring them into compliance with these guidelines. *(Criterion 1. Potential for the Study to fill critical gaps in evidence)*

2.3 FIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

The University of Pittsburgh IRB has deemed this a minimal risk study. The research procedures include a Pure Tone Hearing Survey, a Hearing Specific Health Related Quality of Life Survey (Hearing Handicap Inventory for the Elderly, HHIE), and the Satisfaction with Participation in Discretionary Social Activities-Short Form 7a) for residents. Family members are completing the Zarit Burden Interview modified 4 question v.1 via mail or weblink and Facility Staff are completing the Michigan Organizational Assessment Questionnaire (MOAQ).

The research measures do not carry inherent risks. The researchers will be sensitive to the possibility of individuals being embarrassed by hearing loss or communication challenges throughout the study. We will attempt to minimize any sense of intrusion given that we are entering the residents' home (facility) to conduct this research. We also will be sensitive to staff burden related to a research study being performed in their place of work. In addition, we will try to minimize burden on families who we will ask to respond to surveys as well.

The Consult and Engage Interventions are standard of care at UPMC and are not included in the IRB research activities. These activities also provide minimal risk. Any risk would be managed by UPMC as the provider of this care.

There are several mechanisms to inform residents, families and staff about the research and related services which we hope will alleviate confusion and stress related to introducing the intervention under investigation. We will work with the managing staff at the 10 facilities throughout the project to minimize disruption.

2.3.2 KNOWN POTENTIAL BENEFITS

In 2019, older adults account for 17% of the US population and this is expected to grow to 24% by 2060.[45] Over half of these individuals are expected to have hearing loss[46] and few use the treatment shown to mitigate ARHL.[47] With over 800,000 older individuals residing in assisted living/personal care facilities and an estimated 8 million living in some type of long-term care facility,[48] senior living communities are an important population in terms of hearing loss intervention. Increasingly, older adults are finding senior communities an appropriate living arrangement as they may need increased care and desire increased social participation. However, the overwhelming presence of untreated hearing loss compromises social participation[22,49–51] as well as contributing to poor health outcomes.[31,52–56] Healthy People 2010[57] and Healthy People 2020[57,58] included "increase the proportion of adults with disabilities who participate in social activities as a goal." Increased social participation is a common goal in senior living facilities. Untreated hearing loss presents a barrier to achieving this goal for the individuals with hearing loss and the individuals with whom they interact. Health and social interventions should focus on prevention, delay, and reversal of risk factors associated with reduced social participation.[59] Hearing loss is a modifiable risk factor for social isolation.[31] Senior Living Facilities provide an ideal environment in which to test interventions targeted at improving hearing and communication to enhance QoL and increase residents' satisfaction with social participation (**RQ-3**). This is a group with a high incidence of hearing loss, a location where interventions can be controlled and are easily accessible, and an environment where social participation opportunities are consistently offered (**PC-1**).

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

The research measures do not carry inherent risks. The researchers will be sensitive to the possibility of individuals being embarrassed by hearing loss or communication challenges throughout the study. We will attempt to minimize any sense of intrusion given that we are entering the residents' home (facility) to conduct this research. We also will be sensitive to staff burden related to a research study being performed in their place of work. In addition, we will try to minimize burden on families who we will ask to respond to surveys as well.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
Compare the effectiveness of a Consult Model versus an Engage Model in improving satisfaction with participation in social activities for all residents.	Satisfaction with Participation in Discretionary Social Activities – Short Form 7a V1.0	This is a measure with adequate psychometric data to support its use in identifying change in satisfaction with participation which is of primary interest when improving communication through hearing.
Compare the effectiveness of a Consult Model versus an Engage Model in increasing hearing-specific health-related quality of life (HRQoL) in residents with measured hearing loss.	Hearing Handicap Inventory for the Elderly (HHIE) – Screening V1.0	The HHIE is a reliable, valid measure of self-perceived hearing handicap. This is a direct measure of the intervention for individuals with hearing loss.
Secondary		
Compare the effectiveness of a Consult Model versus an Engage Model in increasing Staff Satisfaction.	Michigan Organizational Assessment Questionnaire (MOAQ)	This is a standardized measure of perceived stress by staff. Our previous stakeholders indicated that the staff questionnaire should be brief (3 questions).
Compare the effectiveness of a Consult Model versus an Engage Model in decreasing Family Burden.	Zarit Burden Interview - Modified 4 question V1.0	Reduction of burden is of interest in this study and the Zarit Burden Interview provides a standardized way to probe this outcome.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Tertiary/Exploratory		
Define a threshold of improvement with exposure to the intervention	The HHIE and Satisfaction with Participation in Discretionary Social Activities will be used to assess threshold of improvement as a function of exposure to the Engage Model.	The two primary resident measures are of interest when defining a threshold or improvement over time.

4 STUDY DESIGN

4.1 OVERALL DESIGN

The Engage Intervention is a complex intervention and as such we have followed the Medical Research Council Framework[39,40] to develop, pilot, and now propose evaluation and subsequent dissemination of this intervention. The complexity of the intervention is not only in its multiple aspects but also in the complex interactions with other stakeholders indirectly impacted by the intervention. When hearing and communication are supported for residents there is potential to impact other non-treated residents improving their QoL as well **(SCI-1**). Changes in these groups potentially impact interactions with staff and family and improved family interactions may impact relationships with staff. It is not the goal of this project to tease out which components of this complex intervention produce the desired outcomes, but it is critical to understand and acknowledge the complexity of the intervention being delivered. The underlying mechanism of change when hearing loss is managed in an aging individual is critical to understanding this complex intervention. Emerging evidence suggests that the underlying mechanism related to positive outcomes subsequent to treating age-related hearing loss is the reduction in cognitive energy required to communicate and participate[67–71] (**SCI-2**). Diminished hearing produces increased cognitive load required to decode the incomplete or distorted signal which the older adult may ill afford given their need for cognitive resources for other activities (e.g., navigating the environment, interpreting the conversation, etc.) (**SCI-5**). The cascade hypothesis suggests that the untreated hearing loss increases need for cognitive resources that cannot be allocated for other, important activities whereas treating hearing loss releases these cognitive resources allowing for social engagement which in turn improves quality of life for the individual and communication partners[72] (**CI-1**).

Comparators: The typical pathway to hearing health care includes a self-selected subset of individuals working with an audiologist to obtain hearing aids.[47] We label this the Consult Model and it represents usual care provided in senior living facilities[3–6]. Age-related hearing loss, however, is a chronic condition and may be better served with an ongoing self-management support model (Engage Model)[8–10,74] supported by a CF who is available to the resident, family, and staff on a weekly basis (two days per week) along with oversight and support from an audiologist who is available virtually to the CF and available to the facility monthly (**RQ-5**).

Expected Outcomes: We hypothesize that Engage Model participants will have significantly greater satisfaction with participation in social activities across residents regardless of hearing status and an increase in hearing-specific HRQoL in residents with hearing loss compared to those receiving the Consult Model. Additionally, we expect to find higher staff satisfaction and lower perceived family burden after stakeholders have experienced the Engage Model as compared to the Consult Model.

Study Deign: We propose an open cohort stepped-wedge cluster randomized design (see Table below, **CI-3**) with a phased, randomized roll out (**RQ-2**). The stepped wedge design is a useful design for the evaluation of complex health care interventions[75] particularly when the intervention is believed to be beneficial with minimal risk.[76] This design is increasingly being used to evaluate interventions involving health care delivery and has several advantages: (1) allowing the research team and clinical teams to roll out the intervention in a small number of facilities in a timely, systematic manner[77]; (2) possibly increasing participation and buy-in since all facilities will eventually implement the intervention during the study,[75,78,79] (3) possible increase in statistical power compared to a cluster randomized trial due to increase in data collection and within cluster comparisons.[75] Our intervention is applied at the facility level (cluster) but the primary outcomes are obtained at the resident level (**RC-1**). In this open cohort design, all residents in a facility are identified to participate but some may leave the facility and others will move into the facility over the course of the study.[80] *(Criterion 3. Scientific merit)*

Five pairs of 10 facilities will be assigned the intervention (Engage Model, gray cells) randomly over the course of 28 months with the first 4 months used as a baseline period (total data collection period is 28 months).[81] Residents enrolled in the study during any time period will be followed until the end of the study or until they are no longer a resident of the facility, whichever comes first. This implies that crossover to the intervention is not only at the facility level but also the resident level.[75] Once the intervention is available at a facility, residents will be exposed to the intervention continuously. The resident level outcomes of satisfaction with social participation and hearing-specific HRQoL will be measured every 5 months for the duration of the study.

	Baseline (4 months)	Time 1 (5 months)	Time 2 (5 months)	Time 3 (5 months)	Time 4 (5 months)	Time 5 (5 months)
Facility 1-2	60					60
Facility 3-4	60					60
Facility 5-6	60					60
Facility 7-8	60					60
Facility 9-10	60					60

Randomization and Allocation: The stepped wedge design implies a baseline period, in which no clusters are exposed to the intervention.[79] Then, at the chosen time interval, two facilities will be randomized to cross from the control to intervention. This process continues until all ten facilities have crossed over to the intervention.

		Percent of Total Data Collected by this Date											
	0%	4 months	**17%**	5 months	**34%**	5 months	**51%**	5 months	**68%**	5 months	**85%**	5 months	**100%**
	6/1/2021	Baseline	9/1/2021	Time 1	2/1/2022	Time 2	7/1/2022	Time 3	12/1/2022	Time 4	5/1/2023	Time 5	10/1/2023
Facilities 1-2													
Facilities 3-4													
Facilities 5-6													
Facilities 7-8													
Facilities 9-10													
		Consult Model											
		Engage Model											

The order of this cross over process will be randomized. We will randomize 2 facilities to switch from the control to intervention at each step using SAS version 9.4 (**RC-5**). The statistician will communicate the sequence to the Study Team for intervention implementation preparation (**IR-2**). If the expected number of individuals across the 10 facilities are not recruited in a timely manner we will expand to other Assisted Living/Personal Care Facilities at UPMC. Triggers for expanded recruitment will include 1) lower census in the building than targeted (10% lower than expected) and/or 2) inability to meet enrollment milestones over two check points as outlined on the Milestone chart.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

We considered several other designs including individual randomized parallel arm, cluster randomized parallel arm, and cluster randomized cross-over. We believe the individual randomized design would not be feasible to implement in a facility due to the high likelihood of intervention contamination between residents randomized to the intervention arm and those randomized to control (**RC-2**). The cluster randomized parallel arm trial did not fit with our assumption and observations that the intervention will benefit all residents. Therefore, randomizing facilities to control did not seem appropriate and would not bode well with our facility collaborators. The standard cluster randomized trial also had much lower power given the number of clusters available. Due to the type of intervention, a cluster randomized crossover trial would not be feasible since we would have to take away the facilitator from facilities that were randomized to have it first and there may be large carryover effects of having the facilitator in place previously.

