LEAD IT!

An App to Enable Persons With Early Stage Dementia to Lead Group Activities for Their Peers

Project Also Known As:

PEER: Purposeful Engagement for Every Resident

NCT05516342

Study Protocol

1.0 STUDY OVERVIEW

Study Title:
LEAD IT! An App to Enable Persons with Early-Stage Dementia to Lead Group Activities for Their Peers
(Also Known As "PEER: Purposeful Engagement for Every Resident")

The purpose of this study is to develop and evaluate a tablet-based app called PEER that will enable persons with dementia (PWD) to lead group activities for their peers (i.e., other PWD). This Phase 2 Small Business Innovation Research (SBIR) grant is focused on evaluation of the PEER app and its impacts on users.

A quasi-experiment will be conducted. It will be a cluster randomized trial (CRT), consisting of pre- and post-intervention measurements of two nonequivalent groups: a Treatment Group (TG)—i.e. 48 PWD who receive the intervention – and a Control Group (CG)– i.e., 48 PWD receiving standard programming / care. Since this experiment will occur after all enhancements to the PEER App are complete, it will represent the definitive trial of PEER's proximal and distal effects.

The Phase 2 study will be conducted by two teams. The **Development Team (DT)** will be responsible for content and software development for the PEER app. The team will consist of Mr. Skrajner (PI and Team Leader), John Zeisel (Content Development Expert), Mr. Knapp (Software Engineer), and Mr. Lombardo (Graphic Designer). This team has previously worked together on SBIR projects. As was the case for Phase 1, Mr. Skrajner will storyboard the app and create all activity content; Dr. Zeisel (Content Development Expert) will assist with this process, as well. The structure, storyboard, and logic for the app will be communicated to Mr. Knapp and Mr. Lombardo using Pencil (pencil.evolus.vn) and Behavior Driven Development (BDD) methodology (Solis & Wang, 2011). Mr. Knapp will again develop the app using Adobe PhoneGap and a separate Ruby on Rails application. Mr. Lombardo will work on the graphic design of the app. The goal will be to create a clean, simple, and aesthetically pleasing design that reduces distractions (which could confuse PWD) and is age-appropriate (e.g., cartoonish design elements will not be used). As discussed below, we will elicit feedback from PWD and staff on the design of the app, by providing various options to them. The **Experimental Team (ET)** will be tasked with all investigatory work for both PWD and Staff Participants (SPs). This team will be led by Mr. Gorzelle, who has served as a PI on several SBIR studies, as well as two RA's.

The final sample size will consist of 96 PWD—i.e., at each of 8 sites, there will be 10 Resident Players (RPs) and 2 Resident Leaders (RLs) who complete all study procedures. To accommodate for attrition of up to 25%, we will initially enroll 120 PWD—i.e., 12 RPs and 3 RLs at each site. The experiment will also include 24 Staff Participants (SPs). PWD will be 55+ years old, diagnosed with any type of dementia, speak and read English, and must reside in an ALF or NH. RPs must score at least five on the Mini-Mental State Examination (MMSE) -OR- score at least one (1) on the I'm Still Here Skills Inventory – PEER Version (ISH-SI-PV); RLs must score at least 13. In addition, RLs must perform adequately on the PEER leader assessment. PWD will be excluded from the study if they show signs of rapid cognitive decline or physical deterioration

over the last six months, as reported by staff (this last exclusion criteria is defined more specifically below). SPs must be at least 18 years old and speak English.

Randomization: Sites will be randomized with respect to condition (Control or Experimental) at the beginning of the experiment. Individual random assignment is not feasible, because a single site cannot practically serve as both a control and treatment site. That is, if a single site had some control participants and some treatment participants, control participants may still find their way into PEER sessions, which would cause contamination of the control group and, in turn, be a threat to validity.

PWD will take part in the study for about 6.5 months. During a one-month Baseline Period, PWD will take part in baseline assessments, during which time researchers directly interview PWD to assess cognition, depression, and quality of life. Researchers will also observe PWD participating in standard activities and interview caregivers to obtain data related to agitation and neuropsychiatric symptoms exhibited by PWD.

PWD will then enter the Intervention Period. *For PWD at Experimental Sites*, PWD will be invited to participate in PEER sessions twice per week for 4.5 months; each PEER session is expected last about 45 minutes. If PWD or staff are unable to attend (e.g., due to illness or a doctor's appointment), researchers will simply note their absence. *For PWD at Experimental Sites,* PWD will participate in standard care for 4.5 months.

After the Intervention Period, researchers will directly interview PWD to reassess depression and quality life, as well as interview caregivers to obtain data related to agitation and neuropsychiatric symptoms exhibited by PWD.

SPs will only be enrolled at Experimental Sites since their only involvement will be related to providing feedback about the PEER training and intervention. SPs will participate in the study for about 6.5 months. Their participation will begin by attending an in-person training on PEER. Prior to and after the training, SPs will take a quiz (to examine knowledge transfer). In addition, satisfaction questions will be posed to staff after taking the training. Staff will then enter the Intervention Period. Staff will be invited to participate in PEER sessions twice per week for 4.5 months; each PEER session is expected last about 45 minutes. Satisfaction questions will be posed to SPs at the end of each PEER session. After the Intervention Period has ended, SPs will also be posed final satisfaction questions.

2.0 STUDY ORGANIZATION AND RESPONSIBILITIES

Table 1: Staff Roster

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3.0 STUDY FLOW

An overview of the study processes, presented in a flow diagram in Figure 1, describes each of the study's major steps.

Figure 1: Study Flow Diagram for PWD

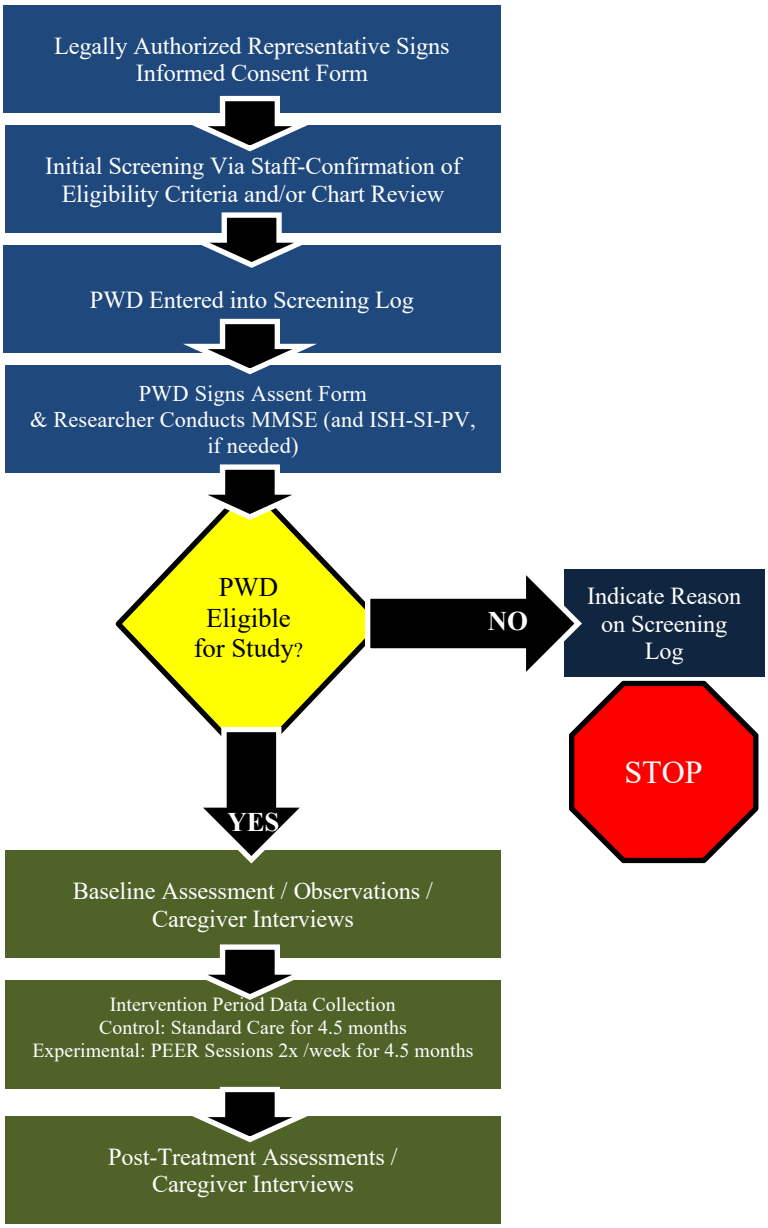
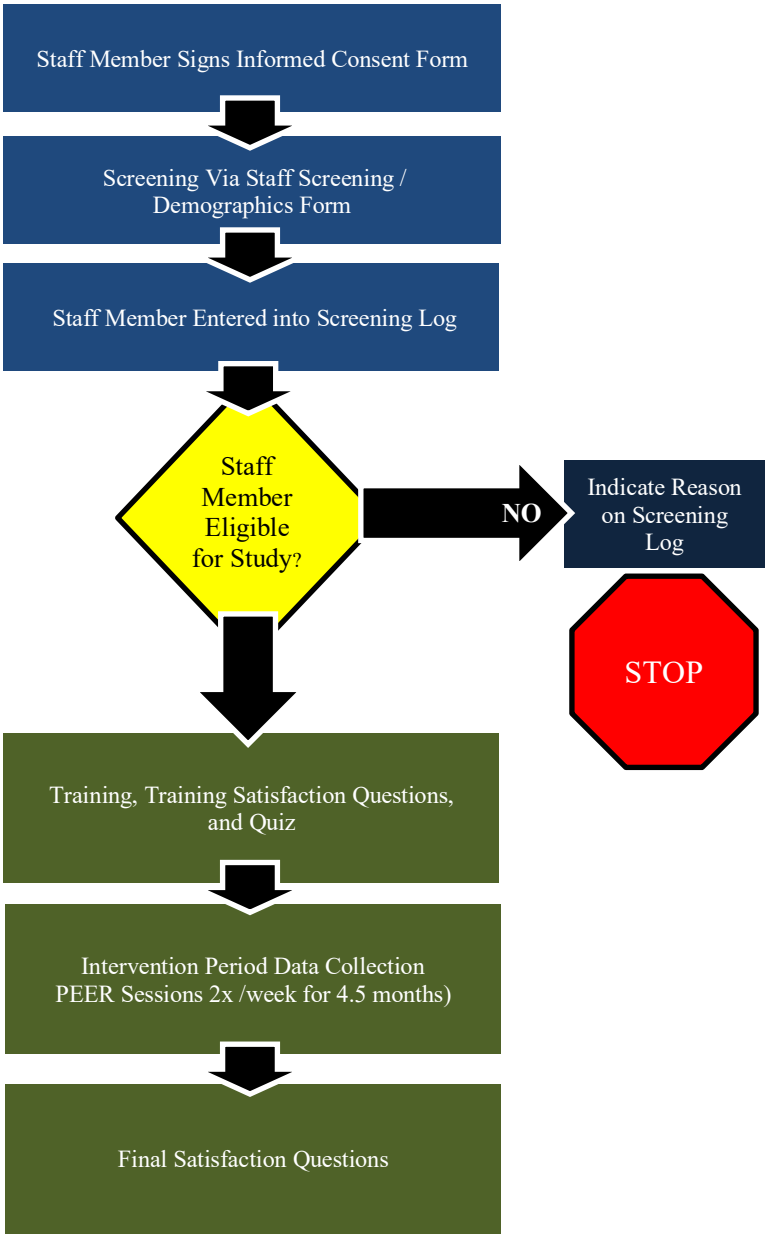


