The BRAIN App: Building Relationships Using Artificial Intelligence and Nostalgia
NCT05515679

Study Protocol

7/27/22

STUDY OVERVIEW

Study Title:
The BRAIN App: Building Relationships using Artificial Intelligence and Nostalgia

This is a quasi-experiment using a pre-post design—i.e., baseline vs. treatment / post-treatment. The study investigates the effects of an Artificial Intelligence-enabled Cognitive Stimulation Therapy (CST) app on persons with dementia (PWD). The primary objective is to examine the impact of the app on engagement / affect. More specifically, the study will examine whether the app produces increases in Constructive Engagement, Passive Engagement, and Pleasure and/or decreases in Other Engagement, Non-Engagement, and Anxiety/Sadness. A secondary objective is to examine the impact of the app on quality of life, neuropsychiatric symptoms, and the quality of the carer-patient relationship.

This study will be conducted at one CCRC, in their nursing home (NH) and assisted living facility (ALF). The study will involve 24 PWD (12 from a NH and 12 from an ALF), 20 staff members (10 from a NH and 10 from an ALF), and 24 family members (12 related to PWD from a NH and 12 related to PWD from an ALF). PWD will be 65+ years old, diagnosed with any type of dementia, and speak and read English. In addition, the exhibit at least one responsive behavior at baseline, based upon the NPI-NH (Neuropsychiatric Inventory-Nursing Home) and/or score below the maximum on the Dementia Quality of Life (DEMQOL) scale. To accommodate for attrition, 28 PWD, 24 Staff Members, and 28 Family Members will initially enroll in the study.

The study will last six months, although the early part of the study will involve software development of the app itself. PWD will participate in a one-month baseline period, a one-month intervention period–during which time they will use the app three times per week—and a two-week post-treatment period. So, overall involvement in the study for PWD will be about three months. Staff Members will participate in a one-month baseline period, a one-month intervention period–during which time they will initially take a training on how to use the app and then facilitate activities with the PWD three times per week—and a two-week post-treatment period. So, overall involvement in the study for Staff Members will be about three months. Family Members will participate in the study exclusively by filling out the Life Story Questionnaire, which will provide background information about their loved one / the PWD. This will occur during the baseline period. As such, Family Member involvement will last one day for about 30 minutes.