An open cohort stepped-wedge cluster randomized design with a phased, randomized roll out was used by Leontjevas et al (2013)[82] successfully in a skilled nursing facility with interventions related to depression. Our design is consistent with that study.

4.3 JUSTIFICATION FOR INTERVENTION

A systematic review of interventions to improve hearing aid use found that ongoing communication support improves participation and communication (**SR-1**).[7] Yet, the authors also concluded that data in this area are limited and that well-controlled studies directly comparing usual care (audiology visit) versus a model of care that includes ongoing communication support are needed (**RQ-1**). Given the paucity of data to guide informed choices between the Consult and Engage Model, we conducted two pilot studies that focused on the Development and Feasibility & Piloting stages of the Medical Research Council framework for complex interventions.[39,40] In the first pilot study, we created the support personnel training program, engaged stakeholders to identify outcomes of importance, and tested the feasibility of providing interventions and measuring these outcomes.[41] Residents and family stakeholders identified increased social participation and perceived decrease in limitations due to hearing loss as critical outcomes (**PC-1**). Participants were able to respond to questionnaires focused on these two areas (85% of residents completed the study). Significant change was measured on both primary outcomes within 4 months when an Engage Model was implemented as compared to a control group with the Consult Model (**CI-3**). The second study revealed that 84% of residents in Assisted Living/Personal Care had significant hearing loss with less than 5% using personal amplification. Only 56% of individuals with significant hearing loss accurately self-identified that they had hearing loss and less than 50% of health care providers accurately identified significant hearing loss in individuals with hearing loss. Interestingly, 63% of residents with measured hearing loss whether they had self-identified hearing loss or not accepted a non-custom amplifier.

These preliminary data support the need for hearing loss identification to be part of a broad intervention program. Figure 1 illustrates that hearing screening in aging adults is rare,[42] yet the Welcome to Medicare guidelines include hearing screening for all individuals turning 65. It is not possible to promote and support individualized hearing solutions if the underlying problem is not identified. Our pilot data reveal that simply asking someone if they have hearing loss is neither sensitive nor specific in identifying individuals with significant hearing loss.[43] Hearing screening with response to calibrated sounds identifies the target population. As part of the feasibility study, noise survey data were collected to determine if accurate hearing screening and testing could be conducted in senior living facilities. Background noise ranged from 25-67.5 dB SPL (with peaks as high as 78.4 dB SPL) which is consistent with previously reported data.[44] Importantly, the frequency response of the background noise was measured and found to be below the range of frequencies most critical for valid hearing screening procedures. Hearing testing is conducted with insert earphones that sufficiently reduce the background noise to allow for accurate testing.

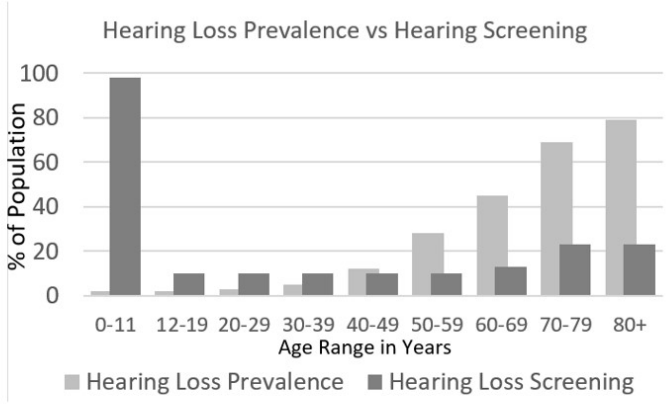


Figure 1. Hearing loss prevalence vs hearing loss screening across the lifespan.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline assessments and 5 more assessment time points (at 5-month intervals) as shown in the Schedule of Activities (SoA, **Section 1.3**) for the duration of the 28 month study. Alternatively, a participant will have completed the study if they are no longer a resident in the facility regardless of what time point coincides with that change in living arrangement. Staff and Family members have completed the study at the end of the 28-month period or at which point a Staff member is no longer working in the facility or the Family member no longer has a relative in the facility.

5 STUDY POPULATION

All residents in the 10 Assisted Living Facilities will be eligible to participate in the study. Every resident will be approached to participate. Residents who agree to be enrolled will participate in the Pure Tone Hearing Survey and the two questionnaires. All residents, regardless of enrollment in the study will be exposed to the intervention (Engage Model) because this intervention happens at both the individual and facility level.

One Family member for each resident will be invited to participate in the study. They will receive a link to an electronic version of the survey or will be mailed a paper version of the study with a self-addressed stamped envelope for return depending on their preference.

All Staff working in the facility will receive a paper version of the Job Satisfaction Survey so they can participate in the study.

5.1 INCLUSION CRITERIA

Resident Inclusion Criteria:
The participant must be a current resident in one of 10 Assisted Living Facilities.
Staff Inclusion Criteria:
The participant must be currently employed in some capacity at one of the 10 Assisted Living Facilities.
Family Inclusion Criteria:
The Family member must be the primary contact for the resident in one of the 10 Assisted Living Facilities.

5.2 EXCLUSION CRITERIA

Resident Exclusion Criteria:
The participant is not a current resident in one of 10 Assisted Living Facilities.
They are not able to communicate in English.
They are identified through interactions as having a cognitive challenge that does not allow them to respond to the hearing survey or the questionnaires.
Staff Exclusion Criteria:
The participant is not currently employed in some capacity at one of the 10 Assisted Living Facilities.
Family Exclusion Criteria:
The individual does not have a family member in one of the 10 Assisted Living Facilities.

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Residents unable to communicate in English or unable to respond to the hearing survey or the questionnaires because of cognitive challenges will be considered ineligible. All family members and staff are included.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

a. Facility Recruitment
The UPMC Senior Living Communities provide an opportunity to conduct intervention research. Within the 12 Assisted Living Facilities, we were able to collaborate with 7 facilities that have not experienced the Engage Model and currently have the Consult Model active. We included 3 non-UPMC facilities as well. These facilities were identified by the President of Senior Living as being appropriate to include in this study. We have existing relationships with all 10 facilities because two UPMC audiologists already provide the Consult Model of care in these facilities. These facilities have similar demographics of residents (age range, education, family caregivers, etc.), similar staff positions, years of experience, and responsibilities, similar physical layout, and similar week-to-week programming. This allows us to achieve the number of participants we need to complete the proposed intervention study. This coordinated system at UPMC also ensures that if there are any changes implemented in Senior Living during the investigation, they will be implemented across all facilities. For the three non-UPMC facilities, we will monitor any changes that might occur in these locations. The facilities also are geographically close to the University of Pittsburgh making intensive data collection (resident survey completion) practical.

b. Facility Retention
Sites that start the study are anticipated to complete the entire study and continue to participate for the full duration of the study. Throughout the study PI Dr. Palmer will continue to maintain relationships with the Directors at each facility and be in communication with them regarding recruitment/research activities and to answer any questions/concerns the site may have. The Data Survey Coordinator, Jon Rivera, will be in monthly contact with the facilities as well.

c. Resident, Family, and Staff Recruitment
Flyers and advertising on the Facility televisions will be used to introduce the study to residents, staff, and families. Residents will be individually introduced to Data Collectors by current facility staff. This method was recommended by our Stakeholder Advisory Panel and was deemed appropriate by the facility leadership with whom we interact on an ongoing basis. In each facility, we will work with directors to provide surveys to staff through the mechanism deemed most appropriate (paper left in an area where staff receive notifications, direct interaction with Data Survey Coordinator, and/or email). This approach was recommended by our Stakeholder Advisory Panel given that staff in different facilities receive information through different mechanisms. We will work with the facility directors to contact family members through this individual to introduce them to the study and to determine if they would like to be contacted via mail or email for survey completion.
In addition, the mechanisms for providing information described above as well as resident/family meetings will be used to introduce the Engage Model (intervention) into the facility. Families also will receive descriptions of the study and later the Engage Model by mail in case they are not in the facilities. The Engage Model is an intervention at the Facility and Individual Level so all residents, staff, and families are exposed whether they have enrolled in the study or not. This care is provided as part of UPMC Senior Living care and is extended to the three non-UPMC facilities. The Consult Model is already present at all facilities at the beginning

of the study. This is an ongoing intervention that was started 5 years ago. At the time of introduction, the same techniques as listed above were used to inform residents, families, and staff about the program. The Consult Model continues to be promoted through flyers and electronic media (TV screens) in facilities. In addition, all new residents are provided about the access to an Audiologist that the Consult Model provides.

d. Resident, Family, and Staff Retention

We will work with the staff at each facility to recruit as many residents as possible into the study. Because this is being conducted in the facility where they live, it is easy to participate and the interventions will be woven into everyday life in addition to individual hearing solutions. Just prior to enrollment of each group, we will conduct informational sessions introducing the Engage Model for residents, families, and staff to ensure understanding of the program, how to access resources, and who to contact with questions. Our preliminary data in three facilities indicate that approximately 85% of residents will participate in completing the outcome measures. The intervention includes support from the CF (two days per week) which will help keep residents engaged in this study. Adequate personnel are budgeted to ensure that residents who need assistance will have someone to help them complete surveys (**PC-2**).