Figure 2: Study Flow Diagram for Staff Members (*Experimental Sites Only*)



4.0 INFORMED CONSENT

PWD

Recruitment packets will be mailed to persons responsible for the medical decisions of all PWD. Included in the recruitment packet will be a cover letter, a study flyer, two copies of the consent form (one copy to be signed and returned, and one copy to be retained for the person's records), and a self-addressed/postage-paid envelope. The cover letter, consent form, and flyer will have phone numbers, addresses, and email addresses for the PI and the designated IRB. The person will be invited to contact any of these individuals if he/she has any questions. The consent form will include detailed information about what participation in the study entails for PWD. It will also list all of the potential risks of the study and ways in which researchers will be protecting against the risks. Potential benefits will also be described. In all recruitment materials, it will be made clear that participation in this study is voluntary, and that participants can stop participating at any time, for any reason. For those who do not wish to take part in the study, currently provided services will continue to be made available. Also, it will be made clear to persons responsible for the medical decisions of potential participants that their loved ones will still have a choice as to whether they want to take part in the study. That is, even if a family member provides consent for the study, the resident himself/herself can still decide whether or not he or she wants to take part in the study (through the assent process, described next). Once a consent form is received by researchers via mail or electronically, an ID number will be assigned to the participant. Researchers will determine whether the participant meets basic eligibility criteria (i.e., the person is at least age 55, able to read/speak English, diagnosed with dementia, and does not show signs of rapid cognitive decline or physical deterioration over the past 6 months (this final item is defined in more detail below)) by contacting site staff and/or conducting a chart review. If the PWD meets the basic eligibility criteria, a researcher will speak with the participant about the study and provide the person with an assent form. The assent form will be a simpler and shorter version of the consent form, with large, easy to read font. The researcher will answer any questions that the resident might have, and then ask the resident if he or she is interested in participating in the study. If so, the resident will sign the assent form (or verbally indicate that he/she is willing to participate, if he/she cannot sign his/her name). The researcher will then conduct the MMSE and, if needed, the ISH-SI-PV to determine final eligibility for the study (details about how these measures determine eligibility are included below). Note: a copy of the full consent form will also be available to the LAR and resident, in case they would like to review the full consent form. Copies of signed consent and assent forms will be provided to participants and placed in their digital file folders.

Copies of the study flyer, legally authorized representative consent form, and PWD assent form are included in the Appendix.

Staff Members

Researchers will initially provide a verbal summary of the study (either in person or via telephone). If the person seems interested in participating based upon the verbal summary, a consent form will be provided to the person. The consent form will provide detailed information about the study, including what taking part in the study entails, risks, protection against risks, and potential benefits. The staff participants will be encouraged to speak to researchers with questions. If the person decides to enroll, he/she will sign the form and return it to researchers. Please note: Staff Members will be invited to participate in the study by researchers, not by their supervisors or other staff at

the facility. This should help to prevent Staff Members from feeling that they are expected—and/or are being coerced—to participate in the study. Furthermore, the consent form will clearly state that a staff member's decision to participate or not participate in the study will in no way affect their employment at the facility. Copies of signed consent forms will be provided to staff participants and placed in their digital file folders.

A copy of the staff member consent form is included in the Appendix.

4.1 HIPAA Authorization

PWD

Included with the consent packet will be a HIPAA authorization form, which will inform the LAR that researchers will collect the PWD's protected health information (PHI) for use in this study, as specified in the consent form. The researcher will ask the LAR to please review and sign the HIPAA authorization form to allow the study team to access the PWD's PHI. Participant information will only be accessed as needed to collect study-relevant data, including the following: diagnoses, medications, psychological test results, medical history, demographics, such as age, race/ethnicity, date of birth, sex, and education level.

Any electronic protected health information (ePHI) collected on human subjects will be transmitted to, stored by, and accessed, via a HIPAA-compliant secure cloud provider. Such services secure the data while in transmission from the local machine to the servers and have high-level encryption in place to secure the data once it has arrived. The system ultimately chosen will have been certified as HIPAA-compliant and have all possible modern safeguards, including but not limited to encryption, high-strength passwords, firewalls, intrusion detection, virus protection, audit trails, provision of a Business Associate Agreement (BAA), and secure off-site backup.

A copy of the HIPAA authorization form is included in the Appendix (it is part of the overall consent form).

Staff Members

HIPAA authorization will not be required for staff members, as PHI will not be collected.

5.0 RECRUITMENT AND RETENTION

5.1 Participant Recruitment

PWD

The PI will speak to the administrator or other staff at the nursing home and assisted living facility and ask that they send recruitment packets to the legally authorized representatives of all residents who have a dementia diagnosis. Included in the recruitment packet will be a cover letter, a study flyer, two copies of the consent form (one copy to be signed and returned, and one copy to be retained for the person's records), and a self-addressed/postage-paid envelope. The cover letter, consent form, and flyer will have phone numbers, addresses, and email addresses for the PI and the designated IRB. The person will be invited to contact any of these individuals if he/she has any questions. The consent form will include detailed information about what participation in the study entails for PWD's. It will also list all the potential risks of the study and ways in which researchers will be protecting against the risks. Potential benefits will also be described. In all recruitment

materials, it will be made clear that participation in this study is voluntary, and that participants can stop participating at any time, for any reason. For those who do not wish to take part in the study, currently provided services will continue to be made available. Also, it will be made clear to persons responsible for the medical decisions of potential participants that their loved ones will still have a choice as to whether they want to take part in the study. That is, even if a family member provides consent for the study, the resident himself/herself can still decide whether or not he or she wants to take part in the study (through the assent process, described next). Once a consent form is received by researchers via mail or electronically, an ID number will be assigned to the participant. Researchers will determine whether the participant meets basic eligibility criteria (i.e., the person is at least age 55, able to read/speak English, diagnosed with dementia, and does not show signs of rapid cognitive decline or physical deterioration over the past 6 months (this final item is defined in more detail below)) by contacting site staff and/or conducting a chart review. If the PWD meets the basic eligibility criteria, a researcher will then speak with the participant about the study and provide the person with an assent form. The assent form will be a simpler and shorter version of the consent form, with large, easy to read font. The researcher will answer any questions that the resident might have, and then ask the resident if he or she is interested in participating in the study. If so, the resident will sign the assent form (or verbally indicate that he/she is willing to participate, if he/she cannot sign his/her name). The researcher will then conduct the MMSE and, if needed, the ISH-SI-PV to determine final eligibility for the study (details about how these measures determine eligibility are included below.) Note: a copy of the full consent form will also be available to the resident in case he or she would like to review the full consent form. Copies of signed consent and assent forms will be provided to participants and placed in their digital file folders.

Staff Members

Researchers will initially provide a verbal summary of the study (either in person or via telephone). If the person seems interested in participating based upon the verbal summary, a consent form will be provided to the person. The consent form will provide detailed information about the study, including what taking part in the study entails, risks, protection against risks, and potential benefits. The staff participants will be encouraged to speak to researchers with questions. If the person decides to enroll, he/she will sign the form and return it to researchers. Please note: Nursing Assistants, Activity Staff, and other staff members will be invited to participate in the study by researchers, not by their supervisors or other staff at the facility. This should help to prevent staff from feeling that they are expected—and/or are being coerced—to participate in the study. Furthermore, the consent form will clearly state that a staff member's decision to participate or not participate in the study will in no way affect their employment at the facility. Copies of signed consent forms will be provided to staff participants and placed in their files.

5.2 Participant Retention

Study staff will be in regular contact with staff members and PWD to assist in any way possible to lessen burden and make the experience of participating in the study as easy as possible. We will also provide contact information to participants so that they can discuss any issues with the PI at any point. Please also note that we will oversample to accommodate a reasonable level of attrition. In the event that a participant is unavailable or refuses to participate in portions of the study, the PI and/or Experimental Team Leader will speak to the participant.

6.0 SCREENING AND ELIGIBILITY CRITERIA

6.1 Screening

The following screening procedures will be used for each type of participant:

PWD

INITIAL ELIGIBILITY

A researcher will confirm the following with staff at the community and/or conduct a chart review to determine **initial eligibility** by determining whether the PWD meets the following inclusion / exclusion criteria:

a. He/she is age 55+
b. He/she is able to read and speak English
c. He/she is diagnosed with dementia (of any type)
d. He/she does NOT show signs of rapid cognitive decline or physical deterioration over the last 6 months
    i. He/she is NOT bed confined.
    ii. He/she is NOT completely unable to communicate verbally.
    iii. He/she is NOT cognitively and/or physically impaired to such a point that they are unable to participate in group activities.
    iv. He/she is actively dying.
    v. His/her health is declining so rapidly that they are going to be unable participate in group activities in next week.

For efficiency, in most cases, confirmation of eligibility will be obtained for all residents at a given site at the same time via a table that will be sent to staff (*see screenshot of this table in the Appendix*). Information from this table will be de-identified (names redacted) and data will be saved in a folder called "Raw Data→Bulk Data→Site Name." Data from the form will then be entered individually for each PWD into the PWD Initial Screening / Inclusion Form.

FINAL ELIGIBILITY

If the person meets the initial inclusion / exclusion criteria, a researcher will meet directly with the person with dementia and ask him/her to sign the assent form. If the resident signs the assent form, the researcher will continue to interview him/her and determine **final eligibility** by administering the Mini-Mental Status Examination (MMSE—described in detail below) and, if needed, the ISH-SI-PV (described in detail below).

- If the person scores at least 5 on the MMSE, he/she is eligible to be a RP in the study.
- If the person scores below 5 on the MMSE, the researcher will conduct the ISH-SI-PV
    - If the person scores at least 1 on the ISH-SI-PV, he/she is eligible for the study
- If the person scores at least 13 on the MMSE, he/she is eligible to be a RL in the study.
    - Final determination as to whether the PWD is appropriate to be a RL will be determined by conducting the PEER Leader Assessment. In order to be eligible to be a RL, the person must perform adequately on the PEER Leader Assessment.

Staff Members

A researcher will ask the staff member to complete a form to determine whether the staff member meets the following criteria:

a. He/she is age 18+
b. He/she is able to read and speak English
c. He/she does not only work third shift

6.2 Screening Log

After completing the screening process, the researcher will enter data into the Screening Log. The Screening Log will be digital in nature (a spreadsheet) include all relevant screening data (as listed above).

A screenshot of the study's Screening Log with sample data entered is included in the Appendix.

6.3 Eligibility Criteria

Inclusion Criteria

PWD
PWD will be eligible if they meet the criteria listed in section 6.1 (see PWD subsection).

Staff Members
Staff will be eligible if they meet the criteria listed in section 6.1 (see Staff Member subsection).

7.0 STUDY INTERVENTION

Description of the PEER App

PEER will be the first product and app that will enable persons with early stage dementia (PESD) to lead seven different types of Montessori activities for other PWD. While leaders and participants will ostensibly view PEER as a set of enjoyable activities, it will actually be an evidence-based intervention aimed at reducing responsive behaviors in PWD and enabling PESD to fill meaningful social roles. As an innovative peer support intervention, PEER aims to maximize the abilities of PWD and give meaning to their lives. The primary user of the app will be PWD in LTC, so the primary purchaser will be activity professionals and other LTC staff. A secondary target will be PWD attending adult day centers (ADCs).