STUDY FLOW

Figure 1: Study Flow Diagram for PWD

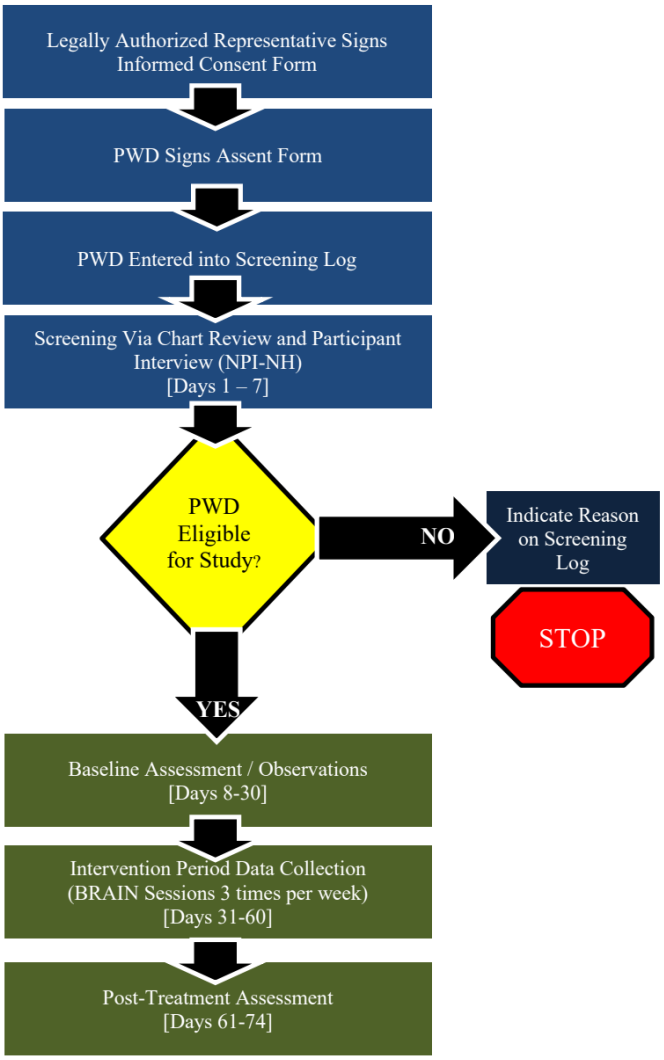


Figure 2: Study Flow Diagram for Staff Members

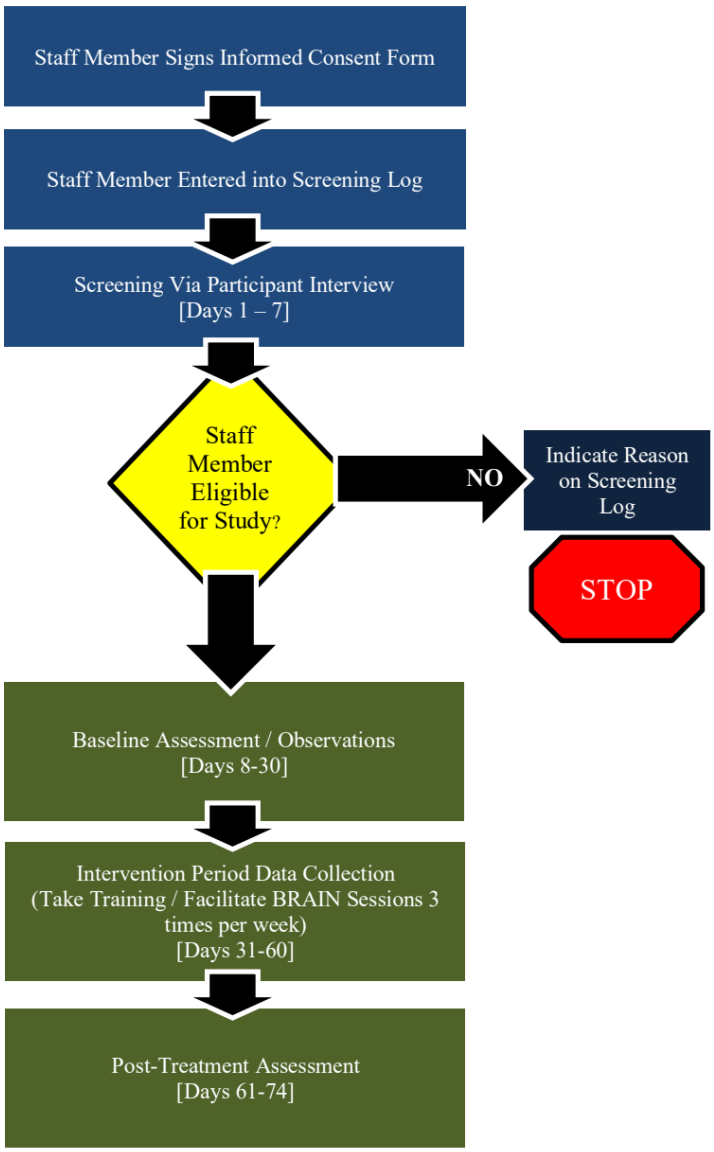
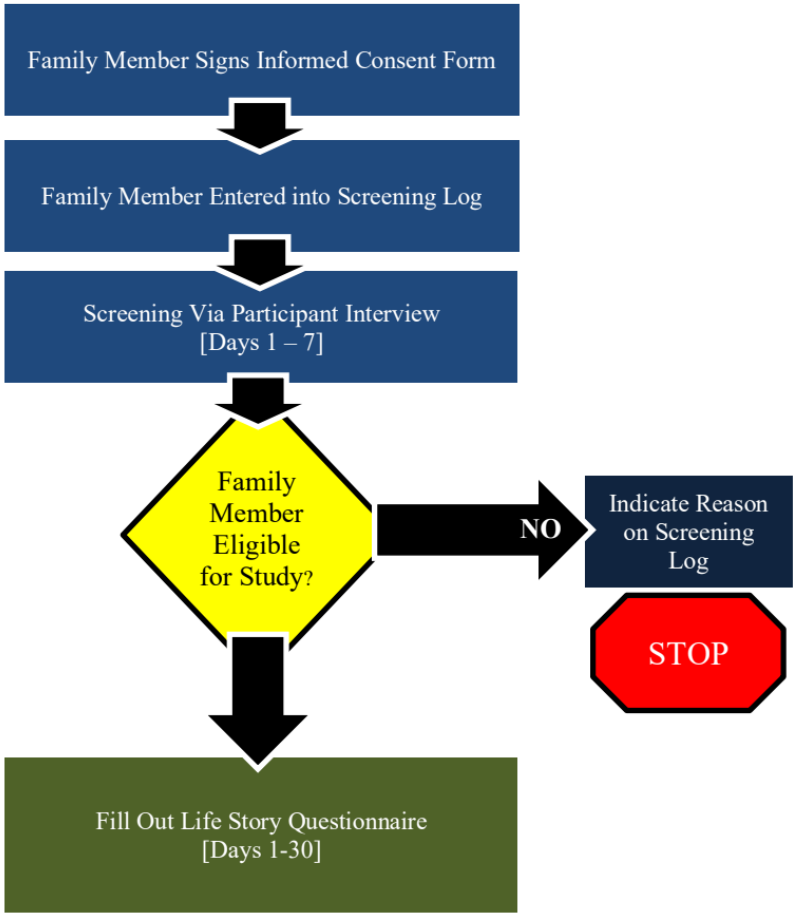


Figure 3: Study Flow Diagram for Family Members



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, Project Manager, 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 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. They 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. 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 files.

ADDED ON 8/31/21: The determination as to whether a PWD will provide his/her own consent will be based upon documentation at the ALF / NH. If the ALF / NH indicates that the person with dementia (PWD) has someone who makes his/her medical decisions, then we would obtain consent from the family member / legally authorized representative and obtain assent from the PWD. If the ALF / NH indicates that the PWD provides his/her own consent, then we will obtain full consent from the PWD.