Based on suggestions from our Stakeholder Advisory Panel (SAP), residents will be provided with a small gift (e.g., water bottle and other useful items) after each data collection session (every 5 months). The item will be labeled with the study name to encourage the resident's friends to ask about the study and perhaps increase interest in participating. The Data Collector will leave a University of Pittsburgh folder with each resident after the first data collection interaction that provides the Data Collectors name and picture and a log with the date of the visit along with a note about what they talked about (e.g., resident told the Data Collector about grandchildren, family, facility activities). The date of the next visit will be recorded as well. This serves the purpose of reminding the resident of the study and the date the Data Collector will return. This also provides information for a family member who may be interested in their loved one's interactions. In the 5-month period between data collection visits, the Data Collector will send 3 notes to say "hello" to the resident and remind them of the study. The SAP thought that this was important given the 5-month period between visits.

e. Total target sample size for primary analysis

Target sample size is 304 residents for the primary analysis. This has changed from the original proposal due to decrease in census and higher decline rate than predicted from the pilot study. This represents 60% of the total census (approximately 30 individual per site is the minimum goal).

Target sample size for families is 178. This has changed from the original proposal because census and resident enrollment targets have changed. The percent of families enrolled in relation to residents enrolled has not changed; this remains at 58%.

Target sample size for staff is 279. This has not changed from the original proposal. We were not able to meet this goal at baseline but have received stakeholder input that should assist us in reaching this target in the future.

f. Historical resident volume and estimated eligible N across study sites (numbers as of 05.01.2021).
Residents: The estimated eligible N across study sites is 440 residents.
Family Members: The estimated eligible N across study sites is 440 family members.
Staff Members: The estimated eligible N across study sites is 358 staff members.

Location	UPMC or Non-UPMC Facility	Assisted Living or Personal Care	Total Census*
Location 1	UPMC	Personal Care	60
Location 2	UPMC	Personal Care	25
Location 3	UPMC	Personal Care	22
Location 4	non-UPMC	Personal Care	74
Location 5	non-UPMC	Personal Care	47
Location 6	UPMC	Assisted Living	67
Location 7	UPMC	Personal Care	34
Location 8	non-UPMC	Assisted Living	55
Location 9	UPMC	Assisted Living	69
Location 10	UPMC	Assisted Living	54
Total			507

***Census as of 05/01/2021. Census shifts as people leave and enter the facilities.**

g. Estimated yield/consent

Residents:
Our pilot data suggest that we should expect that 85% of residents will agree to or be available to participate in the study measures (Pure Tone Hearing Survey, Hearing Specific Health Related Quality of Life Questionnaire and Satisfaction with Participation Questionnaire). After starting baseline data collection, it became evident that both the Census and the rate of decline has changed from when we completed the pilot study. We adjusted the study to accommodate these changes by adding two locations and adding a data collection time point. Census across the 10 facilities suggests that there are 452 residents and we have planned the study around collecting data from 304.

Families:
Our pilot data suggest that we should expect 58% of family members (compared to enrolled residents) to participate in the survey that will be sent to them.

Staff:
Our pilot data suggest that we should expect 90% of the staff in each facility to participate in the survey that will be sent to them.

h. Estimated lost to follow-up/attrition

Residents:
The updated 60% yield accounts for individuals who decline to participate and individuals who may move or otherwise no longer be in one of the facilities. In our pilot work, no residents dropped out of the study unless they were no longer in the facility. Individuals will move into the facilities over the three years and the study design accounts for including these individuals regardless of the timing of their entry into the study.

Family Members: In our pilot study 58% of families participated and 0 dropped out (this was 58% of the resident enrollment). With this study extending over 3 years there will be families who no longer have a family member in a facility who will stop participating. New families will be included as new residents move into the facilities.

Staff Members: In our pilot study, 2% of staff dropped out over time because they changed positions and moved to different facilities. We will collect surveys on any new staff who join the facility over the time period of the study.

i. Gender and Race

The Table below provides the current Race/Ethnicity and Gender distribution in the 10 facilities that are participating in this study (data from enrollment time point as of September 1, 2021). This represents the individuals who were enrolled at baseline. These representations may change slightly over the course of the study.

Race/Ethnicity and Gender Enrollment Table

Race	**Male**	**Female**	**Missing Gender**	**Total**
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Black/African American	1	5	0	6
Hawaiian/Pacific Islander	0	0	0	0
White	66	235	0	301
Multi-race	0	1	0	1
Other	1	0	0	1
Prefer not to say	2	3	0	5
Missing Race	0	0	12	12
Ethnicity				
Hispanic(Latino/Latina)	0	0	0	0
Non-Hispanic	69	238	0	307
Missing Ethnicity	0	0	12	12
Prefer not to say	1	6	0	7

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The typical pathway to hearing health care includes a self-selected subset of individuals working with an audiologist to obtain hearing aids.[47] We label this the Consult Model and it represents usual care provided in senior living facilities[3–6]. Age-related hearing loss, however, is a chronic condition and may be better served with an ongoing self-management support model (Engage Model)[8–10,74] supported by a

CF who is available to the resident, family, and staff on a weekly basis (two days per week) along with oversight and support from an audiologist who is available virtually to the CF and available to the facility monthly (**RQ-5**).

The Consult Model (i.e., usual care) is an acute care strategy, relying on a monthly Audiologist visit to the facility.[3–6]
The Engage Model is a chronic care approach to supportive hearing loss self-management of ARHL.[7–13] Engage includes (a) hearing screening for all residents, (b) an individualized communication plan for those with an identified hearing loss (e.g., one-to-one, group, telephone, television plans, hearing aid trouble shooting, communication strategies, etc.), (c) provision of simple, non-custom amplifiers, (d) referral to audiology if needed, and (e) ongoing support provided by trained personnel (Communication Facilitator) under the supervision of the audiologist.

The Communication Facilitators are provided with standardized training at UPMC to provide consistent hearing care to residents in Senior Living Facilities. The training manual is uploaded as a separate document.

6.1.2 ADMINISTRATION AND/OR DOSING

The Consult Model of care consists of an Audiologist visiting the facility once per month. This is considered usual care and is in place in all of UPMC Senior Living Communities.

The Engage Model is the intervention under study. The following description provides support for the dose of two visits per week per facility when in the Engage Model.

The Communication Facilitator was present 5 days per week in the original pilot study (1 year). During that time, Hearing Specific Health Related Quality of Life as measured by the Hearing Handicap for the Elderly- short version (HHIE-S) was assessed pre- and post-treatment (after 4 months of the Model in place in each of two facilities). There were two arms in the study, one facility with the Engage Model and one facility with the Consult Model. Data were analyzed for those residents completing the HHIE with a resulting baseline score of >8 which indicates perceived handicap. The same group of residents in each facility was assessed 4 months later with their respective models of care in place. In the pilot study, identifying information was not collected so individual participant changes cannot be assessed; only mean data can be evaluated (the same individuals completed the pre- and post-test). Planned t-tests were used to test significant differences between groups and between time points within groups. A Bonferroni correction was applied given the multiple comparisons ($p<0.05/4 = 0.0125$ was considered significant). The first two rows of data in Figure 1 indicate that there was a significant reduction in perceived handicap between pre- and post-treatment (4 months) for the group in the Engage Model ($p <0.0125$) whereas there was no difference for the group in the Consult Model ($p > 0.0125$). In addition, the Engage group had significantly lower self-perceived hearing handicap 4 months into treatment than the Consult group ($p< 0.0125$). The 95% confidence interval for the HHIE-S is 10%[1] meaning an individual would experience clinically significant benefit in the psychosocial domain of function given this change. The group experiencing the Engage Model experienced >10% change in this pilot study but individual

changes could not be evaluated due to a lack of identifying information collected during the pilot investigation.

At the end of the 1-year pilot study, our plan was to discontinue the CF model until we received funding to further investigate this model. The impact of the CF on resident quality of life and satisfaction with participation, reduction of perceived family burden, and staff satisfaction compelled us to maintain the Engage Model in this targeted facility. We were able to do this with a CF two days per week as opposed to 5-days per week which was a change in the model. Given this change, we decided to re-survey the residents who had completed the HHIE-S. We re-administered the questionnaire six months after changing to a 2x per week dose of CF support. The goal was to establish whether the positive outcome of increased Hearing Specific Health Related Qualify of Life was maintained when the CF support was reduced to 2x per week. The last row in the Figure below reveals that the reduction in handicap (increase in Hearing Specific HR QoL) was maintained six months after the reduction in CF support (no significant difference between the 4-month treatment data with CF 5x per week versus 6 months of treatment with the CF 2x per week, p>0.0125). This allowed us to continue the Engage Model with the CF present 2X per week which is what we are proposing in the current study.

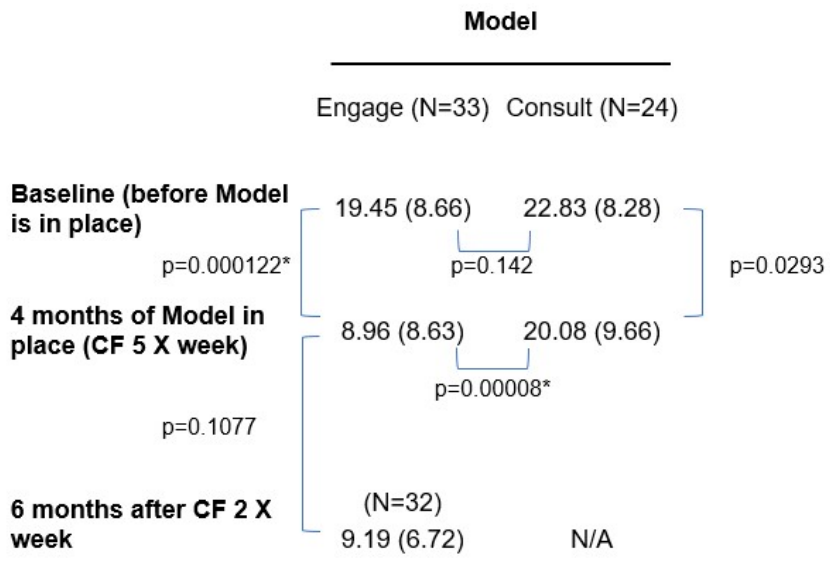


Figure. Hearing Specific Health Related Quality of Life (Hearing Handicap Inventory for the Elderly-Short Version). Means (standard deviations) for each Model of care at baseline (pre-treatment), treatment (4 months of Model in place), and six months into the Engage Model where the CF support was reduced to two visits per week. Higher scores indicate greater perceived hearing handicap. Significant differences are indicated by *.