The seven types of PEER activities that will be included in the market-ready version of the product are (1) Hearthside Book Club® (HBC), (2) Lingo Bingo (LB), (3) Sort It Out (SIO), (4) Critic's Corner (CC), (5) Quote Vote (QV), (6) Would You Rather, and (7) DiscussIT.

The PEER App will have three modes. Each mode will be used by different people and serve a different purpose.

(1) Admin Mode will be used exclusively by staff. The purpose of this mode will be to provide

staff with tools for successfully selecting RLs and Resident-Players (RPs) and training RLs. The Admin Mode will consist of the PEER Leader Assessment and PEER Training Resources. The PEER Leader Assessment will be used to determine the extent to which a PWD would be a successful leader. PEER Training Resources will consist of PDF versions of training materials.

(2) Leader Mode will be used exclusively by RLs and provide them with all instructions and leader versions of activities needed to facilitate activities. Details are provided below. Safeguards in the app will prevent RPs from entering this mode.

(3) Player Mode will be used exclusively by RPs; the purpose of this mode is to provide the activity materials needed for RPs to take part in activities led by a PESD. Details are provided below.

Leader Selection. In past research, we found that selecting an appropriate leader is an important component of successfully implementing resident-led programming. The PEER training will describe the key characteristics of a successful leader and also teach staff members how to implement the PEER Leader Assessment. After completing the training, staff will have the knowledge needed to identify appropriate RLs.

PEER Activity Setup. The activity is set up with five RPs and one RL seated around a table. This setup was successfully used in Phase 1 and is rooted in Montessori Activity Programming. Groups of different sizes can certainly be used, but past research this size is optimal. Staff members prepare the tablets prior to the beginning of PEER sessions by opening the PEER app on each tablet, selecting leader mode on one tablet and player mode on the others, selecting the activity type for that day (e.g., "Hearthside Book Club®"), and placing the tablets on the table. Ideally, each tablet will be placed on a tablet stand, to ensure that the tablet is at an appropriate viewing angle. In addition, if the staff member overseeing PEER knows that residents at his/her community have difficulty tapping the screen of the tablet, an adaptive switch is also be placed in front of the tablets. We found that an adaptive switch is helpful for participants who are frail, in the advanced stages of dementia, and/or having trouble pressing the tablet's screen with the fleshy part of their finger. While we purposefully limit the number of times RPs need to press a button on the screen, the switch was a very helpful for those limited times when they were asked to press the screen.

Figures 1a-1d. First four screens for RL & RPs

Starting a PEER Activity. Since a staff member prepares the tablets ahead of time, when the residents arrive, the activity type for that day has already been chosen. As shown in Figures 1a-1d, the four starting screens on all activities are basically the same. As shown in Figure 1a, the first screen on the RL's tablet reads, "*Say*, 'Welcome to [insert name of activity],'" while the RPs' tablets read, "Welcome to [insert name of activity.]" (Please note: italicized text, which is also yellow in the app, represents *instructions* for the RL, while all other text, which is white, represents *words that should actually be read aloud*.) As shown in Figure 1b, the second screen on the RL's tablet reads, "*Say*, 'My name is [insert name of leader]. What is your name?' *Give everyone a chance to say their name*," while the RPs' tablets say, "Say your name out loud when asked." As shown in Figure 1c, the third screen on the RL's tablet reads, "*Say*, 'Please tap the topic you would like to discuss today.' *Give everyone a chance to vote.*' while the RPs' tablets read, "Please tap the topic you would like to discuss today.' The RPs' screens also display two large buttons with the topics for that day. These two

topics are either randomly chosen by the app (in which case the app excludes recently-used topics) or pre-chosen by the staff member (an option that is helpful when the activity staff member is facilitating theme-based programming). RPs cast their votes by pressing the on-screen button with the topic of their choice. Alternatively, if adaptive switches are being used, RPs can press a color-coded adaptive button—i.e., they can choose the topic on the left side (with a white border) by pressing the left/white button, or they can choose the topic on the right side (with a yellow border) by pressing the right/yellow button. As shown in Figure 1d, once an RP has chosen his/her preferred topic, the tablet proceeds to a fourth screen that reads, "Thank you for voting!" After RPs cast their votes, results are sent to the RL's tablet. As shown in Figure 1d, the RL's screen automatically proceeds to a screen that reads, "*Say*, 'Most people chose [insert topic with most votes.] Let's begin!'" The RL then presses the NEXT button and the activity with the most votes begins. (Please note: if an RP fails to vote, results are presented to the RL after a predetermined length of time.)

Please note: in most cases, the RL is the only person who needs to tap the screen to proceed from one screen to the next. That is, when the RL presses the NEXT button to get to a new screen, the RPs' tablets automatically proceed to the next screen. One exception to this general rule is when the RPs' are asked to vote for a topic. In this case, RPs are, in fact, expected to tap the screen (or adaptive switch). However, it is important to note that, even in cases where RPs are asked to tap the screen, if an RP fails to do so, he/she is still able to proceed with the activity, as the app automatically moves them along to the next step at the right time. This functionality is made possible through the use of WebSockets.

In the next section, descriptions of the seven PEER activities are provided. For HBC and LB, we provide *very* detailed descriptions of exactly how the PEER version of the activity is implemented. These detailed descriptions are provided to demonstrate how carefully we have considered and created every single aspect of the app to ensure that RLs and RPs have a successful experience. Brief descriptions of the five remaining activities will be provided. Similar approaches (task breakdown, leader notes, etc.) are used in all of the PEER activities.

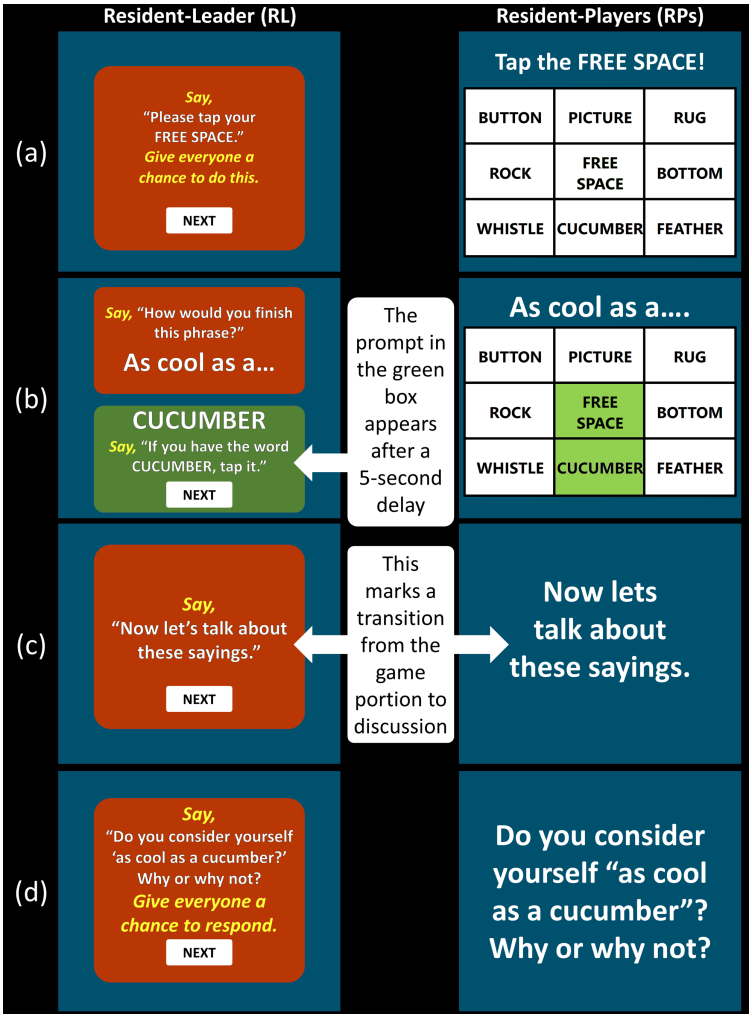
1. Hearthside Book Club® (HBC) is a reading and discussion activity developed and tested by Mr. Skrajner [PI] in a Phase 2 SBIR study [5R44AG039907]. Participants take turns reading a story that has interesting facts about topics likely to be of interest to older adults. Large (40pt) bold font is used to accommodate for vision issues. In addition, the content of each page stands on its own, so there is no need to remember information on previous pages. Half of the pages include narrative with interesting information. On 25% of the pages, discussion questions that are appropriate for PWD are included. The remaining 25% of the pages contain an image along with a caption that contains a discussion question.

As shown in Figure 2a, in the PEER version, the first HBC-specific screen displays the title page for the activity. On the RP's version of the title page screen, only the title page itself appears. The RP's screen is purposefully very simple, as we wish to refrain from including extra information, which could be distracting to RPs. On the RL's version of the title page screen, there are three parts. First, at the top, there is a leader prompt (≈10% of the screen vertically), which says, "*Say*, 'The title of this story is [insert title of HBC story].'" Second, the title page itself appears in the middle of the screen (≈ 70% of the screen). Third, there is a leader prompt at the bottom of the screen (≈20% of the screen), with a custom discussion question related to the title page. For instance, for the National Parks story, the bottom prompt says, "*Say*, 'What do you like to do at a park? Enjoy the scenery? Walk? People-watch? Other things?'" When being trained, the RL is encouraged always to begin at the top of the screen and proceed downward, reading the prompts and instructions. So, the RL reads the top prompt, looks at the title page, and finally reads the bottom prompt. The RL then engages the participants in discussion about the question. When discussion ends, the RL presses the NEXT button to continue. As seen in Figure 2b, at this point, the second HBC-specific screen is displayed, which is actually Page 1 of the story. The RPs' tablets automatically proceed to the next screen—i.e., they do not need to press anything. As was the case for the title page, the RPs' version of this screen simply displays Page 1. The RL's version of this screen again consists of three sections: a top prompt, Page 1 itself, and a bottom prompt. As shown in Figure 2c, from this point forward, the top prompt is always "*Say*, 'We are on Page [insert page number]. Would someone like to read this page?'" If the page simply includes narrative, the bottom prompt includes a discussion question—e.g., "*Say*, 'Do you think that it was a 'great idea' to create the National Park system?'" If the page already includes a discussion question, the bottom prompt is "*Say*, 'Thank you for discussing this with me. We will now go to

Figures 2a-2c. PEER version of HBC for RLs and RPs

the next page.'" The same approach is used all remaining pages.

2. Lingo Bingo (LB) is a combination of bingo and trivia. This activity has been developed and tested in several NIH-funded studies [R21MH063395, 1R34MH075799, and 5R44AG049579]. The PEER version, which is shown in Figures 3a-3d, is facilitated in the following way. After the group chooses a topic, each RP is randomly assigned a game board. As shown in Figure 3a, the game board fills the bottom 80% of each RP's screen, and consists of a 3 x 3 matrix, with 9 total squares. The middle square is a FREE SPACE; each of the other eight squares contain a single word. The goal of LB is to cover—or more precisely, fill in—all of the squares ("blackout bingo"). A square is "filled in" when it turns green. So, the first person to turn all of the squares green is considered the "winner." However, the game is played until all RPs have bingo. As shown in Figure 3a, when the game boards appear on RPs' screens, the RL's tablet displays the following message, "*Say*, 'Please tap your FREE SPACE'" *Give everyone a chance to do this*." Meanwhile, the RPs screen shows the game board, along with the phrase "Tap the FREE SPACE" at the top of the screen. The RPs tap the FREE SPACE on the board, at which time the square will be "filled in" (it will turn green). If an adaptive switch is being used, either button can be pressed to fill the FREE SPACE. After the RL gives participants time to fill the FREE SPACE, he/she presses the NEXT button. (Please note: if the RPs fail to fill the FREE SPACE, it is automatically filled when the RL advances the game.)