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

Family Members

Family Members will initially be contacted by telephone and have the recruitment packets mailed to them upon request after the phone call. 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, Project Manager, 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 Family Members. 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. Once a consent form is received by researchers via mail or electronically, an ID number will be assigned to the participant. Copies of signed consent forms will be provided to participants and placed in their files.
A copy of the family member consent form is 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: Nursing Assistants 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 Nursing Assistants 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 participants and placed in their files.
A copy of the staff member consent form is included in the Appendix.

HIPAA Authorization

PWD
The researcher will explain to the legally authorized representative that study coordinator will collect the PWD's protected health information (PHI) for use in this study, as specified in the consent form they have signed. The researcher will ask the participant to please review and sign the HIPAA authorization form to allow the study team to access their 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.
A copy of the HIPAA authorization form is included in the Appendix.

Family Members
HIPAA authorization will not be required for family members, as PHI will not be collected.
Staff Members
HIPAA authorization will not be required for staff members, as PHI will not be collected.

RECRUITMENT AND RETENTION

Participant Recruitment

PWD
The PI will speak to the administrator or executive director of the nursing home and assisted living facility and as 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, Project Manager, 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 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. They 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. 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 files.

Family Members

Family Members will be contacted after their loved one / the PWD has enrolled in the study. Family members will be contacted by telephone and have the recruitment packets mailed to them upon request after the phone call. 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, Project Manager, 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 Family Members. 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. Once a consent form is received by researchers via mail or electronically, an ID number will be assigned to the participant. Copies of signed consent forms will be provided to participants and placed in their files.

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 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 Nursing Assistants 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 participants and placed in their files.

Participant Retention

Study staff will be in regular contact with staff members, family members, and PWD and 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 make several contacts using all of the contact information provided by the participant. This will include sending certified return receipt letters to the participant's listed address.

SCREENING AND ELIGIBILITY CRITERIA

Screening

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

PWD

After obtaining consent from the PWD's legally authorized representative and assent from the PWD himself/herself, the following procedures will be followed to determine whether the PWD is eligible for the study. The Screening Process will occur 1-7 days after the informed consent document and assent are signed.

1. **A researcher will conduct a CHART REVIEW at the community to determine whether the PWD meets the following inclusion / exclusion criteria:**
    a. He/she is age 65+
    b. He/she is able to read and speak English
    c. He/she is diagnosed with dementia (of any type)
    d. He/she is NOT bed confined,
    e. He/she is NOT completely unable to communicate verbally
    f. He/she does NOT have serious visual or hearing impairments
    g. He/she does NOT show signs of rapid cognitive decline or physical deterioration over the last 6 months
2. **The NPI-NH will be conducted by a researcher by interviewing a staff member who is familiar with the PWD.**
    a. The NPI-NH is a screening instrument to be used by the nursing staff to evaluate 12 neuropsychiatric symptoms in dementia patients in a long-term care setting, including the following: Delusions, Hallucinations, Agitation, Depression / Dysphoria, Anxiety, Apathy, Irritability, Euphoria, Disinhibition, Aberrant Motor Behavior, Night Time Behavior, and Appetite / Eating Changes
    b. Each item is initially rated as present or absent.

i. 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
ii. 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 is 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.
   ii. The PWD will be deemed eligible if and only if he/she scores greater than 0 on the NPI-NH (and meets the other criteria for enrollment--i.e. age 65+, dementia diagnosis, and speaks and reads English)

PLEASE NOTE: The above screening process will occur 1-7 days after the consent/assent are signed.

Staff Members

After obtaining consent from the staff member, the following procedures will be followed to determine whether the staff member is eligible for the study. The Screening Process will occur 1-7 days after the informed consent document is signed.

1. **A researcher will conduct a DIRECT INTERVIEW with the staff member determine whether the PWD 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

PLEASE NOTE: The above screening process will occur 1-7 days after the consent is signed.

Family Members

After obtaining consent from the family member, the following procedures will be followed to determine whether the family member is eligible for the study. The Screening Process will occur 1-30 days after the informed consent document is signed.

1. **A researcher will conduct a DIRECT INTERVIEW with the family member to determine whether the PWD meets the following criteria:**
   a. He/she is age 18+
   b. He/she is able to read and speak English

PLEASE NOTE: The above screening process will occur 1-30 days after the consent is signed

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 the following information: the individual's initials, identification number (screening number), age, gender, race, ethnicity, screening date, and eligibility status. (e.g., eligible for study participation and date enrolled; ineligible for study participation and reason; refused consent and reason). The file will be saved on the Hopeful Aging servers.

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

Eligibility Criteria

Inclusion Criteria

PWD

PWD must reside in an ALF or NH, be 65+ years old, diagnosed with any type of dementia, speak and read English, and exhibit at least one responsive behavior at baseline, based upon the NPI-NH (Neuropsychiatric Inventory-Nursing Home).

Staff Members

Staff Members must be at least 18 years old and speak and read English.

Family Members

Family Members must be at least 18 years old and speak and read English.

Exclusion Criteria

PWD will be excluded if they are bed confined, completely unable to communicate verbally, have serious visual or hearing impairments and/or show signs of rapid cognitive decline or physical deterioration over the last 6 months, as evidenced by medical records.

Staff Members will be excluded if they only work third shift (e.g., 11pm – 7am).

Family Members will be excluded if they indicate that they have no knowledge of their loved one's background.