Satisfaction with participation in discretionary social activities as measured by the PROMIS Form7a also was assessed pre- and post-treatment (after 4 months of the Model in place in each of two facilities). Data were assessed for all willing participants in these two facilities. The same group of individuals were assessed at baseline and at 4 months but identifying data were not collected so individual changes cannot be assessed; only group differences can be analyzed and discussed. The first two rows of data in Figure 2 provide the mean and standard deviations for each group across time points. Planned t-tests were completed to compare the groups at each time point and to compare time points within each group. There was a statistically significant difference after initiation of treatment for the Engage Model ($p< 0.0125$) but no difference for the Consult Model at the 4-month time point ($p>0.0125$). In addition, the Engage Group was more satisfied after 4 months than the Consult Group (higher scores indicate

greater satisfaction, p<0.0125). The PROMIS scales provide data on "minimally important differences" (MID) which are interpreted as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate a change in the patient's management".[2,3] A change of 4.5 is considered a minimally important difference on this measure and although we cannot provide individual changes because identifying information was not collected, as a group the individuals experiencing the Engage Model did achieve this difference in Satisfaction in Participation (higher scores indicating greater satisfaction).

After moving to the 2x per week CF dose, we resurveyed Satisfaction in Participation at the 6-month time point (same timing as the HHIE-S data collection) and found that the increase in Satisfaction with Participation was maintained. The last row in the Figure below reveals that the increase in satisfaction was maintained six months after the reduction in CF support (no significant difference between the 4-month treatment data with CF 5x per week versus 6 months of treatment with the CF 2x per week, p>0.0125). This provided further evidence to support continuation of the Engage Model with the CF present 2X per week.

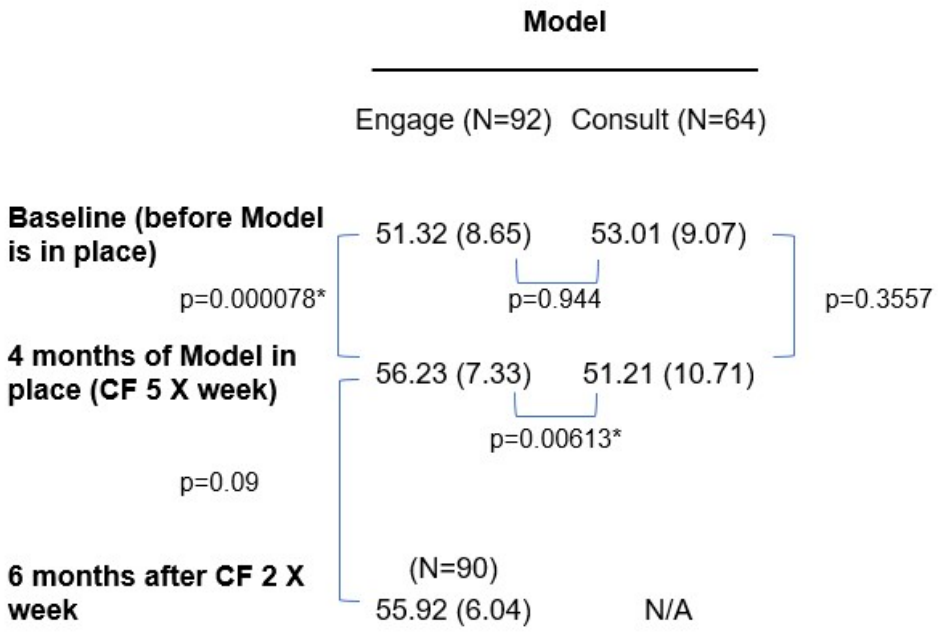


Figure. PROMIS Satisfaction with Participation in Discretionary Social Activities – Short Form 7a. Means (standard deviations) for each Model of care at baseline (pre-treatment), treatment (4 months of Model in place), and six months into the Engage Model where the CF support was reduced to two visits per week. Higher scores indicate greater satisfaction with participation. Raw scores are transformed to standardized scores (T-scores) for analysis. Significant differences are indicated by *.

6.2 FIDELITY

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The Engage Model is dependent on the Communication Facilitator. Communication Facilitators have standard training at UPMC prior to moving into their positions. The Training Manual for Communication Facilitators has been uploaded separately.

The Fidelity measures in the Table below will be tracked throughout the duration of the study to ensure that Communication Facilitators are able to provide appropriate hearing care and to verify that there are different levels and amounts of care being provided in different facilities.

Timing	Item	Plan for Measurement	Secondary Measurement
Baseline			
	HHIE (Scale)	% completed	
	Satisfaction with Participation (Scale)	% completed	
	Family - Zarit Burden	% completed	
	Staff - MOAQ	% completed	
	Hearing Test	% completed	
5-month intervals for research measures	HHIE (Scale)	% completed compared to baseline	
	Satisfaction with Participation (Scale)	% completed compared to baseline	
	Family - Zarit Burden	% completed compared to baseline	
	Staff - MOAQ	% completed compared to baseline	
	Hearing Test	% completed on any residents newly enrolled	
During Engage Model Only			
	Hearing Screening	% screened	
	Residents who failed hearing screening offered a hearing test by audiologist	% offered	time from offer to test by audiologist

	Individuals with documented hearing loss provided with a Communication Plan	% Communication Plans completed	
	Action items on Communication Plan Completed	% of action itmes implemented within 3 months	% residence adherance with plan
	Non-custom amplifiers	# dispensed	% use of non-custom amplifiers for all residents provide with a non-custom amplifier
	Ongoing support of individuals using technology (custom, non-custom, group)	% seen over 1 week period	
	Staff Educational Sessions conducted within a facility	# of sessions	% of staff attending educational session
	Resident educational sessions conducted within a facility	# of sessions	% of residents attending educational sessions
	Presence of CF	% of weeks	
	Presence of Audiologist	% of months	

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

The study is randomized at the facility level with pairs of facilities randomized to cross over to the intervention. Pairing is not random, rather pairing will be conducted to have comparable N across pairs.

The Data Entry System (REDCap) and Database will be constructed in a manner that will not allow the DCs to determine what intervention is currently present in the building (Consult Model or Engage Model). The DCs will be blinded in this manner but may be unintentionally unblinded by resident comments when they are interacting. The research team does not anticipate needing to unblind data collectors at any point however if necessary, to unblind will be the decision of the PI in consultation with the leadership team. The research team is not blinded due to the need to work with the Data Coordinating Center to implement the Engage Model across the study.

The University of Pittsburgh Physical Therapy Data Center will serve as the Data Coordinating Center (DCC) under the direction of Dr. Patterson (**IR-7**). We will use an electronic data capture (EDC) system which will be built around standardized case report forms. The system will have additional applications

including participant tracking, file uploads, and reporting. The electronic data management system will allow the trial to be paperless, as all data will be input directly by the research staff into a secure web-based system. Data will be collected on facilities, staff, residents and family members with linkage through unique, study specific identifiers. For residents, the data collected are minimal: demographics, hearing test results, use of hearing devices, satisfaction with social participation, hearing- specific HRQoL, hospitalizations, and change in status such as moving or death. The data core analysts will be blinded to condition (**IR-6**).

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

The Fidelity measures outlined in 6.2.1 will confirm that participants are accessing the intervention at the individual level. Participants also are impacted at the Facility level and the DSC will collect monthly data from the facility about the use of group amplification systems.

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

The Engage Intervention is both at the Facility and Individual level. It is care that is provided through UPMC Assisted Living and therefore the resident will be exposed whether enrolled in the study (research measures) or not. The most common reason for a resident to discontinue any level of intervention will be that the resident no longer lives in the building. This also would be the reason for a family member to stop participating. The most common reason for staff to stop participating in the intervention would be relocation of his/her job. All data collected to this point will be used in the analysis.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Residents

The reason for participant discontinuation or withdrawal from the study will be recorded on the DCDemographicsBaseline1 (Time1, Time 2, Time 3, Time 4, Time 5) Case Report Form (CRF). All new residents entering the facility during the study will be invited to enroll.

Reasons for discontinuation or withdrawal:
Moved to higher level of care
Moved to hospice care
Deceased
Moved to family