Figures 3a-3d. PEER version of LB for RLs and RPs.

As shown in Figure 3b, after the RL presses the NEXT button, the RP's screen displays the first LB clue in the top 20% of the screen. Each LB clue is a well-known phrase with the final word missing (e.g., As cool as a…). Meanwhile, on the RL's tablet, the following information appears, "*Say,* 'How would you finish this phrase?' As cool as a…" The answer does not initially appear on the RL's screen. However, after five seconds—a length of time shown to be appropriate in Phase 1— the following phrase appears, "CUCUMBER. Say, "If you have the word CUCUMBER, tap it." RPs are given time to tap the square that contains that word, if it appears on their board. To make it easier, RPs can actually press *anywhere* on the game board to fill the square. If an adaptive switch is being used, either button can be pressed to fill the square with the word. If the RP does

not have the word that has been called on their game board, but they tap a square, the square briefly turns light green and returns to being white after about one second. This gives a dynamic feel to the app and was used in Phase 1 with great success. After the RL gives RPs time to press the square on their board, the RL presses the NEXT button. At this point, the same basic process occurs for the second clue. The game continues in this way until all RPs get bingo.

Once all RPs have covered all their squares, the RL presses the NEXT button. As shown in Figure 3c, at this point, a transitional statement appears, marking a change in the focus on the activity: "*Say*, 'Now let's talk about these sayings.'" While the first half of LB focuses on playing a bingo-style game, the second half focuses on reminiscence and discussion related to the sayings used in the game. After the leader says, "Now let's talk about these sayings," he/she presses the NEXT button and the first discussion question appears. As shown in Figure 3d, on the RP's tablets, only the discussion question appears—e.g., the screen simply displays the statement, "Do you consider yourself 'as cool as a cucumber?' Why or why not?" The RL's tablet displays additional leader instructions—e.g., the RL tablet displays: "*Say*, 'Do you consider yourself "as cool as a cucumber?" Why or why not?' *Give everyone a chance to respond*." After the RL engages the RPs in discussion, he/she taps the NEXT button. Then, the next discussion question appears. This basic process continues for all remaining discussion questions.

The decision to split the activity into two parts—i.e., the game of bingo first, and then discussion and reminiscence—was made after extensive testing in Phase 1. Initially, discussion about each clue came immediately after the clue appeared. However, RPs had difficulty alternating between playing the game and engaging in discussion—i.e., they got confused about which statements made by the RL were clues and which ones were "merely" discussion questions. For this reason, the discussion and reminiscence part of the activity was split into a separate, later part of the activity.

Figure 4. PEER version of SIO for RLs and RPs

3. Sort It Out (SIO) is an activity in which RPs sort words or photos into one of two categories. For example, as shown in Figure 4, for the topic "Pets," a photo of an alligator, along with the caption "Alligator" beneath the image, might appear. Above the image is a prompt question that asks: "Would this make a good pet?" Below the image, two choices appear as large buttons—e.g., "No" and "Yes." SIO was developed and tested in three NIH-funded studies.

4. Critic's Corner (CC) allows participants to discuss famous works of art. It is inspired by more than 15 years of experience providing specialized art museum tours to PWD by Dr. Zeisel [Senior Research Collaborator], as part of the ARTZ program. In addition, Critic's Corner was developed

and tested in Mr. Gorzelle's [Experimental Team Leader] HOME 4 CARE® study [5R44AG049579, Gorzelle PI].

5. Quote Vote (QV) presents RPs with brief, dementia-appropriate quotes about love, nature, family, beauty, etc. RPs vote on whether they like the quote and then discuss it. QV was developed and tested in an NIH-funded study.

6. Would You Rather gives participants a chance to choose between two different concepts or ideas. For instance, they might be asked, "Would you rather be able to fly or be able to become invisible." Residents cast a vote for their person choice and then a discussion occurs related to that topic.

7. DiscussIT presents participants with an interesting fact, such as "Baseball player Wade Boggs ate only chicken on the day of a game." Participants are then presented with a discussion question related to that fact, such as "Could you eat only chicken for an entire day?"

Ending the Activities. In an effort to capitalize on procedural memory (Squire, 2004), all activities end the same way. The following message appears on all screens: "Thank you for doing this with me. Would you like to do it again some time?"

Description of the Intervention Period in the PEER Experiment

Sites will be randomized with respect to condition (Control or Experimental) at the beginning of the experiment.

PWD

For PWD at Experimental Sites, at the beginning of the Intervention Period, PEER groups will be formed. Each group will consist of one Resident-Leader (RL) and five Resident-Players (RPs). Each RL will serve as a facilitator for a consistent group of RPs. There will be two groups per Experimental site. PWD will be invited to participate in PEER sessions twice per week for 4.5 months (36 total sessions); each PEER session is expected last about 45 minutes. If PWD or staff are unable to attend (e.g., due to illness or a doctor's appointment), researchers will simply note their absence. MPES data will be collected during PEER sessions, as well as Treatment Fidelity / Process measures—i.e., Session Observation / Evaluation Forms (described below). Observations of the PEER groups will be conducted in person or via web stream as an infection control protocol, to limit exposure of participants to additional staff. For RLs, we will track the extent to which he/she follows each of the key steps required for successfully implementing each activity and the degree of staff assistance required.

For PWD at Experimental Sites, PWD will participate in standard care for 4.5 months.

SPs

SPs' participation will begin by attending an in-person training on PEER. Prior to and after the training, SPs will take a quiz (to examine knowledge transfer). In addition, satisfaction questions will be posed to staff after taking the training.

In addition, researchers will implement two PEER sessions with residents while site staff observe and assist, so site staff will become familiar with the app in a real-life setting.

The knowledge and experience that staff gain from the training will prepare them to properly implement the PEER intervention. To help remind staff members of the key aspects of the training, two quick-reference sheets will also be available in the app to staff at the completion of the training modules: one quick reference sheet for the "Setting Up PEER Activity Session" and one quick reference sheet for "10 Tips for 'Training' a Resident to Lead PEER Activities." These quick reference sheets (each of which will be one page) will include key information from the training, stated as succinctly and clearly as possible.

We have purposefully decided not to use a long and detailed implementation manual for two main reasons. First, the PEER app will guide the staff member and Resident Leader through each activity step by step, so an implementation manual is essentially be embedded within the app. Second, in past studies, we had given staff members extensive implementation manuals, but the manuals were typically ignored by staff. This is not surprising, since staff are very busy with main caregiving and other responsibilities. If they need to refer to a long reference manual, it would be nearly impossible for them to have time to implement an intervention. In addition, some staff have low literacy (especially caregivers) and/or speak English as a second language. For such staff, it may be difficult to comprehend and remember all of the information included in such a detailed manual.

As such, we have found that the best way to ensure staff properly follow an intervention such as the PEER app is to (a) embed the steps required to implement the intervention into the app itself, (b) provide high-quality, interactive, training on how to use the intervention, (c) provide an opportunity for staff to observe researchers implementing PEER with residents, and (d) provide quick reference sheets (in this case, one quick reference sheet for each of the two training modules).

After taking the PEER training and observing researchers facilitating at least two PEER sessions, staff will then enter the Intervention Period. Staff will be invited to participate in PEER sessions twice per week for 4.5 months; each PEER session is expected last about 45 minutes. Activity staff will oversee programming. Other staff (CNAs, managers, etc.) will observe programming so feedback can be elicited. Each activity type will be used at least six times by each PEER group. Satisfaction questions will be posed to SPs at the end of each PEER session. After the Intervention Period has ended, SPs will also be posed final satisfaction questions.

8.0 STUDY MEASUREMENTS AND PROCEDURES

All measures are included in the Appendix

PWD

Baseline Assessments / Observations

1. **Chart Review Form**
    a. A researcher will conduct a CHART REVIEW to collect the following data:
        i. Demographics (race/ethnicity, education level, marital status, and number of years living in LTC)
        ii. All diagnoses
        iii. Type of dementia
        iv. All meds
2. **Mini Mental Status Exam (MMSE)**

A researcher will conduct a direct interview with the PWD to complete the MMSE.

a. The MMSE is a structured evaluation aimed at evaluating aspects of cognition in elderly residents. The MMSE assesses patient attention, level of orientation, and ability to recall information. These are the sections of the MMSE assessment:
    i. **Orientation to Time**: temporal orientation is evaluated by asking the resident to recall temporary coordinates (current year, season, month, day of the week, and date). These are to be asked in separate questions and about 30 seconds are to be given for response. [TOTAL POSSIBLE POINTS: **5**]
    ii. **Orientation to Place**: the resident is asked details of their current location (name of the state, county, city, building, and floor of the building). These are to be asked in separate questions and about 30 seconds are to be given for response. [TOTAL POSSIBLE POINTS: **5**]
    iii. **Registration**: the resident is asked to repeat three words that are to be given by the assessor. The accuracy of their word reproduction is assessed. Also, the resident is informed that they will need to remember the words at a later moment during the evaluation. [TOTAL POSSIBLE POINTS: **3**]
    iv. **Attention and Calculation**: the resident is asked to subtract 7 from 100, and then continue to subtract 7 from each answer (in a series of 5: *93–86–79–72–65*). The accuracy of their calculations is assessed. If the resident refuses to perform the series of calculations, the assessor will ask the resident to spell the word "WORLD" forward, then backward. Only the accuracy of the backward-spelling (per-letter) is assessed. [TOTAL POSSIBLE POINTS: **5**]
    v. **Recall**: the resident is asked to recall the three words given in the *Registration* stage of the assessment. The accuracy of their recollection of all three words is assessed. [TOTAL POSSIBLE POINTS: **3**]
    vi. **Naming**: the resident is asked to name two separate items that the assessor points to, typically starting with the assessor's writing implement (assessor points to pencil or pen). The second item is typically a wristwatch, but this can be substituted if the assessor isn't wearing a common wristwatch. Substituted items must be visually recognizable/familiar, such as a pair of eyeglasses, a standard key (to a door), or a simple water bottle. The accuracy of the terms/names given to both items by the resident is assessed. [TOTAL POSSIBLE POINTS: **2**]
    vii. **Repetition**: the resident is asked to repeat an entire phrase to be stated by the assessor ("No ifs, ands, or buts.") The accuracy of the resident's reproduction of the phrase is assessed, with one point given only if each word (including pluralization) in the phrase is repeated correctly. [TOTAL