STUDY INTERVENTION

All PWD will receive the same intervention. Namely, they will take part in one-on-one activity programming for four weeks, using the BRAIN app three times per week. Each activity session will last 15-25 minutes and be led by a professional care partner (CP—e.g., nursing assistant, caregiver, activity professional, etc.).

The total length of participation in the study for persons with dementia will be three months, including one month for baseline, one month for the intervention period, and about two weeks for post-treatment.

Staff Members will be involved in the study for a total of three months: one month for baseline, one month for intervention period data collection (during which time they will implement the BRAIN intervention three times per week, with each session lasting 15-25 minutes), and one month for post-treatment data collection.

Family Members will participate for just one day for about 30 minutes. Their only involvement will involve filling out the Life Story Questionnaire (which provides background information about their loved one / the PWD).

Staff Members at the PWD's community will implement the BRAIN Intervention with the PWD three times per week for four weeks (for each PWD). Staff members will be trained on how to use the app when they take the two training modules that are incorporated into the CP Training Dashboard:

(1) "Using the BRAIN App," which will cover the "nuts and bolts" of using the app—e.g., how to install the app, how to access recommended activities for a particular resident, how to connect to the resident's tablet, etc. This training will take about 15 minutes to complete.

(2) "Top 10 Tips for Facilitating Activities with Persons with Dementia," which will cover overall best practice tips for facilitating activities with PWD. This training will take about 30 minutes to complete.

The knowledge and experience that they gain while taking these two training modules will prepare them to properly implement the BRAIN intervention. To help remind staff members of the key aspects of the training, two quick-reference sheets will also be provided to staff at the completion of the training modules: one quick reference sheet for the "Using the BRAIN App" training and one quick reference sheet for "Top 10 Tips for Facilitating Activities with Persons with Dementia." These quick reference sheets (each of which will be one page) will include key information from each 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 BRAIN app will guide the staff member through each activity step by step, so an implementation manual will 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 many staff have low literacy (especially caregivers) and/or speak language as a second language. Therefore, such staff have difficulty comprehending and remembering all of the information included in such a detailed manual. Furthermore, staff are very busy with their 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.

As such, we have found that the best way to ensure staff properly follow an intervention such as the BRAIN 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, and (c) provide quick reference sheets (in this case, one quick reference sheet for each of the two training modules).

STUDY MEASUREMENTS AND PROCEDURES

PWD

Screening

After obtaining consent from the PWD's legally authorized representative and assent from the PWD himself/herself, the following procedures will be followed to determine whether the PWD is eligible for the study. The Screening Process will occur 1-7 days after the informed consent document and assent are signed.

1. **A researcher will conduct a <u>CHART REVIEW</u> at the community to determine whether the PWD meets the following inclusion / exclusion criteria:**
    a. He/she is age 65+
    b. He/she is able to read and speak English
    c. He/she is diagnosed with dementia (of any type)

d. He/she is NOT bed confined,
e. He/she is NOT completely unable to communicate verbally
f. He/she does NOT have serious visual or hearing impairments
g. He/she does NOT show signs of rapid cognitive decline or physical deterioration over the last 6 months

2. **The <u>NPI-NH</u> will be conducted by a researcher by interviewing a staff member who is familiar with the PWD.**
    a. The NPI-NH is a screening instrument to be used by the nursing staff to evaluate 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
    b. Each item is initially rated as present or absent.
        i. 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
        ii. 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 is 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.
        ii. The PWD will be deemed eligible if and only if he/she scores greater than 0 on the NPI-NH (and the PWD also meets the other criteria for enrollment--i.e..., age 65+, dementia diagnosis, and speaks and reads English)

PLEASE NOTE: The above screening process will occur 1-7 days after the consent/assent are signed.

Baseline Assessments / Observations

1. **BIMS**
    a. A researcher will conduct a direct interview with the PWD to conduct the BIMS.
    b. The BIMS is a structured evaluation aimed at evaluating aspects of cognition in elderly patients. The BIMS assesses patient attention, level of orientation, and ability to recall information. There are three assessment stages in the BIMS assessment:
        i. During part I, the patient is asked to repeat three words that are to be given by the assessor. The accuracy of the word reproduction is assessed. Also, the patient is informed that they will need to remember the words at a later moment during the evaluation.
        ii. During part II, temporal orientation is evaluated by asking the patient to recall temporary coordinates (current year, month and day of the week). These are to be asked in separate questions and about 30 seconds are to be given for response.
        iii. During part III the patient is asked to recall the three words given in part I. If needed, cues may be given after waiting for 5 seconds for spontaneous recall.

c. Each of the seven items that BIMS consists of, is awarded a number of points ranging from 0 to 3. The higher the score, the lower the impairment to the cognitive response. Scores closer to 0 indicate severe cognitive impact whilst scores closer to 15 indicate an intact cognitive response
    i. Score Interpretation
        0 - 7 Severe cognitive impact
        8 - 12 Moderate impairment
        13 - 15 Intact cognitive response