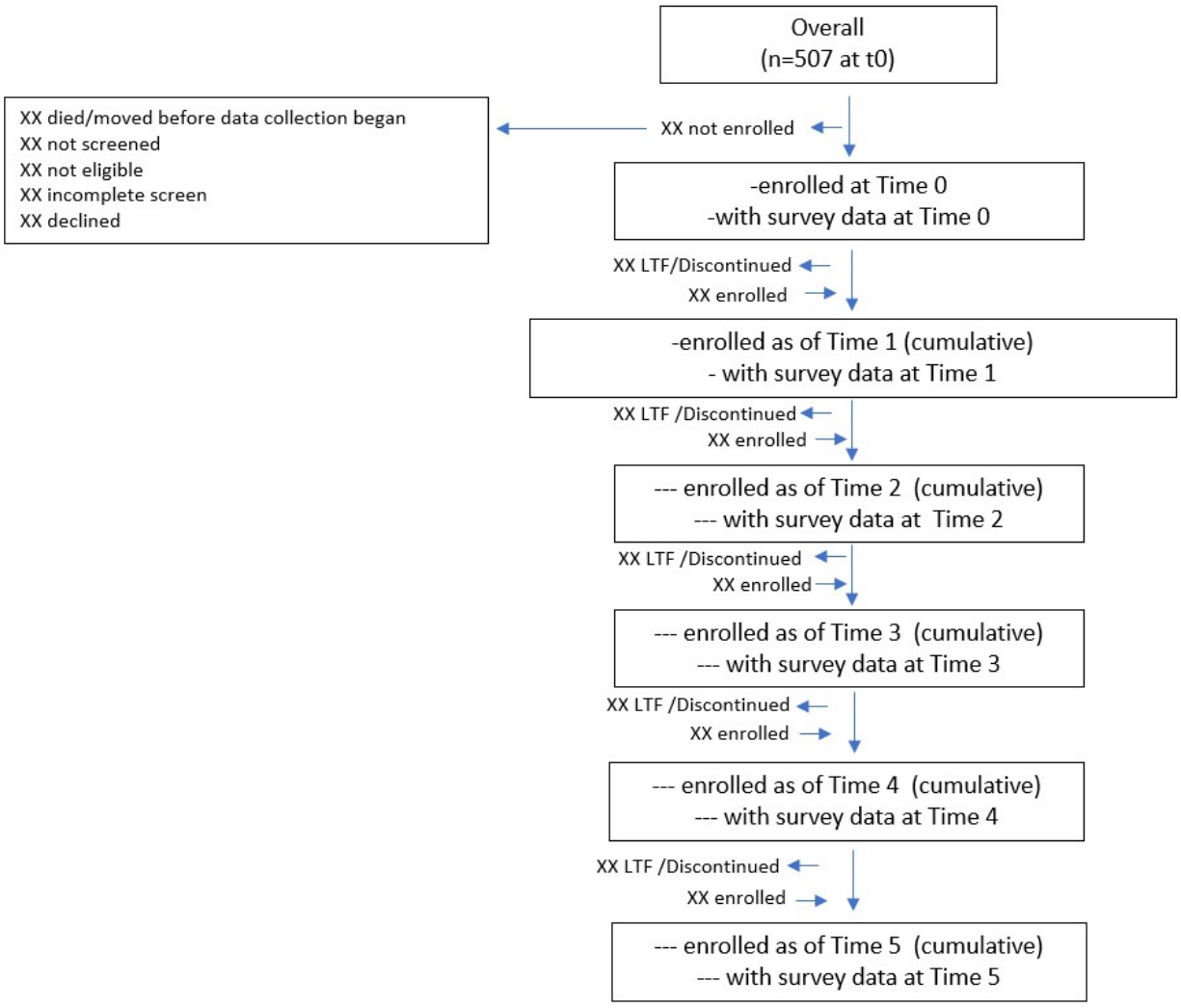
Family Members

Typically, family members discontinue or withdraw based on the status of the resident.

Staff Members

Staff members withdraw or discontinue if their job placement moves to another location.

The sample CONSORT diagram below illustrates the tracking of enrollment, loss to follow up, and new individuals entering the study (i.e., people who move into the facility during the study). Individuals lost to follow up will be further characterized related to why they were lost to follow up.



7.3 LOST TO FOLLOW-UP

Missing data prevention and analysis plan: To minimize missing data, we will create a tracking system with reminders in the electronic data capture system that will prompt research staff as to which residents are due for follow-up (**MD-1**). If the resident is temporarily unavailable, e.g., hospitalized, visiting family, the research staff member will document the reason for the missing survey and make multiple attempts to follow up with the individual (**IR-7**). We will continue to attempt to collect data throughout the 7-8 week time frame where the Data Collector is in the building every 5-months. We expect to have at least 1 follow-up assessment for at least 85% of the participating residents, based on our pilot data. We will compare baseline characteristics (e.g., age, hearing loss, original responses to surveys of hearing and satisfaction in participation, sex, race, ethnicity, date entered facility) between residents with any missing follow-up to those without to assess potential biases. We will try to obtain reasons for missed assessments so that we can assess the missing data mechanism (**MD-3**). Missed assessments are captured in the REDCap survey when a staff member or resident can tell us why data was not collected (e.g., the resident is out of the facility due to hospitalization or due to family visit, resident does not want to participate on this day, etc.). The linear mixed models proposed for the analyses assume missing data at random (**MD-2**) and perform as well as multiple imputation given the same assumption of the missing data mechanism. We will conduct sensitivity analyses (**MD-4**) assuming non-ignorable missingness with differential imputation of poor scores and pattern mixture models (**MD-2**). We will compare the results from the sensitivity analyses to our primary analyses to assess the robustness of findings.

As a way to explore the issue of attrition and inclusion of residents after baseline, we propose a sensitivity analysis as was done in a similarly designed open cohort stepped wedge trial for depression management in nursing homes (82). We will use two dummy variables for newcomers and non-completers (lost to follow up, died, relocated) and interactions between these variables and the intervention to see if the intervention effect is different for these subgroups of residents.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

The set of research measures will be conducted at Baseline 1, , Time 1, Time 2, Time 3, Time 4, and Time 5 (see the Schedule of Activities in section 3.1) for residents, families, and staff. The MOP has all of the CRFs in the appendices.

Residents:
Data will be collected by trained data collectors. Training will include:

DCs will consist of audiology students from the University of Pittsburgh, and the DSC Jonathan Rivera. These students have experience in hearing testing and interviewing in their clinical training which makes them ideal data collectors in this study. In addition, they have experience with geriatric populations and managing communication with individuals with communication challenges. Since June 2020, they also have experience using appropriate PPE and following strict sanitation guidelines related to clinical interactions. These same guidelines will be followed in resident interactions to ensure safety. Training of the DC's will include:

- Virtual audiometer simulation to ensure accuracy in completing Pure Tone Hearing Surveys. Adequate accuracy is defined as establishing thresholds within +/- 5 dB from the target air conduction threshold across four frequencies (500, 1000, 2000, 4000 Hz) in 10 simulation cases. The cases are set to have a variety of patient response types to mimic what the DC's will experience on site.
- Pure tone hearing surveys on 5 classmates will allow for practice with equipment placement and testing in a real environment (rather than simulated).
- The DSC will train the DC's in the use of the iPad interface with the REDCap data collection system. The DC's will collect practice data on two individuals using the interface. Data includes consent, demographics, and two surveys (Hearing Specific Health Related Quality of Life and Satisfaction with Social Participation).
- Practice interviewing will be completed through role playing with Dr. Mormer to ensure that DC's are ready to handle a variety of situations that may present themselves while interacting with older adults in Assisted Living environments. Interviewers will be instructed on methods for determining if a participant becomes distressed during an interview. If this situation occurs, the interviewer will be trained to temporarily discontinue the interview and ask the participant if they wish to terminate the interview and/or to resume at a later time.
- The DSC will coordinate all site-specific training for the DC's.

Measures include:

Demographic Information

Facility

Date entered facility

Ethnicity

Race

Sex

Hearing Handicap for the Inventory – Short Version

Satisfaction with Participation in Discretionary Social Activities – Short Form 7a

Pure Tone Hearing Survey (quietest sound that can be heard at 500, 1000, 2000, 4000 Hz in each ear.

CRFs for these forms are found in the Appendix of the MOP.

Family:

The DSC will send surveys to family members via email or mail depending on what they prefer.

Measure includes:

Zarit Burden Interview -modified 4 question v. 1.0

CRFs for this form is found in the Appendix of the MOP.

Staff:

The DSC will provide paper surveys to the Staff based on the lack of use of email accounts at these locations.

Measure includes:

Michigan Organizational Assessment Questionnaire (MOAQ)

CRFs for these forms are found in the Appendix of the MOP.

No results from the Pure Tone Hearing Survey or the questionnaires for any group will be shared with participants. If a resident is concerned about their hearing, they will be encouraged to see the Audiologist who comes to the facility once per month. This service is always available to them.

Intervention Data

The CF and Audiologist routinely track data for QA and QI as part of their work at UPMC. These data will be used to track the intervention at the individual and facility level. The activities of the CF (described in detail in the MOP) will be recorded in the REDCap database which will allow the Data Survey Coordinator (DSC) to view reports of missing data for each visit. The DSC will follow up with Elizabeth Dervin (UPMC Communication Facilitator on the Stakeholder Advisory Panel) if there are missing data on a consistent basis so she can provide re-training to the CF. The Audiologist sees scheduled patients during the monthly audiology visits. We will collect number of visits per facility to track consistency and again, will follow up with the audiologist if there are discrepancies between facilities.

CRFs for the Engage and Consult Model are found in the Appendix of the MOP.

Data related to the complex intervention core functions and forms will be collected and are outlined in the table below.

Problem/Need	Core Functions	Forms (dependent on context, individualized)	Intermediate Outcomes
1.Lack of awareness of hearing loss (HL)	A. Provide accessible hearing screening	I. Promote HL awareness and availability of hearing screenings through: a. facility media (digital boards, flyers, etc.)	Within 3 weeks of screening ask resident to describe the results and recommendations (i.e., teach back)
		a. facility media (digital boards, flyers, etc.	
		b. Letters to residents	
		c. Letters to families	
		II. Provide screening in central areas and apartments	
	B.Provide recommendation to see the Audiologist for a full hearing test	III. Tracking and follow-up to ensure patients receive screening and follow-up hearing tests	Adherence to recommended follow-up audiological exam
		V. Recommend hearing test following a "fail" on hearing screening	Within 3 weeks of testing ask resident to describe the recommendations that were provided at the time of the test (i.e., teach back)
		VI. Schedule hearing test at time of completion of the hearing screening	

2.Lack of knowledge and devices to independently manage hearing loss	A.Creation of Individual Communication Plan	I. Use of personal amplification device (custom or non-custom) if appropriate	Ask resident to demonstrate battery removal and re-insertion (this is an direct way to determine that the device has been used given that the battery would need to be changed) three weeks after receiving the amplification. CF records self-reported and staff-reported use biweekly.
		II. TV device if appropriate	Ask resident to demonstrate use (turn it on, off, put headset on, etc.) 2 weeks after delivery. CF records self-reported and staff-reported use biweekly.
		III. Amplified Phone Device	Call resident in order to test ability to use the device successfully. CF records self-reported and staff-reported use biweekly. CF will interact with each resident with a Communication Plan once per week to ensure there is adequate and consistent observation. Staff are assigned to a specific number of residents and therefore

			can provide these observations weekly.
		IV. Communication Strategies	Observation of specific communication strategy use by resident when engaged with the CF (e.g., muting TV when room is entered, looking at speaker, etc.). CF records self-reported and staff-reported use biweekly. CF will interact with each resident with a Communication Plan once per week to ensure there is adequate and consistent observation. Staff are assigned to a specific number of residents and therefore can provide these observations weekly.
3.Lack of Communication Accessibility in the Facility related to group activities	A. Use of sound field equalization (amplification) systems	I. Hands on staff training.	Once per month, CF plans timing of facility visit to coincide with planned group activity (e.g., crafts, discussion group, bingo) and record if staff are using room amplification system and if they are passing the microphone to

		different speakers (reinstruct as necessary).
B. Use of group TV amplifying headsets	II. Hands on staff training with system	Once per month, the CF plans timing of facility visit to coincide with group TV activity (movie time, sports event, etc.) and record if staff are offering to assist residents with group TV amplifiers.