POSSIBLE POINTS: **1**]

viii. **Comprehension**: the resident is asked to carry out three short tasks within a one-sentence instruction: "Take this paper in your right hand, fold it in half, and put it on the table (*or* hand it back to me)." The assessor pauses briefly between each task when giving the instruction before handing the resident a blank piece of paper. The assessor does not repeat instructions once the resident begins the tasks. The resident's ability to accurately recall and perform each of the three tasks is assessed. [TOTAL POSSIBLE POINTS: **3**]

ix. **Reading**: the assessor holds up a piece of paper with the words "CLOSE YOUR EYES" largely typed in the center and asks the resident to "Please read this and do what it says." The resident can read the words aloud or to themselves, but the point is only given if the resident successfully completes the instructed task by closing their eyes. [TOTAL POSSIBLE POINTS: **1**]

x. **Writing**: the resident is provided a pen or pencil and asked to write a sentence on a blank piece of paper (the same/unfolded blank paper used in the *Comprehension* stage of the assessment) provided by the assessor. If the resident is confused or overwhelmed with the broad instruction, the assessor rephrases the instruction with more specificity: "Write a sentence about the weather." Errors in spelling or grammar are ignored, but a point is given only if the resident's written sentence is comprehensible and contains a subject and a verb. [TOTAL POSSIBLE POINTS: **1**]

xi. **Drawing**: the resident (still provided with a pen or pencil) is provided with a paper showing two intersecting pentagons and asked to reproduce/copy the design anywhere on the page's available space remaining. A point is given based on the geometric accuracy of the design (if the resident's drawing consists of two 5-sided figures that intersect to form a 4-sided figure). [TOTAL POSSIBLE POINTS: **1**]

b. Each stage of the MMSE consists of one to five separately scored items, with each item awarded 1 or 0 points, and a total of 30 items. The higher the score, the lower the impairment to the cognitive response. Scores closer to 0 indicate severe cognitive impact whilst scores closer to 30 indicate an intact cognitive response.

i. Score Interpretation

0 - 9	Severe cognitive impact
10 - 16	Moderate impairment
17 - 30	Intact cognitive response

3. I'm Still Here Skills Inventory – PEER Version (ISH-SI-PV)

a. Please note: the ISH-SI-PV is only administered if the PWD scores below 5 on the MMSE)

b. This assessment asks the participant to read / respond to three pages of information.

i. On the first page, the PWD is asked to read the following aloud: "Today we take the telephone for granted. We can pick up the phone and call anywhere in the world. This would have seemed like magic to people who lived before 1876."

1. Scoring:

0 - Unable to Read Aloud

1 - Able to Read 1 – 3 words aloud (out of 31)
2 - Able to Read 4 – 25 words aloud (out of 31)
3 - Able to Read 26 – 31 words aloud (out of 1)

ii. On the second page, there is a photo of an old telephone, along with the following text, which the PWD is asked to read aloud: "This is an early phone from Sweden. Do you think it would be easy to use?"

1. Scoring:

a. Reading Ability

0 - Unable to Read Aloud
1 - Able to Read 1 – 3 words aloud (out of 16)
2 - Able to Read 4 – 11 words aloud (out of 16)
3 - Able to Read 12 – 16 words aloud (out of 16)

b. Ability to Answer Question

0 - No Response
1 - Unintelligible Response
2 - Simple Response (e.g., "yes" or "no" or "not sure" or "hard to say")
3 - Response with additional details (e.g., "No. I would have no idea how to use it…")

iii. On the final page, there is the question "Do you like this food?" along with a photo of Brussel sprouts (with a caption beneath it that reads "Brussel Sprouts") and buttons that say YES and NO.

1. Scoring:

a. Reading Ability

0 - Unable to Read Aloud
1 - Able to Read 1 – 2 words aloud (out of 5)
2 - Able to Read 3 - 5 words aloud (out of 5)

b. Ability to Answer Question

0 - No Response
1 - Unintelligible Response
2 - Simple Response (e.g., "yes" or "no" or "not sure" or "hard to say")
3 - Response with additional details (e.g., "No. That looks gross!")

iv. All items are added together to calculate the Total Score

1. The score can be interpreted as follows:

0 = INAPPROPRIATE for PEER Activities (ineligible)
1 – 3 = POTENTIALLY appropriate for PEER Activities (eligible)
4 – 10 = LIKELY to be appropriate for PEER Activities (eligible)
11 – 14 = DEFINITELY appropriate for PEER activities (eligible)

4. Dementia Quality of Life (DEMQOL)

a. A researcher will conduct a direct interview with the PWD to complete the DEMQOL. However, if the PWD is unable to respond to questions on the DEMQOL, this measure will be collected via proxy interview (with a staff member who is familiar with the PWD).
b. The DEMQOL is a 28-item self-reported measure related to health-related quality-

of-life (HRQL) in residents with dementia. The DEMQOL takes cognition, negative emotion, positive emotion, social relationships, and loneliness into consideration. The DEMQOL-Proxy is a 31-item measure completed by the staff/caregiver and focuses on cognition, negative emotion, positive emotion, daily activities, and appearance.

i. Each item on the DEMQOL (and DEMQOL-Proxy) has four response-options:
   Not at all
   A Little
   Quite a Bit
   A Lot

ii. Most items are scored as follows
   Not at all = 4
   A Little = 3
   Quite a Bit = 2
   A Lot = 1

iii. However, since some questions are worded differently, they are reverse coded in the following manner:
   Not at all = 1
   A Little = 2
   Quite a Bit = 3
   A Lot = 4

iv. The total possible score on the DEMQOL ranges from 28 - 112, with lower scores indicating a lower quality of life. The total possible score on the DEMQOL-Proxy ranges from 30 to 120. If a DEMQOL-Proxy is conducted, the total score is calculated and scaled to fit the same scoring range as the DEMQOL. If DEMQOL-Proxy total score = **X**, then $(^{X}/_{30}) \, x \, 28$ = DEMQOL (summary/scaled) total score.

v. The final item on the DEMQOL (and DEMQOL-Proxy), asks how the PWD would rate his/her overall quality of life. This item has the following options and coding:
   Poor = 1
   Fair = 2
   Good = 3
   Very Good = 4

vi. This final item is not included in the total score on the DEMQOL (nor on the DEMQOL-Proxy)

5. Geriatric Depression-Short Form (GDS-SF)

a. A researcher will conduct a direct interview with the PWD to complete the GDS-SF.

b. The GDS-SF is a 15-item self-reported measure of depression in older adults that is conducted via direct interview.

i. Each item on the GDS-SF has two options:
   YES
   NO

ii. Each YES/NO item is coded with a *one* or *zero* depending on the question's

positive or negative assumed premises, scoring points for responses symptomatic of depression.

1. Scoring example: Item 1
    a. *Are you basically satisfied with your life?*
        YES = 0
        NO = 1
2. Scoring example: Item 4
    a. *Do you often get bored?*
        YES = 1
        NO = 0

iii. The total possible score on the GDS-SF ranges from 0 – 15, with higher scores indicating signs of depression.

6. PEER Leader Assessment

a. A researcher will conduct the Leader Assessment by interviewing a resident using the assessment form.

b. The assessment uses various portions of multiple PEER activities to determine the ability of a resident to lead an activity.

7. Neuropsychiatric Inventory-Nursing Home (NPI-NH)

a. A researcher will conduct the NPI-NH by interviewing a proxy (staff/caregiver) who is familiar with the PWD.

b. The NPI-NH is a comprehensive assessment of psychopathology in PWD, focused on people residing in nursing homes. The NPI-NH evaluates 12 neuropsychiatric symptoms in dementia patients in the nursing home setting, including the following: Delusions, Hallucinations, Agitation, Depression / Dysphoria, Anxiety, Apathy, Irritability, Euphoria, Disinhibition, Aberrant Motor Behavior, Nighttime Behavior, and Appetite / Eating Changes.

i. Each item is initially rated as *present* or *absent*.

ii. If the symptom is present, the interviewee is asked to rate the frequency (1 to 4) and severity (1 to 3) of the symptom for the PWD

iii. A *frequency x severity* score is then calculated for each item; if a symptom is absent, the frequency x severity score is 0. As such, the total possible score for each of the twelve symptoms ranges from 0 to 12.

c. A total score is then calculated across all twelve items

i. The total possible score on the NPI-NH ranges from 0 to 144.

8. Cohen Mansfield Agitation Inventory (CMAI)

a. A researcher will conduct the CMAI by interviewing a proxy (staff/caregiver) who is familiar with the PWD.

b. The CMAI is a scale intended to systematically assess agitation in long-term care residents, including those with dementia. The CMAI consists of 14 items that are posed to a proxy (staff/caregiver) pertaining to the PWD based on observed behaviors over the past two weeks; for example: "During the past two weeks, did the resident display cursing or verbal aggression?" and "Did the resident display constant request for attention for help."

c. The frequency of each item is rated on a scale of one (*behavior never occurs*) to five (*behavior occurs a few times an hour or continuous for a half an hour or more*). Therefore, total scores on the CMAI can range from 14 to 70, with higher scores

indicating higher levels of agitation.

9. **Observations of PWD in Standard Activities w/ MPES**
    a. Researchers will observe PWD's engagement and affect during standard, staff-led activities using the MPES (Camp, Skrajner, & Gorzelle, 2015). The MPES is an observational scale that measures four types of engagement: Constructive Engagement: motor/verbal behavior exhibited clearly in response to the target activity; Passive Engagement: listening/watching a target activity; Distracted Engagement: motor/verbal behavior exhibited in response to something other than the target activity; and Non-Engagement / Apathy: outward signs/indicators of apathy, such as sleeping, closing one's eyes, and staring into space. The MPES also measures Pleasure, defined as clearly observable smiling or laughing. Each observation period lasts five minutes, with multiple observations taken on each participant. To ensure MPES data provides a robust comparison for treatment programming, each participant will be observed multiple times, so that averages can be calculated for each type of engagement/affect

Intervention Period Data Collection

1. **Treatment Fidelity / Process and Satisfaction Measures**
    a. The PWD will be invited to participate in two PEER sessions per week for 4.5 months. For each session, a Session Observation / Evaluation Form will be completed.

Session Observation / Evaluation Form

i. The following is a full description of the Session Observation / Evaluation Form.
    1. Items that specifically apply to Resident-Leaders (RLs) are preceded with **RL***
    2. Items that specifically apply to Resident-Players are preceded with **RPs***

ii. During each session, a two-page Session Observation / Evaluation Form will be completed. Since the steps required to lead each activity type differ, distinct Session Observation / Evaluation Forms have been created for each activity type (e.g., there is a Hearthside Book Club Session Observation / Evaluation Form, a Lingo Bingo Session Observation / Evaluation Form, etc.) However, certain parts of the form remain the same for all activities, as described next.
    1. On the top of PAGE 1 of ALL Session Observation / Evaluation Forms, the following data is collected (i.e., these data are consistently collected across all activity types):
        a. Date of session
        b. Person filling out form (researcher)
        c. Site
        d. # of Leader Form for the Day
        e. **RL*/RPs*** # of Residents Attended the Activity (for that session)
        f. Topic (or HBC Story)
        g. Session Start Time

h. Session End Time
i. Length of Session
j. Staff ID (site staff member)
k. **RL*** Resident Leader (RL) ID
l. **RPs*** Resident Player (RP) IDs (all who attended)