2. DEMQOL

a. A researcher will conduct a direct interview with the PWD to conduct 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 patients with dementia. The DEMQOL takes cognition, negative emotion, positive emotion, social relationships, and loneliness into consideration. The DEMQOL-Proxy is a 31-item test completed by the caretaker and focuses on cognition, negative emotion, positive emotion, daily activities, and appearance.
    i. Each item on the DEMQOL (and DEMQOL-Proxy) has four 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 = 4
        A Little = 3
        Quite a Bit =2
        A Lot=1
    iv. The total possible score on the DEMQOL ranges from 28 - 112, with lower scores indicating a lower quality of life.
    v. There is also a 29th item on the DEMQOL, which asks the PWD to 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

3. Document All Diagnoses, Type of Dementia, Meds, and Demographics

a. A researcher will conduct a CHART REVIEW to collect the following data:

i. All diagnoses
ii. Type of dementia
iii. All meds
iv. Demographics (race/ethnicity, education level, marital status, and number of years living in LTC)

4. **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 at least 12 times, so that averages can be calculated for each type of engagement/affect
5. **Observations of PWD in Standard Activities w/ EPWDS**
    a. Participants will also be observed at baseline using the EPWDS (Jones et al., 2018). This scale measures engagement in 5 domains: affective, visual, verbal, behavioral, and social. At least 12 EPWDS observations will be taken for each participant, to enable calculation of average scores.
    b. Each item on the scale is scored on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree)

PLEASE NOTE: all of the above measures will be completed 8-30 days after the informed consent document and assent form are signed.

Intervention Period Data Collection

1. **Treatment Fidelity / Process Measures**
    a. The PWD will be invited to participate in three BRAIN sessions per week for four weeks. A Session Summary 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. The following data will be collected on the Session Summary form:
        i. PWD ID#
        ii. Date of Session
        iii. Time of Session
        iv. Facilitator ID#
        v. Did the PWD attend the session? (Yes/No)
            1. If NO to previous question, please indicate why the PWD did not attend? (Unavailable / Refused / Other)
            2. Reason for unavailability or refusal
        vi. Length of Session

2. **Observations of PWD in BRAIN Sessions w/ MPES**
    a. Researchers will observe PWD's engagement and affect during BRAIN sessions using the MPES (Camp, Skrajner, & Gorzelle, 2015). The MPES is described above. Each participant will be observed at least 12 times during the intervention period, so that averages can be calculated for each type of engagement/affect.
3. **Observations of PWD in BRAIN Sessions w/ EPWDS**
    a. Participants will also be observed at baseline using the EPWDS (Jones et al., 2018). The EPWDS is described above. At least 12 EPWDS observations will be taken for each participant during the intervention period, to enable calculation of average scores.
4. **Satisfaction Questions**
    a. At the end of each session a researcher will pose the following three questions to the PWD:
        i. Did you enjoy the activity? Yes/No
        ii. Would you do an activity like this again sometime? Yes/No
        iii. Would you recommend this activity to others? Yes/No

PLEASE NOTE: all the above measures will be completed during the Intervention Period, which occurs 31-60 days after the informed consent document and assent form are signed.

Post-Treatment Assessments

1. **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.
2. **DEMQOL**
    a. A researcher will conduct a direct interview with the PWD to conduct 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.

PLEASE NOTE: all of the above measures will be completed 61-74 days after the informed consent document and assent form are signed.

Staff Members

Screening

After obtaining consent from the staff member, the following procedures will be followed to determine whether the staff member is eligible for the study. The Screening Process will occur 1-7 days after the informed consent document is signed.

1. **A researcher will conduct a <u>DIRECT INTERVIEW</u> with the staff member determine whether the PWD 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

PLEASE NOTE: The above screening process will occur 1-8 days after the consent is signed.

Baseline Assessments

1. **QCPR**
    a. A researcher will conduct a direct interview with the staff member to conduct the QCPR.
    b. The QCPR is a 14-item scale measures warmth and/or absence of conflict or critique on a 5-point Likert scale, ranging from "totally disagree" to "totally agree."
        i. For warmth/affection items, "totally disagree" responses are scored with one point and "totally agree" responses are scored with five points. Intermediate responses are scored with two, three, or four points.
        ii. For conflict/criticism items, "totally agree" responses are scored with one point and "totally disagree" responses are scored with five points. Intermediate responses are scored with two, three, or four points.
        iii. A score under 42 reflects a poor relationship, while a score over 56 reflects a good relationship. The remaining scores (between 42 and 56) indicate that the quality of the relationship is common, i.e., a standard relationship (Spruytte et al., 2002).
2. **Pre-Training Quizzes for Training Modules**
    a. Staff will be asked to complete two 15-item quizzes--i.., one 15-item quiz for "Training Module 1: Using the BRAIN App" and one 15-item quiz for "Training Module 2: Top 10 Tips for Facilitating Activities with Persons with Dementia."
    b. All questions will be multiple choice in nature.
    c. Staff will complete the quizzes independently on a computer, tablet, or smartphone

PLEASE NOTE: the above measures will be completed 8-30 days after the informed consent document is signed.