8.2 SAFETY ASSESSMENTS

There are no known risks related to the study measures (Pure Tone Hearing Survey and questionnaires). The Intervention is being provided by UPMC Audiology and is provided elsewhere in the UPMC system. There have been no reported risks or adverse events related to the Consult or Engage Model of intervention. The Study Team will monitor all procedures and the DSMB will monitor the study as well. The DSC will visit each facility at each Test Time point to make sure all DCs are following the standard protocol for interacting with residents, enrolling residents, and collecting data.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS

For this study, the following standard AE definitions are used:

Adverse event: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

Serious Adverse Event: Any AE that results in any of the following outcomes:

- Death
- Life-threatening
- Event requiring inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

There is no expectation of serious adverse events related to the research study. The research measures include a Pure Tone Hearing Survey and questionnaires. There is no expectation of a serious adverse event related to the intervention which includes typical hearing care.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

AEs will be collected and entered into the electronic data capture system.

AEs are graded using the Common Terminology Criteria for Adverse Events (CTCAE) according to the following scale:

Mild: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. An experience that is transient and requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. This includes transient laboratory test alterations.

Moderate: Minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL. An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. Includes laboratory test alterations indicating injury, but without long-term risk.

Severe: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care Activities of Daily Living (ADL). An experience that requires therapeutic intervention. The experience interrupts usual daily activities. If hospitalization (or prolongation of hospitalization) is required for treatment it becomes a SAE.

Life-threatening: Urgent intervention indicated

Fatal/Death: Death related to AE.

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

The study uses the following AE attribution scale:

Unrelated: The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible, and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).

Unlikely: The AE is likely not related to the study procedures (i.e., another cause of the event is plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event) but causality cannot be clearly ruled out.

Reasonable Possibility: An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

Definite: The AE is clearly related to the study procedures.

AEs are identified through the Data Collectors who will be interacting with residents in the facilities. For Staff and Families, there is no direct interaction because they will be responding to surveys through mail or web link.

All SAEs and AEs will be recorded in the electronic data capture system immediately upon notification of the occurrence of the SAE or AE. If the event is deemed reportable (serious, unanticipated, and related), the AE will be reported per the IRB AE reporting.

SAEs and AEs related to study measures (considered very unlikely) will be reviewed by the Study Team to determine appropriate resolution. SAEs and AEs related to the intervention (considered very unlikely) will be reviewed by a licensed audiologist and UPMC risk manager for resolution.

8.3.3.3 EXPECTEDNESS

An Audiologist with appropriate expertise in hearing care will be responsible for determining whether an adverse event (AE) is expected or unexpected related to the intervention. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures. This is a minimal risk study with no expected risks to participants.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

All SAEs and AEs will be recorded in the electronic data capture system immediately upon notification of the occurrence of the SAE or AE. DCs will be responsible for recording this information. In addition, the DC will alert the DSC who will notify the PI. If the event is deemed reportable (serious, unanticipated, and related), the AE will be reported per the IRB AE reporting.

8.3.5 ADVERSE EVENT REPORTING

The study team does not anticipate any AEs due to the nature of the research activities. All AEs will be recorded in the electronic data capture system immediately upon notification of the occurrence of the SAE or AE. If the event is deemed reportable (serious, unanticipated, and related), the AE will be reported per the IRB AE reporting guidelines.

The Consult and Engage Interventions are care provided by UPMC staff and are not included in the IRB research activities. If there are Adverse Events related to these models of care, this would be reported in UPMC Risk Master and handled through UPMC protocols for adverse events related to clinical care.

Management of any AEs will be managed on a case-by-case basis and will be coordinated with the care team at the resident's facility if needed. AEs will be reported to the University of Pittsburgh IRB and PCORI within 10 days of the investigator first learning about the event. AEs will be included in DSMB reports.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the University of Pittsburgh IRB, PCORI, and the DSMB no later than 10 working days after the investigator first learns of the event.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

Given the low risk of this project, unanticipated problems should be at a minimum. An unanticipated problem is any incident, experience, or outcome that is unexpected in terms of nature, severity, or frequency, given the intervention protocol and characteristics of the residents or staff.

The study team does not anticipate any UPs due to the nature of the research activities. The study procedures for residents consist of a Pure Tone Hearing Survey and two questionnaires completed in interview format. For staff and families, they will complete a short survey through the mail or internet. Note: The Consult and Engage Interventions are standard of care at UPMC and are not included in the IRB research activities. If there are UPs related to these models of care, this would be reported in UPMC Risk Master and handled through UPMC protocols for adverse events related to clinical care.

Management of any UPs will be managed on a case-by-case basis and will be coordinated by the PI with the care team at the resident's facility if needed.

8.4.2 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

If any unanticipated problems occur, the Director of the facility will be notified and the PI and Data Survey Coordinator will work with the Director to determine the best way to disseminate information to residents. Depending on the unanticipated problem we may need to communicate with all residents, residents enrolled in the study, or only the resident directly impacted. These decisions will be made in consultation with the facility Director and the University of Pittsburgh IRB. Communication also may be directed at the family of the resident(s) depending on the issue.

Staff member who observes or is involved in the unanticipated problem will immediately notify PI Catherine Palmer of a problem that involves a risk to residents or others (e.g. staff, residents, family).

PI Catherine Palmer will report these unanticipated problems to the IRBs and PCORI within 48 hours.

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

H_1
We hypothesize that Engage Model participants will have significantly greater satisfaction with participation in social activities across residents regardless of hearing status compared to those receiving the Consult Model.
H_o
There will be no difference in satisfaction with participation between participants in the Engage and Consult Model.
H_1
We hypothesize that Engage Model participants with hearing loss will have an increase in Hearing-Specific HRQoL compared to those receiving the Consult Model.
H_o
There will be no difference in Hearing-Specific HRQoL between participants with hearing loss in the Engage and Consult Model.

- Secondary Endpoint(s):

H_1
We hypothesize that Engage Model staff will have higher job satisfaction compared to staff in the Consult Model.
H_o
There will be no difference in job satisfaction between staff in the Engage and Consult Model.
H_1
We hypothesize that Engage Model family members will have reduced burden compared to staff in the Consult Model.
H_o
There will be no difference in family burden between staff in the Engage and Consult Model.

9.2 SAMPLE SIZE DETERMINATION

We used a method to estimate sample size that takes into account the cluster randomization, the stepped wedge design, and the longitudinal data on residents[84] (**RC-3**). Our study design originally included 8 clusters (facilities) with 5 time periods (including the baseline), 4 steps, 2 facilities switching from control to intervention at each step, and an average of 65 residents per facility

being continuously followed (**CI-2**). We expect some residents to leave the facility for different reasons and our design will allow new residents to contribute data from the time of moving into the facility until the end of the study period. We conducted sample size analyses accounting for intracluster correlation (ρ=0.20) (**RC-3**), individual autocorrelation (τ=0.5), and cluster autocorrelation (π=0.9)[84]. The *intracluster correlation* is a measure of correlation among residents measured at the same facility within the same time frame. Cluster randomized trials typically assume values between 0.01-0.10 with higher values indicating more similarity in outcomes within clusters such as schools, primary care clinics, or providers. We assumed a higher correlation given that residents are living within the same quarters and sharing the same residential experience. The *individual autocorrelation* is the correlation between any two measures within the same resident over time. We conservatively assumed this to be 0.5 as a lower bound because repeated measures within person are often highly correlated. The *cluster autocorrelation* is the correlation between two population means from the same cluster at different times. We assumed this would be very high (0.9) given the stability of the population in the facilities over time. This design achieves 80% power to detect the hypothesized effect size of 0.3 for either primary outcome (satisfaction with participation or hearing-specific health-related quality of life) between control and intervention periods (two-sided, α=0.025 for each outcome). An effect size of 0.3 translates to a difference between groups of 3 points on the satisfaction with communication scale assuming a standard deviation between 9 and 10 based on our preliminary data from local facilities. An effect size of 0.3 translates to a difference between groups of 3.6 points on the hearing-specific health-related quality of life measure assuming a standard deviation of 12 based on our preliminary data from local facilities. These differences are considered clinically meaningful. We believe this hypothesized effect exists because of previous literature using these measures in clinical populations and from our pilot data.[62,64]

The original sample size analysis for the study used a closed solution formula for a *closed* cohort design, fixed sample size per cluster, and an underlying model with assumptions valid for a large number of clusters. The study is an *open* cohort design allowing participants to drop out of the study (move out of the facility) and new residents to come into the study as they move into the facilities. In addition, the number of clusters is small (only 8) and the number of residents per facility is variable. We conducted simulations to assess the power and Type I error rate of our study given the open cohort design, variability in sample size across facilities, and statistical analysis model that accounts for the small number of clusters. We found the estimated power to be 77-79% with α=0.025 and 85-87% with α=0.05 with minimal to no inflation in the Type I error rates (observed 0.025 to 0.033 for α=0.025 and 0.045 to 0.058 for α=0.05) assuming a drop out (churn rate) of 7.5% per period. These simulations were sent to the DSMB and approved prior to study start. Once the study began, the targeted sample size per facility (~65) was deemed not to be achievable due to lower than expected census and higher than expected resident decline to participate. Additional simulations showed that with 10 facilities, 5 steps (2 facilities per step), and 30 residents per facility, we achieved 85% power for the same hypothesized effect size and correlation parameters.

9.3 POPULATIONS FOR ANALYSES

All enrolled residents will be included in the analyses. The Engage Model is a Facility and Individual Level intervention so all residents are potentially impacted by the intervention.
All staff and family members willing to participate will be included in the analysis.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Descriptive statistics will be used to characterize the overall cohort and each facility cohort for the variables of interest. Summary statistics will include means with standard deviations for normally distributed data and medians with interquartile ranges for skewed data. Categorical data will be summarized with frequencies and percentages. All tests will be two-sided and conducted at α=0.05 and all confidence intervals calculated at 95% unless otherwise stated. All variables for the primary analyses are stated below. Although we will assess normality assumptions for the primary and secondary outcomes, we do not plan to use transformations for these scale outcomes due to lack of interpretability and the large sample size of the trial providing robustness to normality deviations in estimating and testing intervention effects. A full Statistical Analysis Plan is available as a separate document (HearCARE Statistical Analysis Plan, October 6, 2021).