2. The remainder of PAGE 1 includes items that are unique to each activity type; these items track…
    a. **RL*** the extent to which the Resident Leader (RL) *completed* each step required to facilitate that particular activity'
        i. For steps that only occur once (e.g., say your name out loud), there are two options: YES and NO.
        ii. For steps that occur more than once (e.g., ask someone to read the page aloud), there are thre options : YES, MORE THAN ½ OF THE TIME; YES, UP TO ½ OF THE TIME; and NO.
    b. **RL***the amount of staff help needed for that step.
        i. There are three options: NOT AT ALL, A LITTLE, AND A LOT.
    c. To see the exact steps tracked for each activity, see the forms themselves in the Appendix.
3. On PAGE 2 of ALL Session Observation / Evaluation Forms, the following data is collected (i.e., these data are consistently collected across all activity types):
    a. **RL*** Did the RL use the physical button? (YES / NO / N/A)
    b. **RL*** If NO TO 16, why not?
    c. **RL*** How often did the NEXT button work successfully for the RL, even if he/she had to try more than once? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    d. **RL*** How often did RL have to press more than once to get the NEXT button to work? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    e. **RL*** How often did the STAFF member press the NEXT button for the RL? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    f. **RL*** In the researcher's opinion, did the STAFF member assist the RL more than necessary? (Could the staff member allow the resident-leader more autonomy/independence in leading activity?) (YES / NO / N/A)
    g. **RL*** How often did the RL have difficulty pressing the NEXT button? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)

h. **RL*/RPs*** Would you do this again sometime? (tally all participants, even if not study)
i. **RL*/RPs*** Did you like the activity? (tally all participants, even if not study)
j. **RL*/RPs*** Would you recommend it to others? (tally all participants, even if not study)
k. **RL*** How often did the RL read a prompt too soon? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
l. **RL*** How often did the RL read a prompt too quickly for participants to understand/hear? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
m. **RL*** How often did the RL read a prompt unnecessarily? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
n. **RL*** How often did the RL press the next button too soon? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
o. **RL*** How often did the RL seem quite confused about what to do next? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
p. STAFF 1. Did STAFF successfully and appropriately set up the tablets? (YES / NO / N/A)
q. STAFF 2. Did STAFF have any difficulty using the special table (if applicable)? (YES / NO / N/A)
r. STAFF 3. Did the STAFF member attach the button to the RL tablet? (YES / NO / N/A)
s. STAFF 4. Did the STAFF member attach the button to the RP tablets? (YES / NO / N/A)
t. STAFF 5. Did you enjoy this activity? (YES / NO / N/A)
u. STAFF 6. Do you think the residents enjoyed it? (YES / NO / N/A)
v. STAFF 7. Would you do it again sometime? (YES / NO / N/A)
w. STAFF 8. Would you recommend it to colleagues? (YES / NO / N/A)

2. Observations of PWD in PEER Sessions w/ MPES

a. Researchers will observe PWD's engagement and affect during PEER sessions using the MPES (Camp, Skrajner, & Gorzelle, 2015). The MPES is described above. There are six different types of activities, and each activity type will be used at least six times by each PEER group. Each participant will be observed multiple times during the intervention period, so that averages can be calculated for each type of engagement/affect.

Post-Treatment Assessments

1. DEMQOL

a. A researcher will conduct a direct interview with the PWD to complete the DEMQOL. However, if the PWD is unable to respond to questions on the

DEMQOL, this measure will be collected via proxy interview (with a staff member who is familiar with the PWD). The DEMQOL is described above.

2. **GDS-SF**
    a. A researcher will conduct a direct interview with the PWD to complete the GDS-SF. The GDS-SF is described above.
3. **NPI-NH**
    a. The NPI-NH will be conducted by a researcher by interviewing a staff member who is familiar with the PWD. The NPI-NH is described above.
4. **CMAI**
    a. The CMAI will be conducted by a researcher by interviewing a staff member who is familiar with the PWD. The CMAI is described above.

Staff Members

Baseline Assessments

1. **Only the following demographic data will be collected:**
    a. Type of community
    b. Age
    c. Gender
    d. Race/ethnicity
    e. Education level
    f. Primary language
    g. Job title
    h. How long at current job
    i. How long worked in elder care / long-term care
    j. How many residents do you work with?

Intervention Period Data Collection

1. **PEER Training**
    a. The PEER training will be done in person and the topics to be covered include:
        i. *What is PEER?*
        ii. *Characteristics of a Successful Leader*
        iii. *Using the ISH-SI-M*
        iv. *Preparing the Environment*
        v. *Preparing the Tablets*
        vi. *Steps to Training a Resident to Lead Activities*
        vii. *Tips for PEER Training and PEER Programming*
2. **Pre-Post Quiz for Training**
    a. A 15-item quiz will be presented to staff before and after the training to examine knowledge transfer
3. **Satisfaction Questions for PEER Training**
    a. Satisfaction questions will be posed to staff after they take the PEER training
4. **Treatment Fidelity / Process Measures**

b. The Staff Member will be invited to oversee two PEER sessions per week for 4.5 months (enough for PWD PEER participants to attend at least six PEER sessions for each of the six activity types featured on the PEER app). For each session, a Session Observation / Evaluation Form will be completed.

Session Observation / Evaluation Form

i. The following is a full description of the Session Observation / Evaluation Form.
    1. Items that specifically apply to Staff Members are preceded with **SM***

ii. During each session, a two-page Session Observation / Evaluation Form will be completed. Since the steps required to lead each activity type differ, distinct Session Observation / Evaluation Forms have been created for each activity type (e.g., there is a Hearthside Book Club Session Observation / Evaluation Form, a Lingo Bingo Session Observation / Evaluation Form, etc.) However, certain parts of the form remain the same for all activities, as described next.
    1. On the top of PAGE 1 of ALL Session Observation / Evaluation Forms, the following data is collected (i.e., these data are consistently collected across all activity types):
        a. Date of session
        b. Person filling out form (researcher)
        c. Site
        d. # of Leader Form for the Day
        e. # of Residents Attended the Activity (for that session)
        f. Topic (or HBC Story)
        g. Session Start Time
        h. Session End Time
        i. Length of Session
        j. **SM*** Staff ID (site staff member)
        k. Resident Leader (RL) ID
        l. Resident Player (RP) IDs (all who attended)
    2. The remainder of PAGE 1 includes items that are unique to each activity type; these items track…
        a. the extent to which the Resident Leader (RL) *completed* each step required to facilitate that particular activity'
            i. For steps that only occur once (e.g., say your name out loud), there are two options: YES and NO.
            ii. For steps that occur more than once (e.g., ask someone to read the page aloud), there are thre options : YES, MORE THAN ½ OF THE TIME; YES, UP TO ½ OF THE TIME; and NO.
        b. **SM*** the amount of staff help needed for that step.
            i. There are three options: NOT AT ALL, A LITTLE, AND A LOT.
        c. To see the exact steps tracked for each activity, see the forms themselves in the Appendix.

3. On PAGE 2 of ALL Session Observation / Evaluation Forms, the following data is collected (i.e., these data are consistently collected across all activity types):
    a. Did the RL use the physical button? (YES / NO / N/A)
    b. If NO TO 16, why not?
    c. How often did the NEXT button work successfully for the RL, even if he/she had to try more than once? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    d. How often did RL have to press more than once to get the NEXT button to work? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    e. **SM*** How often did the STAFF member press the NEXT button for the RL? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    f. **SM*** In the researcher's opinion, did the STAFF member assist the RL more than necessary? (Could the staff member allow the resident-leader more autonomy/independence in leading activity?) (YES / NO / N/A)
    g. How often did the RL have difficulty pressing the NEXT button? (whether using the on-screen button or physical button) (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    h. Would you do this again sometime? (tally all participants, even if not study)
    i. Did you like the activity? (tally all participants, even if not study)
    j. Would you recommend it to others? (tally all participants, even if not study)
    k. How often did the RL read a prompt too soon? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    l. How often did the RL read a prompt too quickly for participants to understand/hear? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    m. How often did the RL read a prompt unnecessarily? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    n. How often did the RL press the next button too soon? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    o. How often did the RL seem quite confused about what to do next? (NOT AT ALL / UP TO ½ / MORE THAN ½ / N/A)
    p. **SM*** STAFF 1. Did STAFF successfully and appropriately set up the tablets? (YES / NO / N/A)
    q. **SM*** STAFF 2. Did STAFF have any difficulty using the special table (if applicable)? (YES / NO / N/A)
    r. **SM*** STAFF 3. Did the STAFF member attach the button to

the RL tablet? (YES / NO / N/A)

s. **SM*** STAFF 4. Did the STAFF member attach the button to the RP tablets? (YES / NO / N/A)
t. **SM*** STAFF 5. Did you enjoy this activity? (YES / NO / N/A)
u. **SM*** STAFF 6. Do you think the residents enjoyed it? (YES / NO / N/A)
v. **SM*** STAFF 7. Would you do it again sometime? (YES / NO / N/A)
w. **SM*** STAFF 8. Would you recommend it to colleagues? (YES / NO / N/A)

9.0 TIMELINE AND VISIT SCHEDULE

***PWD* Timeline and Visit Schedule**				
Assessment / Interview / Data to Collect	**Screening**	**Baseline**	**Intervention Period**	**Post-Treatment**
Informed Consent Form (Legally Authorized Representative)	**X**			
Initial Screening (for Basic Criteria) Via Staff Report and/or Chart Review (PWD Initial Screening Form)	**X**			
Document / Confirm All Diagnoses, Type of Dementia, Meds, Demographics (Chart Review Form)	**X**			
Initial Enrollment (if person meets basic eligibility criteria)	**X**			
Assent (Person with Dementia)	**X**			
Mini-Mental Status Exam (MMSE)	**X**			
I'm Still Here Skills Inventory – PEER Version (ISH-SI-PV) [if person scores below 5 on MMSE]	**X**			
Final Enrollment	**X**			
Dementia Quality of Life (DEMQOL)Geriatric Depression Scale-Short Form (GDS-SF)		**X**		
PEER Leader Assessment (if potential RL)		**X**		
Neuropsychiatric Inventory-Nursing Home (NPI-NH)		**X**		
Cohen-Mansfield Agitation Inventory (CMAI)		**X**		
Observations of PWD in Standard Activities w/ Menorah Park Engagement Scale (MPES)		**X**		
Session Observation / Evaluation Form ***(Experimental Only)*** Observations of PWD during PEER activities ***(Experimental)*** and Standard Activities ***(Control)*** using the MPES			**X***	
DEMQOL				**X**
GDS-SF				**X**
NPI-NH				**X**
CMAI				**X**

As noted in the first column of this table, some Intervention Period measures differ between Experimental and Control.

Staff Participants Timeline and Visit Schedule			
Assessment / Interview / Data to Collect	**Screening/ Baseline**	**Intervention Period**	**Post-Treatment**
Informed Consent Form	**X**		
Demographics	**X**		
Enrollment (if eligible)	**X**		
PEER Training Pre-Quiz		**X**	
Take PEER Training Course		**X**	
PEER Training Post-Quiz		**X**	
PEER Training Satisfaction Questions		**X**	
Observe/Assist with PEER Session led by Researcher		**X**	
Session Observation / Evaluation Form		**X**	
Final Satisfaction / Focus Group Questions			**X**

10.0 VISIT PROCEDURES

PWD

Screening Procedures

INITIAL ELIGIBILITY

A researcher will confirm the following with staff at the community and/or conduct a chart review to determine **initial eligibility** by determining whether the PWD meets the following inclusion / exclusion criteria:

e. He/she is age 55+
f. He/she is able to read and speak English
g. He/she is diagnosed with dementia (of any type)
h. He/she does NOT show signs of rapid cognitive decline or physical deterioration over the last 6 months
    i. He/she is NOT bed confined.
    ii. He/she is NOT completely unable to communicate verbally.
    iii. He/she is NOT cognitively and/or physically impaired to such a point that they are unable to participate in group activities.
    iv. He/she is actively dying.
    v. His/her health is declining so rapidly that they are going to be unable

participate in group activities in next week.