Intervention Period Data Collection

1. **Take Two Training Modules**
    a. During the first week of the Intervention Period, the staff member will take the two online training modules:
        i. Training Module 1: Using the BRAIN App
        ii. Training Module 2: Top 10 Tips for Facilitating Activities with Persons with Dementia
2. **Learning Management System Automatically Collects Basic Training Data**
    a. The Learning Management System will automatically collect two pieces of data for each training module:
        i. Did the Staff Member complete the training module? (Yes/No)
        ii. How long did it take for the Staff Member to complete the training module (in minutes)?
3. **Post-Training Quizzes for Training Modules**
    a. After completing each training module, the Staff Member will be presented with the two 15-item quizzes that were presented to them at baseline (although the order of the questions will be changed).
4. **Treatment Fidelity / Process Measures**
    a. The Staff Member will be invited to facilitate three BRAIN sessions per week for

four weeks (for each PWD). A Session Summary 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. The following data will be collected on the Session Summary form:

i. PWD ID#
ii. Date of Session
iii. Time of Session
iv. Facilitator ID#
v. Did the PWD attend the session? (Yes/No)
    1. If NO to previous question, please indicate why the PWD did not attend? (Unavailable / Refused / Other)
    2. Reason for unavailability or refusal
vi. Length of Session

5. **Satisfaction Questions**
    a. at the end of each session a researcher will pose the following three questions to the PWD:
        i. Did you enjoy facilitating the activity? Yes/No
        ii. Do you think the PWD enjoyed the activity? Yes/No
        iii. Would you facilitate an activity like this again sometime? Yes/No
        iv. Would you recommend this activity to your colleagues? Yes/No

PLEASE NOTE: all the above measures will be completed during the Intervention Period, which occurs 31-60 days after the informed consent document is signed.

Post-Treatment Assessments

1. **QCPR**
    a. A researcher will conduct a direct interview with the staff member to conduct the QCPR. The QCPR is described above.

PLEASE NOTE: all the above measures will be completed during the Intervention Period, which occurs 31-60 days after the informed consent document is signed.

Family Members

Screening

After obtaining consent from the family member, the following procedures will be followed to determine whether the family member is eligible for the study. The Screening Process will occur 1-30 days after the informed consent document is signed.

1. **A researcher will conduct a <u>DIRECT INTERVIEW</u> with the family member determine whether the PWD meets the following criteria:**
    a. He/she is age 18+
    b. He/she is able to read and speak English

PLEASE NOTE: The above screening process will occur 1-30 days after the consent is signed.

Baseline Assessments

1. **Life Story Questionnaire**
    a. FMs will be asked to fill out the Life Story Questionnaire to provide information about their loved one's background and interests. The questionnaire will be filled out on a computer, tablet, or smartphone. Simple questions with radio buttons and checkboxes will be used, as well as open text fields.
    b. The following categories of information will be included: demographics, hometown, childhood, relationships, previous occupation, hobbies, social preferences, sports interests, TV/movie interests, and food preferences.

PLEASE NOTE: The Life Story Questionnaire will be completed 1-30 days after the informed consent document is signed.

Intervention Period Data Collection

n/a (Family Members will not be involved in the Intervention Period)

Post-Treatment Assessments

n/a (Family Members will not be involved Post-Treatment)

TIMELINE AND VISIT SCHEDULE

PWD Timeline and Visit Schedule				
Assessment / Interview / Data to Collect	**Screening (Days 1-7)**	**Baseline Interview, Chart Review, and Observations (Days 8-30)**	**Treatment Visits (Days 31-60, three visits per week)**	**Post-Treatment Interview (Days 61-74)**
Informed Consent Form (Legally Authorized Representative)	**X**			
Assent (Person with Dementia)	**X**			
Confirm Age 65+ (Chart Review)	**X**			
Confirm Read & Speak English (Chart Review)	**X**			
Confirm Dementia Diagnosis (Chart Review)	**X**			
Confirm Exclusion Criteria Do Not Apply to the PWD (Chart Review)	**X**			
Neuropsychiatric Interview – Nursing Home (NPI-NH) (Proxy Interview)	**X**			
Enrollment (if eligible)	**X**			
Brief Interview for Mental Status (BIMS) (Direct Interview)		**X**		
Dementia Quality of Life (DEMQOL) (Direct Interview or Proxy if unable to respond)		**X**		
Document All Diagnoses, Type of Dementia, Meds, and Demographics (Chart Review)		**X**		
Observations of PWD in Standard Activities w/ Menorah Park Engagement Scale (MPES)		**X**		
Observations of PWD in Standard Activities w/ Engagement for PWD Scale (EPWDS)		**X**		
Treatment Fidelity / Process Measures			**X**	
Observations of PWD during BRAIN activities using the MPES			**X**	
Observations of PWD during BRAIN activities using the EPWDS			**X**	
Satisfaction Questions			**X**	
DEMQOL (Direct Interview or Proxy, if PWD unable to respond)				**X**
NPI-NH (Proxy Interview)				**X**

***Staff Members* Timeline and Visit Schedule**				
Assessment / Interview / Data to Collect	**Screening (Days 1-7)**	**Baseline Interview, Chart Review, and Observations (Days 8-30)**	**Treatment Visits (Days 31-60, three visits per week)**	**Post-Treatment Interview (Days 61-74)**
Informed Consent Form	**X**			
Confirm Age 18+ (Direct Interview)	**X**			
Confirm Read & Speak English (Direct Interview)	**X**			
Confirm Staff Does Not Only Work Third Shift (Direct Interview)	**X**			
Enrollment (if eligible)	**X**			
Quality of Carer-Patient Relationship (QCPR)		**X**		
Pre-Training Quizzes for Training Modules		**X**		
Take Two Training Modules			**X**	
Learning Management System Automatically Collects Basic Training Data			**X**	
Post-Training Quizzes for Training Modules			**X**	
Treatment Fidelity / Process Measures			**X**	
Satisfaction Questions			**X**	
Quality of Carer-Patient Relationship (QCPR)				**X**