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

We will use linear mixed models to test the hypothesis of improving satisfaction with participation and hearing-specific HRQoL specifying the fixed effects of intervention and time and random effects for facility, facility*time, and resident (**RC-4**). These random effects are based on the statistical model referenced in Hooper (2016)[81] that account for the correlation among individuals in the same cluster at the same time point, correlation between observations for the same individual at two time points, and the correlation between two means of the same cluster at two time points. Time will be treated as a categorical variable. We will estimate the mean difference and corresponding 95% confidence interval for the intervention effect (**IR-1**) and test that the difference between intervention and control conditions is significant. A two-sided test α=0.025 for each outcome using a Wald t-test with Kenward Roger correction for small sample bias and Satterthwaite degrees of freedom will be employed. Primary analysis will be unadjusted for covariates.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

We will use linear mixed models to explore the impact of the intervention on staff satisfaction and family burden. The models will be specified with fixed effects for the intervention and time and random effects for facility, facility*time, and participant (**RC-4**). For staff satisfaction, the participant is

the staff member. For each staff member we will measure satisfaction at baseline and at least one measurement per time-period. For family burden, the participant is the family member/caregiver. We will measure family burden at baseline and at least one measurement per time-period the resident is enrolled in the study. These random effects account for correlation among individuals in the same cluster at the same time point, correlation between observations for the same individual at two time points, and the correlation between two means of the same cluster at two time points. We will estimate the mean difference and corresponding 95% confidence interval for the intervention effect.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

We will compare facilities at baseline and the last time period on several characteristics including: number of residents with measured hearing loss, gender composition, age range, race and ethnicity of residents, total occupancy, and annual staff turnover. We will also compare them on the following measures from the previous 5 months: number of unexpected hospitalizations, number of falls, number of residents moving to a higher level of care, and number of deceased residents.

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

In an effort to ascertain whether the intervention is more or less effective for certain resident subgroups (**RQ-4**, **HT-1**), we will explore the following groups (**HT-2**):

(a) those who have different degrees of hearing loss at baseline (~84% expected to have some level of hearing loss) and those who do not;

H_1The intervention provided by the Engage Model and measured by the HHIE and Satisfaction with Participation will have more impact on residents with hearing loss at baseline as compared to residents with no measured hearing loss.

H_0 The intervention provided by the Engage Model and measured by the HHIE and Satisfaction with Participation will not have a different impact on residents with hearing loss at baseline as compared to residents with no measured hearing loss.

(b) those who have different degrees of hearing loss and use a device (~18-32% of 84%; note these are estimates and the actual percent of device use will be used) compared to those who do not use a device but have different degrees of hearing loss;

H_1The intervention provided by the Engage Model and measured by the HHIE and Satisfaction with Participation will have more impact on residents with hearing loss who do not use a hearing device at baseline as compared to residents with hearing loss who do use a hearing device.

H_0 The intervention provided by the Engage Model and measured by the HHIE and Satisfaction with Participation will not have a different impact on residents with hearing loss who do not use a hearing device at baseline compared to residents with hearing loss who do use a hearing device.

(c) those with high social participation at baseline (~50%) and those with lower social participation;

H_1The intervention provided by the Engage Model and measured by Social Participation will have more impact for residents with low social participation at baseline compared to residents with normal or high social participation.

H_0 The intervention provided by the Engage Model and measured by Social Participation will not have a different impact for residents with low social participation at baseline compared to residents with normal or high social participation.

(d) those with high hearing-specific HRQoL (~50%) and those with lower hearing-specific HRQoL. Scores of 0-8 on the HHIE are “low” and 10-40 are “high” with 10% indicating a significant change.[83]

H_1The intervention provided by the Engage Model and measured by HHIE will have more impact for residents with high hearing-specific HRQoL at baseline as compared to residents with hearing-specific HRQoL within normal limits.

H_0 The intervention provided by the Engage Model and measured by HHIE will not have a different impact for residents with high hearing-specific HRQoL at baseline as compared to residents with hearing-specific HRQoL within normal limits.

The individual hearing threshold data will allow us to stratify according to hearing levels. We will use the ASHA classification of degrees of hearing loss (normal -10 to 15; slight 16 to 25; mild 26 to 40; moderate 41 to 55; moderately severe 56 to 70; severe 71 to 90; profound >91 dB).[84] The number of individuals in the HHIE subgroups and hearing level subgroups cannot be adequately estimated and will be known when data collection are complete. We will explore the heterogeneity using interaction terms (**HT-3**) between the factor of interest and the intervention fixed effect. Regardless of the significance, we will estimate the treatment effect for each subgroup with corresponding 95% confidence intervals (**HT-2**).

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

N/A

9.4.9 EXPLORATORY ANALYSES

With respect to the effectiveness of the intervention, we believe there is a threshold of improvement with exposure to the intervention. In other words, there will be a change (i.e., improved hearing specific HR QoL and satisfaction with participation) and then that change will be maintained, it will not increase. However, with the data we will obtain, we will be able to explore if the change over 20 months relative to baseline is the same as the change at 5 months relative to baseline (dose effect within facilities), and the same incrementally for 15 or 10 months of exposure (pooling across facilities). These comparisons are exploratory as they are either completely or partially confounded with time. We also can conduct an analysis used in the depression trial[82] to explore linear and quadratic terms for the number of periods in the intervention condition both at the facility and resident levels and the number of periods the resident was in the study.

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

The University of Pittsburgh IRB has deemed this an Exempt Protocol. All participants will be informed that they are being asked to participate in a research study and the research measures and timing will be explained. In addition, every potential participant will be informed that their participation is voluntary and they can stop participating at any time without impacting their relationship with their Senior Living Community, the University of Pittsburgh, or UPMC. For residents, this description will be read to them and they can take as much time as they like to ask questions. The DC will record either Yes or No related to their willingness to participate. For Staff and Families, they will receive this description either in writing or electronically and will have contact information if they have questions.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

As described in section 10.1.1.1, this is an Exempt protocol and consent will be administered verbally for residents and in writing (paper or electronic) for Families and Staff. All participants will be competent in communicating in English based on self-report.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

Given the current status of the Global Pandemic, this study could be suspended if the Assisted Living Facilities limit non-essential personnel (DCs) from entering the building due to safety concerns for residents. If this happens, the Study Team will notify the University of Pittsburgh IRB and PCORI. This disruption (implementing study questionnaires) will not have an adverse effect on residents, staff, and family. The Intervention (Consult and/or Engage) may not be disrupted depending on the Senior Living Community decision about continuing what may be viewed as essential care, but it could be limited in this same situation. The providers of the hearing care would work directly with the facility and the residents virtually in this case which would be independent of the research project.

The study would resume once concerns about safety of residents due to possible virus exposure were addressed.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.
Participants' identify will be protected by providing everyone with a code consisting of first and last initial, a unique 4 digit identifier and a two letter facility identifier. The key to this code will be kept in secure file that is only accessed by the Study leadership team. An identifier is needed to link data over time and to link resident data to family member data and staff to specific facilities.

All research activities will be conducted in as private a setting as possible.

There is no plan to share data while the study is active. This study is registered with clinicaltrials.gov and results submitted in accordance with PCORI requirements for public release of research findings (**IR-5**). Prior to submission of the Draft Final Research Report, we will enter into an agreement with a PCORI designated data repository (**IR-7**). Prior to the acceptance of the Final Research Report, we will provide a full data package to the PCORI designated repository including an analyzable data set, the full protocol for the study, metadata, a data dictionary, full statistical analysis plan, and analytic code for the Final Research Report. We will maintain the full data package for at least seven years.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Data collected for this study will be analyzed and stored at the University of Pittsburgh Data Coordinating Center. After the study is completed, the de-identified, archived data will be transmitted to and stored at a PCORI designated repository, for use by other researchers including those outside of the study.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Project Directors/Leadership Team (Names REMOVED)

Supporting Research Team (Names REMOVED)

Stakeholder Advisory Panel (Names REMOVED)

This panel will consist of 19 individuals who have either personal or professional experience related to older adults and hearing loss. The panel will initially meet for a series of three kickoff orientation meetings, held virtually. Thereafter, one-hour meetings will occur virtually on a monthly basis.

The Stakeholder Advisory Panel will provide input and feedback on the study protocol, review and advise the research team on data collection and recruitment as needed, and address issues that arise during the study. Additionally, the SAP will provide input and assistance with recommendations that emanate from the study, and with dissemination of study findings.

10.1.6 SAFETY OVERSIGHT

It has been determined under the advisement of the project's coordinating center Institutional Review Board at the University of Pittsburgh, that this study has minimal Risk.

The investigators conducting the trial at the University of Pittsburgh along with the Data Coordinating Center are primarily responsible for trial monitoring. In addition, the Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to monitor study implementation and resident safety. Further details are provided below.

The Data and Safety Monitoring Board Charter and the Data and Safety Monitoring Plan can be found as separate documents.

The Data Coordinating Center at the University of Pittsburgh will produce administrative reports that describe study progress including:

- Accrual by facility
- Demographics in aggregate and by facility
- Study subject status including retention in aggregate and by facility
- Form and visit completeness
- Adherence to inclusion/exclusion criteria and the study protocol in aggregate and by facility

These reports will be reviewed internally by the study leadership (monthly). Similar reports will also be presented to the Data and Safety Monitoring Board (DSMB) and the representative of the Patient Centered Outcomes Research Institute (see below).

The study statistician is Dr. Charity Patterson who will be responsible for overseeing report generation.

Interim reports will be generated by the DCC and distributed to the DSMB at least ten days prior to a scheduled meeting. The contents of the report will be determined by the DSMB. Additions and other modifications to these reports may be directed by the DSMB on a one-time or continuing basis.

Interim data reports generally consist of two parts.