FINAL ELIGIBILITY

If the person meets the initial inclusion / exclusion criteria, a researcher will meet directly with the person with dementia and ask him/her to sign the assent form. If the resident signs the assent form, the researcher will continue to interview him/her and determine **final eligibility** by administering the Mini-Mental Status Examination (MMSE—described in detail above) and, if needed, the ISH-SI-PV (described in detail above).

- If the person scores at least 5 on the MMSE, he/she is eligible to be a RP in the study.
- If the person scores below 5 on the MMSE, the researcher will conduct the ISH-SI-PV
    - If the person scores at least 1 on the ISH-SI-PV, he/she is eligible for the study
- If the person scores at least 13 on the MMSE, he/she is eligible to be a RL in the study.
    - Final determination as to whether the PWD is appropriate to be a RL will be determined by conducting the PEER Leader Assessment. In order to be eligible to be a RL, the person must perform adequately on the PEER Leader Assessment.

Baseline Procedures

Chart Review/Interview with Staff

Researchers will collect the following data from each PWD's chart:

- Demographics (race/ethnicity, education level, marital status, and number of years living in LTC)
- All diagnoses
- Type of dementia
- All meds

Baseline Assessment

A researcher will schedule a time to work with the PWD and conduct a direct interview with him/her to complete the MMSE, ISH-SI-PV (if needed), GDS-SF, and DEMQOL. The researcher will follow standard protocol for conducting these measures and be extensively trained on how to properly use these measures. *Please note that the MMSE is not an outcome measure.*

Caregiver Interview

Researchers will interview a caregiver to obtain data related to neuropsychiatric symptoms (based upon the NPI-NH) and agitation (based upon the CMAI) exhibited by the PWD. In addition, if needed (i.e., if the PWD was unable to respond to the DEMQOL and/or GDS questions), a researcher will interview the caregiver to conduct the proxy version of the DEMQOL and/or GDS.

Observations of Standard Activities

Researchers will observe the PWD taking part in standard activities using the MPES. Multiple observations will be taken with so that an average score can be calculated for baseline, standard activity programming. Researchers will follow the standard protocols for using the MPES and be extensively trained on how to properly use these measures.

Intervention Period Procedures

The PWD will be invited to participate in two PEER sessions per week for 4.5 months. The sessions will be overseen by a staff member at the nursing home or assisted living facility. The staff member will be trained on how to conduct PEER Sessions, as described earlier.

Treatment Fidelity / Process / Satisfaction Measures
Researchers will complete a Session Observation / Evaluation Form for each scheduled session, even if the session does not actually occur due to the PWD's unavailability or refusal to participate. Data collected on the Session Observation / Evaluation Form is detailed above.

There will be no Treatment Fidelity / Process Measures for Control Participants.

Observations of PEER Sessions
Researchers will observe the PWD taking part in PEER sessions using the MPES. We will aim to complete multiple observations for each activity type, so that an average score can be calculated for PEER activity programming. Researchers will follow the standard protocols for using the MPES and be extensively trained on how to properly use these measures.

Post-Treatment Procedures

Post-Treatment Assessment
A researcher will schedule a time to work with the PWD and conduct a direct interview with him/her to complete the DEMQOL and GDS-SF.

Caregiver Interview
Researchers will interview a caregiver to obtain data related to neuropsychiatric symptoms (based upon the NPI-NH) and agitation (based upon the CMAI) exhibited by PWD. In addition, if needed (i.e., if the PWD was unable to respond to the DEMQOL and/or questions), a researcher will interview the caregiver to conduct the proxy version of the DEMQOL and/or GDS.

Staff Members

Please note: staff members will only be enrolled at Experimental Sites.

Screening Procedures

Direct Interview for Eligibility Criteria
After consent is obtained from the staff member, a researcher will ask a staff member to fill out a form that confirms that he/she meets the following criteria:

a. The Staff Member is age 18+
b. The Staff Member is able to read and speak English
c. The Staff Member does not only work third shift

Intervention Period Procedures

Take Training Course

Staff will take part in a live training session.

Pre-Post Training Quiz for Training Modules
Before and after taking the PEER training, the Staff Member will be presented with a 15-item quiz.

Treatment Fidelity / Process Measures
At Experimental Sites, Staff Members will be invited to oversee two PEER sessions per week for 4.5 months. At Control Sites, staff will provide standard activities / care for 4.5 months.

A Session Observation / Evaluation Form will be completed for each scheduled session, even if the session does not actually occur due to the PWD's unavailability or refusal to participate. Data collected on the Session Observation / Evaluation Form is detailed above.

Final Satisfaction Questions

Final Satisfaction Questions
A researcher will schedule a time to work with the staff member to pose final satisfaction questions to the staff member regarding the PEER training and app. The questions will consist of a combination of closed- and open-ended questions.

11.0 FOLLOW-UP

This is a low-risk study of a non-pharmacological intervention. As such, follow up is not required. The final point of contact for PWD will be the post-treatment assessment. The final point of contact for staff members will be the final satisfaction interview.

12.0 EARLY DISCONTINUATION

Participants are free to withdraw from participation in the study at any time and for any reason. If they do withdraw, we will no longer collect data on the person.

13.0 SAFETY REPORTING

For the purposes of this study, a participant is considered enrolled if they have successfully completed the screening procedure outlined above. Safety oversight of the trial is provided by the Principal Investigator (PI), Mr. Skrajner.

After being enrolled in the study, participant safety will be monitored regularly by the PI.

> **Adverse Event (AE):** Any unfavorable and unintended sign, 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 (SAE):** 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

As this is a minimal risk psychosocial activity intervention, no AEs or SAEs are expected per NIH definitions, as none of the risks of the study will affect medical outcomes or occurrences.

- The PI will review study conduct in real time.
- The PI will review accrual, drop-outs, and protocol deviations *on an annual basis.*
- The PI will review AEs *individually in real-time, and in aggregate on an annual basis.*
- The PI will review serious SAEs *in real-time.*
- SAEs and specific procedure-associated AEs will be reported to the Heartland IRB *when the yearly IRB report is due, unless the SAE or AE is "possibly related" or "related" to the study procedures.*
    - *If the SAE or AE is "possibly related" or "related" to the study procedures, the SAE or AE will be reported to the IRB within 24 hours.*
    - If any SAEs occur, the PI will, with the assistance of the IRB, determine if any modifications need to be made to the study protocol and procedures. As this is a minimal risk study, this is highly unlikely.

13.1 Specification of Safety Parameters

As this is a non-medical, short duration trial with no interim measures (pre-post design), there are no lab values or test scores that fill this role. If a participant becomes extremely embarrassed or agitated during an assessment or activity, they will be redirected, and the programming will stop. If this occurs at a clinical level that then results in an AE, it will be reported to the IRB when the yearly IRB report is due.

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

The risk profile for this study is low as it is a minimal risk, nonpharmacologic intervention. As such, assessing and recording of the parameters will be done by the PI with the end goal of informing the IRB when the yearly IRB report is due. Since the PI and Experimental Team Lead will be intimately involved in all aspects of the trial, all subject data will be regularly reviewed by them and all staff will report to them on an ongoing basis.

A screenshot of the "Adverse Event and Serious AE Log" with sample data is included in the Appendix

13.3 Reporting Procedures

SAEs and specific procedure-associated AEs are reported to the Heartland IRB when the yearly IRB report is due, unless the SAE or AE is "possibly related" or "related" to the study procedures. If the SAE or AE possibly related" or "related" to the study procedures, the SAE or AE will be reported to the IRB within 24 hours.

13.4 Severity of Event

AEs will be graded according to the following scale:

Mild: 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: 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: An experience that requires therapeutic intervention. The experience interrupts usual daily activities. If hospitalization (or prolongation of hospitalization) is required for treatment it becomes an SAE.

13.5 Relationship To Study Intervention

All AEs will have their relationship to study participation assessed with a level of specificity appropriate to the non-pharmacological study design. The study uses the following AE attribution scale:

Not related: 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).

Potentially related: 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.

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

13.6 Follow-up for Adverse Events

Expected AEs

Expected AEs associated with the study procedures include:

- Extreme Feelings of Frustration/Embarrassment during the Assessments / Intervention

AE Management

- Only staff members who have prior experience working with vulnerable populations will be permitted to take part in primary data collection. This will increase the chances that they know how to reduce such feelings in participants
- All staff members will receive training on how to recognize signs of frustration and embarrassment and what to do in such situations.
- Staff members will be instructed that, if such signs are present, the assessment or activity will be discontinued and/or the participant will be given an alternative activity.

13.7 Unanticipated Problems

Upon notification of an Unanticipated Problem, the Experimental Team Leader or PI will notify all appropriate parties as described in the protocol:

1. The Experimental Team Leader will immediately notify the PI.
2. The PI will send a notification email to the IRB.
3. The PI will advise the Study Team regarding screening, enrollment, and ongoing participation.
4. Upon advisement by the IRB, the PI will determine the study's status and notify the Study Team.

14.0 STUDY COMPLIANCE

The PI will maintain a Protocol Deviation / Violation Log, in which he will report of all protocol

deviations/violations, including but not limited to the following:

- Enrollment of an ineligible participant
- Failure to obtain Informed Consent
- Failure to keep IRB approval up-to-date
- Wrong treatment administered to participant
- Follow-up visit at a time point different from that specified in the protocol

A screenshot of the Protocol Deviation / Violation Log is included in the Appendix.

15.0 DATA COLLECTION AND STUDY FORMS

The following documents are used in this study. Descriptions of measures are included above. The measures themselves are also included in the Appendix.

PWD

Screening Documents

1. PWD Initial Screening / Inclusion Form

Baseline Assessments / Observations Documents

1. Chart Review Form
2. MMSE
3. ISH-SI-PV (if needed)
4. DEMQOL
5. GDS-SF
6. NPI-NH
7. CMAI
8. PEER Leader Assessment (Tablet-Based)
9. MPES

Intervention Period Data Collection

1. HBC Session Observation / Evaluation Form [Experimental Only]
2. LB Session Observation / Evaluation Form [Experimental Only]
3. SIO Session Observation / Evaluation Form [Experimental Only]
4. CC Session Observation / Evaluation Form [Experimental Only]
5. QV Session Observation / Evaluation Form [Experimental Only]
6. Would You Rather Session Observation / Evaluation Form [Experimental Only]
7. DiscussIT Session Observation / Evaluation Form [Experimental Only]
8. MPES

Post-Treatment Assessment Documents

1. DEMQOL
2. GDS-SF
3. CMAI
4. NPI-NH

Staff Members

Screening Documents

1. Staff Screening and Demographics Form

Intervention Period Data Collection

1. Pre-Post-Training Quizzes for Training Modules
2. HBC Session Observation / Evaluation Form [Experimental Only]
3. LB Session Observation / Evaluation Form [Experimental Only]
4. SIO Session Observation / Evaluation Form [Experimental Only]
5. CC Session Observation / Evaluation Form [Experimental Only]
6. QV Session Observation / Evaluation Form [Experimental Only]
7. Would You Rather Session Observation / Evaluation Form [Experimental Only]
8. DiscussIT Session Observation / Evaluation Form [Experimental Only]

Final Satisfaction Questions

1. Final Satisfaction Questions / Focus Group Questions for Staff

15.1 Source Documentation

This section describes how participant data are maintained in the study.