***Family Members* Timeline and Visit Scheudle**	
Assessment / Interview / Data to Collect	**Baseline & Screening (Days 1-30)**
Informed Consent Form	**X**
Confirm Age 18+ (Direct Interview)	**X**
Confirm Read & Speak English (Direct Interview)	**X**
Enrollment (if eligible)	**X**
Life Story Questionnaire	**X**

VISIT PROCEDURES

PWD

Screening Procedures

Chart Review for Eligibility Criteria
After consent is obtained from the PWD's legally authorized representative and the PWD him/herself provides assent, a researcher will schedule a time with staff at the nursing or assisted living to review eligibility information in his/her chart (i.e., age 65+, able to read and speak English, diagnosed with dementia (of any type), NOT bed confined, NOT completely unable to communicate verbally, does NOT have serious visual or hearing impairments, and does NOT show signs of rapid cognitive decline or physical deterioration over the last 6 months).

NPI-NH Interview
A researcher will then schedule a time to interview a staff member familiar with the PWD to conduct the NPI-NH. The researcher will follow standard protocol for conducting the NPI-NH and be extensively trained on how to properly use the measures.

Baseline Procedures

Baseline 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 BIMS. 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 BIMS is not an outcome measure. The BIMS is exclusively being conducted so that we can describe the level of impairment of the study sample.*

Chart Review
A researcher will schedule a time with staff at the nursing or assisted living to collect the following data from his/her chart:

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

Observations of Standard Activities
Researchers will observe the PWD taking part in standard activities using the MPES and EPWDS. At least 12 observations will be taken with each measure, so that an average score can be calculated for baseline, standard activity programming. Researchers will follow the standard protocols for using the MPES and EPWDS and be extensively trained on how to properly use these measures.

Intervention Period Procedures

The PWD will be invited to participate in three BRAIN sessions per week for four weeks. The sessions will be facilitated by a staff member at the nursing home or assisted living facility. The staff member will be trained on how to conduct BRAIN Sessions.

Treatment Fidelity / Process Measures
Researchers will complete a Session Summary Form for each scheduled session, even if the session does not actually occur due to the PWD's unavailability or refusal to participate. The following data will be collected on the Session Summary form: PWD ID#, Date of Session, Time of Session, Facilitator ID#, Did the PWD attend the session? (Yes/No), If NO to previous question, please indicate why the PWD did not attend? (Unavailable / Refused / Other), Reason for unavailability or refusal, and Length of Session. Data will be based upon the researchers observation of the actual session taking place. Researchers will be extensively trained on how to properly use the Session Summary Form.

Observations of BRAIN Sessions
Researchers will observe the PWD taking part in BRAIN sessions using the MPES and EPWDS. At least 12 observations will be taken with each measure, so that an average score can be calculated for BRAIN activity programming. Researchers will follow the standard protocols for using the MPES and EPWDS and be extensively trained on how to properly use these measures.

Satisfaction Questions
Researchers will pose the following questions to the PWD at the end of each BRAIN Session. At the end of each session a researcher will pose the following three questions to the PWD: Did you enjoy the activity? Yes/No, Would you do an activity like this again sometime? Yes/No, Would you recommend this activity to others? Yes/No

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.

NPI-NH Interview
A researcher will schedule a time to interview a staff member familiar with the PWD to conduct the NPI-NH.

Staff Members

Screening Procedures

Direct Interview for Eligibility Criteria
After consent is obtained from the staff member, a researcher will interview the staff member to confirm that he/she meets the following eligibility 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

Baseline Procedures

Baseline Interview
A researcher will conduct a direct interview with the staff member to conduct the QCPR. The researcher will follow standard protocols for using the QCPR and be extensively trained on how to properly use the measure.

Pre-Training Quizzes for Training Modules
Staff will be asked to complete two 15-item quizzes--i.., one 15-item quiz for "Training Module 1: Using the BRAIN App" and one 15-item quiz for "Training Module 2: Top 10 Tips for Facilitating Activities with Persons with Dementia." All questions will be multiple choice in nature. Staff will complete the quizzes independently on a computer, tablet, or smartphone

Intervention Period Procedures

Take Two Training Modules
A researcher will show the staff member how to access the online training and then take the two online training modules: Training Module 1: Using the BRAIN App and Training Module 2: Top 10 Tips for Facilitating Activities with Persons with Dementia

Learning Management System Automatically Collects Basic Training Data
The Learning Management System will automatically collect two pieces of data for each training module. Did the Staff Member complete the training module? (Yes/No). How long did it take for the Staff Member to complete the training module (in minutes)? A researcher will enter these data into the participant's digital binder.

Post-Training Quizzes for Training Modules
After completing each training module, the Staff Member will be presented with the two 15-item quizzes that were presented to them at baseline (although the order of the questions will be changed).