(Open Session Report) provides information on study aspects such as participant accrual and demographics, retention, withdrawals, data completeness, adverse events, other study performance measures, any new information on the intervention or disease/disorder that may affect the outcome of the trial, and a list of publications or presentations.

(Closed Session Report) will divide study participants per coded treatment assignment (e.g., Treatments A vs. B), comparing subject demographics and baseline characteristics, rates of and reasons for treatment discontinuation and loss to follow-up, and rates of serious adverse events (SAEs). The Closed Session Report is considered confidential.

Dr. Patterson will work with PI Dr. Palmer to prepare an Executive Summary and response addressing prior concerns regarding the conduct of the study. This will be distributed to DSMB members along with the Open Session report. DSMB meeting data reports will generally include the following types of information, although only the Closed Session data reports will include comparisons by intervention group:

- Monthly and cumulative accrual, compared with targets
- Baseline characteristics overall
- Completeness and quality of data collection forms
- Status of enrolled participants overall
- Compliance with eligibility criteria and other protocol requirements
- Subject adherence to the visits
- Individual adverse events (AEs) and serious adverse events (SAEs) by subject ID number and a table of event-specific cumulative rates

Copies distributed prior to and during a meeting will be requested to be destroyed after the meeting. Data files to be used for interim reporting will have undergone established editing procedures to the greatest extent possible. Interim analyses of efficacy data will be performed only if they are specified and approved in advance and criteria for possible stopping are clearly defined.

Reports from the DSMB

Minutes of the DSMB meeting and recommendations of the DSMB will be summarized by the CCC and sent to the DSMB Chair for review and approval. Each report will conclude with a recommendation to

continue or to terminate the study. This recommendation will be made by formal majority vote. A recommendation to terminate the study will be transmitted to the Primary Investigator and relevant Institutional Officials as rapidly as possible. In the event of a split vote in favor of continuation, a minority report should be contained within the regular DSMB report. The report will not include unblinded data, discussion of the unblinded data, etc. The DSMB chair will also create a separate set of minutes summarizing the unblinded session. Copies of the blinded DSMB report will be sent to the central and local IRB of each site involved in the study.

10.1.7 CLINICAL MONITORING

The clinical care, Consult Model and Engage Model currently exist in the UPMC Health System and are monitored as part of clinical care in the Senior Living Facilities. The study will not interrupt or impact this process. Data collection and research activities will be monitored by the DSMB described in Section 10.1.6.

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The consent process will be monitored with every participant required to provide consent that is tracked in the REDCap data system. Electronic data capture will be monitored by the DSC (described in more detail below). We maintain all source documents to ensure that the electronic data capture mirrors the planned data capture. Data Collection and Intervention Fidelity are monitored on an ongoing basis by the DSC. Protocol deviations will be monitored on a regular basis and dealt with immediately with re-training.

Data Collectors will be trained prior to starting the protocol (see Section 8.1). The DSC will observe each DC in each facility at each data collection time point (Baseline 1, Baseline 2, Time 1, Time 2, Time 3, Time 4). The CRFs related to residents and staff will be captured electronically and directly entered into the REDCap data base built for this study. The Family data will either be electronic (REDCap) survey or returned via paper questionnaire to the DSC who will enter the data. The data from the Audiologist will be provided to the DSC for electronic entry. All routine tracking provided by the CF will be captured directly into the REDCap system. These processes reduce the change of inaccuracies due to manual data entry from paper records. In addition, this methodology protects participant privacy by reducing paper data sheets. The CFs have standard training through the UPMC Audiology Division. The CF Training Handbook is uploaded as a separate document.

For quality monitoring, the DCC will produce reports for the study team to review that will provide information on 1) consent process, 2) completion of data elements, 3) compliance with intervention, fidelity measures (see section 6.2.1) and 4) protocol deviations.

In addition to reporting, the real-time validation and regular data quality monitoring by the SHRS Data Center are intended to detect and correct errors continuously during the study. Real time validation will be implemented by building data entry fields with restricted options or restricted ranges and data quality prompts upon entry of outlying values. The Data Manager will develop data quality checks, monitor incoming data, and generate queries with specific focus on screening, inclusion/exclusion criteria, randomization, intervention data, outcomes, and adverse events. We will monitor for missing items, missing forms, and range of values entered.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

The University of Pittsburgh Physical Therapy Data Center will serve as the Data Coordinating Center (DCC) under the direction of Dr. Patterson (**IR-7**). We will use an electronic data capture (EDC) system which will be built around standardized case report forms. The system will have additional applications including participant tracking, file uploads, and reporting. The electronic data management system will allow the trial to be paperless, as all data will be input directly by the DCs into a secure web-based system. Data will be collected on facilities, staff, residents and family members with linkage through unique, study specific identifiers. For residents, the data collected are minimal: demographics, hearing test results, use of hearing devices, satisfaction with social participation, hearing- specific HRQoL, hospitalizations, and change in status such as moving or death. The data core analysts will be blinded to condition (**IR-6**).

REDCap is a secure, web-based application designed with the flexibility to support data capture for a variety of research projects. REDCap provide management of user-access to the data, a mechanism for validated data uploads from external sources, an intuitive user interface for validated data capture through the execution of real-time validation rules, an audit trail for tracking transactions within the system, such as study system setup and modifications, data imports, data entry and edits, and data exports, and a mechanism for seamless data downloads to common data formats (SAS datasets will be the format of choice for this study).

The web-based data submission software is REDCap version 10.3.7 and all data will be stored on the University of Pittsburgh's servers which are housed at the Network Operations Center (NOC) and managed by the University's Computing Services and Systems Development (CSSD). The NOC is a state-of-the-art technical facility that houses servers and network equipment to ensure stable and reliable service for University enterprise systems. It is a centralized management center that is capable of identifying, notifying, and repairing problems when they occur and projecting when and where they might occur. Data are encrypted and protected behind enterprise network firewalls. CSSD conducts web vulnerability scans to analyze web applications from development through production for security.

Each aspect of REDCap project will be tested in three phases before actual study data is collected. Phase I entails testing each form for accuracy on elements, fields, and options. Phase II entails testing skip patterns and functionality across forms. Phase III entails DC staff and study personnel entering mock data including screen failures, randomized cases, and data for cases fully enrolled and followed. He/she will enter the mock data in the CRFs into each field of each data collection instrument and document the success or failure of a) the user interface for data entry, b) the on-line univariate and range data validation checks, and c) custom functions.

All DCC statisticians use SAS version 9.4 for report and statistical analyses. SAS runs off individual computers. The SAS data files will only contain de-identified data. Data files and programs used for monitoring, reporting, and analysis will be stored on the Office 365 University of Pittsburgh Group for the PTDC. Data will be stored indefinitely.

10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 7 years after publication of study results but can be maintained indefinitely by the Data Management Center. No records will be destroyed without the written consent of the sponsor and funding agency.

10.1.10 PROTOCOL DEVIATIONS

A protocol deviation occurs when, without significant consequences, the activities on a study diverge from the IRB-approved protocol (e.g., staff not completing training within timeframe).

Deviations from protocol will be monitored and documented throughout the study. The protocol deviations will be reported to the University of Pittsburgh IRB as Reportable New Information (RNI). A list will be kept and sent to PCORI with quarterly reports if issues do not meet immediate reporting requirements by PCORI standards.

10.1.11 PUBLICATION AND DATA SHARING POLICY

All dissemination of information will follow PCORI guidelines:

https://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf

All proposed publications must be reviewed by the study team prior to manuscript development. The lead author will be required to draft a manuscript proposal, which will detail the authors of the paper (in proposed order), target journal, objective of the manuscript, data needs, and resource needs. The lead author is responsible for collaborating with and including advisory committee members in dissemination efforts to ensure that stakeholder perspectives are represented.

The manuscript proposal will be reviewed by the study team for approval. At least one member of the leadership team should be included as a contributing author on the manuscript. The lead author will not move forward with the manuscript development until they have received written approval from the study team.

After an article has been accepted for publication, it is the lead author's responsibility to communicate the acceptance along with a full reference of the article to the PI. The PI will be responsible for tracking all publications originating from this study.

This study is registered with clinicaltrials.gov and results submitted in accordance with PCORI requirements for public release of research findings (**IR-5**). Prior to submission of the Draft Final Research Report, we will enter into an agreement with a PCORI designated data repository (**IR-7**). Prior to the acceptance of the Final Research Report, we will provide a full data package to the PCORI designated repository including an analyzable data set, the full protocol for the study, metadata, a data dictionary, full statistical analysis plan, and analytic code for the Final Research Report. We will maintain the full data package for at least seven years.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence, such as by hearing device manufacturers, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the University of Pittsburgh IRB and the PCORI team have established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest. At the time of IRB submission, no conflicts of interest had been disclosed.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
AL	Assisted Living
ACE	Active Communication Education [program]
ARHL	Age Related Hearing Loss

CF	Communication Facilitator
CFR	Code of Federal Regulations
COC	Certificate of Confidentiality
Co-I	Co-Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DC	Data Collectors
DCC	Data Coordinating Center
DHSS	Department of Health and Human Services
DSC	Data Survey Coordinator
DSMB	Data and Safety Monitoring Board
DSMP	Data and Safety Monitoring Plan
DRE	Disease-Related Event
EC	Ethics Committee
GCP	Good Clinical Practice
HearCARE	Hearing for Communication and Resident Engagement
HHIE	Hearing Handicap for the Elderly
HIPAA	Health Insurance Portability and Accountability Act
HRQoL	Heath Related Quality of Life
IB	Investigator's Brochure
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
OHRP	Office of Human Research Protection
QA	Quality Assurance
QoL	Quality of Life
MOAQ	Michigan Organizational Assessment Questionnaire
MOP	Manual of Procedures
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SAP	Stakeholder Advisory Panel
SOA	Schedule of Activities
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale
V1	9/24/2020	Original IRB approved	Original approval
V2	5/26/2021	Added one location	One original location closed and we replaced this site.
V3	7/27/2021	Added two locations	Based on lower census and increased declines, we added two locations for a total of 10 facilities. We extended the study by 5 months (5th time point).
V4	12/30/2021	Editorial changes throughout	Guidance from PCORI

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