Definitions: A source document is any document on which study data are initially recorded. Source documents for this study include demographics forms, medical records, standardized test forms, satisfaction questionnaires, and engagement forms, etc. Most source documents are electronic in nature and will also serve as electronic Case Report Forms (eCRFs) to document study-specific data requirements. This method reduces the likelihood of transcription errors. All data will be checked and cleaned during a QA process to ensure data integrity.

All essential study documents will be retained by the investigator in an electronic Participant Binder and include:

- Source documents
- Measures completed by the participant
- Measures completed by the proxy interviews
- eCRFs
- Applicable *Notes to File (including Notes to File that indicate errors in forms)*

Note: The only exception to this is that Resident Consent Documents are kept in an electronic folder named "Participants and Consents." This keeps the participant name separate from de-identified data.

At the conclusion of the study, all source documents, eCRFs, and other required documentation will be kept with study records as required by protocol and IRB guidelines.

15.2 Forms Maintenance

All forms will be stored in electronic participant "binders." Forms which are collected digitally will automatically be saved to a secure, HIPAA-compliant database and then manually distributed to the correct participant binder. Hard copy forms will be scanned and placed into the proper digital binder.

15.3 General Instructions for Completing Forms

For All forms:

- All forms should be filled out electronically.
- Any hard-copy forms will be scanned as soon as feasible and become the source document.
- Completed forms should be saved in the participant's digital binder (file folder with their ID number)
- To ensure the best possible level of confidentiality, after scanning hard copy forms, these forms will be stored in a secure area. After data from hard copy forms have been entered / double checked, such forms will be shredded.
- The Experimental Team Leader and/or PI will spot check a subset of forms before they are entered into SPSS to ensure that proper protocols are being adhered to and data is appropriately cleaned.
- After data on digital forms are confirmed to be accurate, researchers will flatten the digital form (to prevent accidental changes to the file) and save it to the participant's digital binder.
    - The file name will have descriptive details about what is included in the file (e.g., Resident Assessment, HBC Session Observation / Evaluation Form, etc.)
    - In addition, the researcher will end the file name with his/her initials and the date (e.g., dw_2022_01_01)
- The Experimental Team Leader is responsible for updating forms, as needed.
- The PI will review and approve all changes to forms.
- During weekly meeting, issues with data collection, including possible problems with forms should be discussed by study team members.
- Researchers should be sure to completely fill out all forms.
- Participants must not be identified by name on any study document submitted with the forms. If research sites provide forms with the participants name on them, researchers will redact the participant's name and replace with his/her identification (ID) number.
- Researchers should complete the header information on EVERY page, including pages for which no study data are recorded.
- The participant ID must be recorded on EVERY page, including pages for which no study data are recorded.
- Time: Use a 24-hour clock (e.g., 14:00 to indicate 2:00 p.m.) unless otherwise specified.
- All dates must be verifiable by source documents. Historical dates are sometimes not known (e.g., date of first symptom); therefore, conventions for missing days and/or months should be described (e.g., UNK or 99).
- Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.
- Comments written extraneously on forms cannot be captured in the database; thus, write only in the spaces indicated.

- If an error has been made on the study forms, place a single line through the erroneous entry and record the date and your initials. Indicate the correct response.
- Do not skip any items. Some items may carry "Unknown" or "Not Applicable" response choices which should be checked when necessary.
- Data may not be available to complete the form for various reasons. Circle the item for which data is not available and indicate the reason near the appropriate field:
- If an evaluation was not done, write ND and provide a reason.
- If the information is not available, but the evaluation was done, write NAV.
    - Only in rare circumstances, as in the case of lost documentation, should NAV be recorded on the form. Every effort should be made to obtain the information requested.
- If an evaluation is not applicable, write NA.
- Incomplete or Illegible forms: Incomplete forms that do not have adequate explanation (as described above) compromise the integrity of the entire study.
- If/when site staff members share a document with a participant's name on it, the name of the person will be digitally redacted, and the ID number of the person put in place of the name
    - To preserve privacy, the document with the name of the person will be deleted
    - The version with the ID number will be place in the appropriate digital file folder.

For Digital Forms:
When a form is completed, it should be placed in the digital binder (file folder) for the individual participant.

For Hard Copy Forms:
Hard copy forms should only be used when a tablet and/or internet is unavailable. If used, hard copy forms must be scanned immediately after collection and uploaded to the participant binder. The scanned version will then be considered the source document. Hard copy will then be stored in a secured area. When completing hard copy study forms, print using dark ink.

15.4 Data Flow

Completed forms (whether electronic or hard copy) will be reviewed by a researcher to ensure completeness and accuracy. Any errors will be crossed out, corrected, and then initialed. After data on digital forms are confirmed to be accurate, researchers will flatten the digital form (to prevent accidental changes to the file) and save it to the participant's digital binder.

- The file name will have descriptive details about what is included in the file (e.g., Resident Assessment, HBC Session Observation / Evaluation Form, etc.)
- In addition, the researcher will end the file name with his/her initials and the date (e.g., dw_2022_01_01)

If any accidental references to the person by name is included on the data form, such references will be redacted and initialed by reviewer. Data from the form will then be entered into the study's master database by the research assistant.

15.5 Administrative Forms

A Staff Training Log will be used. A screenshots of this log is included in the Appendix.

15.6 Retention of Study Documentation

After the study ends, study staff shall maintain participant forms in Hearthstone's HIPAA compliant database for three years or as indicated by the protocol, federal regulations, and IRB guidance.

16.0 DATA MANAGEMENT

Data Tracking will be conducted in the following way:

- The Experimental Team Leader will manage a data tracking spreadsheet. Each row will contain a participant ID and each column will contain a piece of data required for the study (e.g., NPI-NH or DEMQOL). This will allow him to track which data has been and which data will need to be collected (and by when). Once data is collected, he will note the person who collected the data and on what date (e.g., Collected by XX on 7/30/21). It should be noted that separate data tracking spreadsheets will be maintained for each type of participant (PWD, Staff Members, and Family Members).

Study Form Review will be conducted in the following way:

- After data on digital forms are confirmed to be accurate, researchers will flatten the digital form (to prevent accidental changes to the file) and save it to the participant's digital binder.
    a. The file name will have descriptive details about what is included in the file (e.g., Resident Assessment, HBC Session Observation / Evaluation Form, etc.)
    b. In addition, the researcher will end the file name with his/her initials and the date (e.g., dw_2022_01_01)

Data Entry will be conducted in the following way:

- The Research Assistant will enter data directly into SPSS by reviewing the forms. Data will be double-checked for accuracy.

Data Analyses will be conducted in the following way:

- The PI will conduct data analyses using SPSS.

16.1 Quality Control Procedures

All study staff responsible for data collection and management will have received human subjects and good clinical practice training/certification. In terms of training for collection of other measures and adherence to other study protocols, all staff will be trained via standard, in-person training protocols on all measures and will achieve a minimum inter-rater reliability rating of 90% on the primary outcome measures.

16.2 Data and Form Checks

Before data is entered into SPSS, a researcher will check the forms for the following possible issues:

- Missing data or forms
- Out-of-range or erroneous data
- Inconsistent and illogical dates over time
- Data inconsistency across forms and visits
- Not completing all fields of a "completed form" or no reason for missing data is provided

16.3 Site Monitoring

This is a single-site clinical trial since there is one investigational site (Hearthstone) conducting and coordinating the study protocol. As such, the PI and Experimental Team Leader will be jointly responsible for the following monitoring activities:

- Ensuring the rights and safety of participants
- Confirming that the study is conducted in accordance with GCP guidelines
- Ensuring maintenance of required documents
- Verifying adherence to the protocol
- Monitoring the quality of data collected
- Ensuring accurate reporting and documentation of all AEs and unanticipated problems

The study team will meet weekly about the project and each of the above items will be part of the meeting agenda each week. Researchers will voice any concerns or issues related to the above areas during the meeting.

17.0 DATA AND SAFETY MONITORING ACTIVITIES

The roles and responsibilities of the entities monitoring participant safety and study quality are described in this section. All clinical trials supported by NIA must have a data and safety monitoring plan. This single-site, minimal risk study will be overseen by the PI.

17.1 Reports

The following reports will be produced for this study:

Safety Reports

- Delivered to the IRB as needed and will include a detailed analysis of study progress, AEs, and SAEs.
- Produced by the Experimental Team Leader

Final Report

- Delivered to NIH and IRB no more than 120 days after the completion of the project.
- Produced by the PI and Experimental Team Leader

17.2 Study Completion and Close-Out Procedures

The following study completion and close-out procedures will be used:

- The PI and/or Experimental Team Leader will verify that study procedures have been completed, data have been collected, and study intervention(s) and supplies are returned to the responsible party or prepared for destruction.
- The PI will ensure that all data queries have been completed.
- The PI will ensure that correspondence and study files are accessible for external audits.
- The PI will ensure that the study records are maintained and any relevant study information reported to the NIA.
- The PI will notify the IRB of the study's completion and store a copy of the notification.
- The PI will prepare a report summarizing the study's conduct.
- The PI will notify participants of the study completion.

17.3 Participant Notification

A close out letter will be sent to participants, with a summary of key results. The letter will also thank them for participating in the study. The PI will have lead responsibility for creating the letter and making sure it is sent to all participants.

17.4 Confidentiality Procedures

The following confidentiality safeguards will be used:

- ***Electronic files*** – Data identifying participants that are stored electronically will be maintained in a separate file that is saved on a secure, HIPAA-compliant server.
- ***Forms*** – Forms or pages containing personal identifying information will be separated from other pages of the data forms and be retained in a secure location.
- ***Data listings*** – Participant name, name code, long-term care chart, record number, and other unique identifiers will not be included in any published data listing.
- ***Data distribution*** – Data listings that contain participant name, name code, or other identifiers easily associated with a specific participant will not be distributed.
- ***Data disposal*** – Computer listings that contain participant-identifying information will be disposed of in an appropriate manner.
- ***Access*** – Participant records will not be accessible to persons outside the site without the express written consent of the participant.
- ***Storage*** – Study forms and related documents will be retained both during and after study completion and will be stored in a secure location
- ***Passwords*** – Passwords will be used to provide limitations on general access to computer systems and to the functions that individuals can use. Passwords will be changed on a regular basis.
- ***User Training*** – Study staff with access to computer systems will be trained in their use and in related security measures. Training will include explanations of how to access the system and a discussion of the need for, and importance of, system security.
- ***System Testing*** – Prior to the use of a new computer system, and after any modifications, the system will be tested to verify that it performs as expected. Testing will verify that the password-activated access system performs as intended.
- ***System Backups*** – Backup copies of electronic data will be made on a regular basis.

17.5 Publications

Study results will be made available to the public as soon as possible. Publication of the results of this trial will be governed by the policies and procedures of Hearthstone, NIH guidelines, and standard industry practice. Any presentation, abstract, or manuscript will be made available for review by the sponsor and the NIA prior to submission.

18.0 MOP MAINTENANCE

The MOP will be updated on an as needed basis. When a new revision is made, the following procedure will be followed:

1. The version date on the cover page and footer will be updated with the latest date.
2. A list of key changes will be listed on the cover pages. All changes will tracked.

3. Previous versions of the MOP will be maintained and saved.