Treatment Fidelity / Process Measures
The Staff Member will facilitate three BRAIN sessions per week for four weeks (per PWD).
A Session Summary 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. The following data will be collected on the Session Summary form: PWD ID#, Date of Session, Time of Session, Facilitator ID#, Did the PWD attend the session? (Yes/No), If NO to previous question, please indicate why the PWD did not attend? (Unavailable / Refused / Other), Reason for unavailability or refusal, and Length of Session.

Satisfaction Questions
At the end of each session a researcher will pose the following four questions to the staff member: Did you enjoy facilitating the activity? Yes/No, Do you think the PWD enjoyed the activity? Yes/No, Would you facilitate an activity like this again sometime? Yes/No, and Would you recommend this activity to your colleagues? Yes/No

Treatment Fidelity / Process Measures

Researchers will complete a Session Summary Form for each scheduled session, even if the session does not actually occur due to the PWD's unavailability or refusal to participate. The following data will be collected on the Session Summary form: PWD ID#, Date of Session, Time of Session, Facilitator ID#, Did the PWD attend the session? (Yes/No), If NO to previous question, please indicate why the PWD did not attend? (Unavailable / Refused / Other), Reason for unavailability or refusal, and Length of Session. Data will be based upon the researchers' observation of the actual session taking place. Researchers will be extensively trained on how to properly use the Session Summary Form.

Observations of BRAIN Sessions
Researchers will observe the PWD taking part in BRAIN sessions using the MPES and EPWDS. At least 12 observations will be taken with each measure, so that an average score can be calculated for BRAIN activity programming. Researchers will follow the standard protocols for using the MPES and EPWDS and be extensively trained on how to properly use these measures.

Satisfaction Questions
Researchers will pose the following questions to the PWD at the end of each BRAIN Session. At the end of each session a researcher will pose the following three questions to the PWD: Did you enjoy the activity? Yes/No, Would you do an activity like this again sometime? Yes/No, Would you recommend this activity to others? Yes/No

Post-Treatment Procedures

Post-Treatment Interview
A researcher will schedule a time to work with the staff member and conduct a direct interview with him/her to complete the QCPR.

Family Members

Screening Procedures

Direct Interview for Eligibility Criteria
After consent is obtained from the family member, a researcher will interview the staff member to confirm that he/she meets the following eligibility criteria:

a. The Staff Member is age 18+
b. The Staff Member is able to read and speak English

Baseline Procedures

Baseline Interview
A researcher will invite the family member to fill out the Life Story Questionnaire, which he/she will fill out on a computer, smartphone, or tablet. This questionnaire will provide background information about their loved one / the PWD. This is the family member's only involvement in the study.

Intervention Period Procedures

N/A (Family Members do not participate in the Intervention Period)

Post-Treatment Procedures

N/A (Family Members do not participate in Post-Treatment)

FOLLOW-UP

The intervention period in this low-risk study of a non-pharmacological intervention is just one month in length. As such, follow up is not required. The final point of contact for PWD and staff member will be the post-treatment assessment / interview.

EARLY DISCONTINUATION

Participants are free to withdraw from participation in the study at any time and for any reason.

REMOVED ON 8/31/21 ~~If they do withdraw, we will continue to follow them, with their permission.~~

SAFETY REPORTING

For the purposes of this study, a participant is considered enrolled if they have successfully completed the screening procedure outlined above. This study will be monitored by an NIA approved Safety Officer (SO). The SO Will follow the procedures and protocols laid out in this document as well as the DSMP.

After being enrolled in the study, participant safety will be monitored regularly by the PI ***with reports being sent to the SO twice per year.***

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. However, if any AEs do occur, whether they appear study-related or not, they will be reported to the SO and the IRB within 48 hours of occurrence. Any deaths to study participants, from whatever cause, will be reported within 24 hours. The SO and IRB will then make the determination of whether they should be reported to the NIA.

If any AEs or SAEs occur, the PI will, with the assistance of the SO and 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.

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 agitated during an 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 SO.

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

SO of any deviations. 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, assuring that all issues are recorded on a timely basis and any AEs or SAEs are reported to the SO within 24-48 hours. The SO will be responsible for analyzing the associated data and determining if there are any study-related issues that need to be intervened upon.

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

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

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

Safety reports will be sent to the SO at least twice a year and will include a detailed analysis of study progress, AEs, and SAEs.

Reporting Procedures

AEs and SAEs will be reported to the SO and the IRB by the PI within 48 hours of occurrence. Any deaths to study participants, from whatever cause, will be reported within 24 hours. The SO and IRB will then make the determination of whether they should be reported to the NIA. The severity of AEs and SAEs will be determined by the PI and Experimental Team Leader in consultation with the SO. The events will be recorded on the "Adverse Events Reporting Form" which includes the instructions for both where the form should be submitted and filed, as well as the reporting timeline required.

How AEs will be classified:

Severity of Event

All AEs will be assessed by a qualified medical professional. Events will be graded using the criteria below. Since this is a non-medical study, no toxicity tables or like criteria can be utilized.

For adverse events (AEs) the following guidelines will be used to describe severity.

- Mild – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- Moderate – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Severe – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious."

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. This study will use a binary assessment (related/not related) for determining AEs. Evaluation of relatedness will consider etiologies such as natural history of the underlying disease, concurrent illness, concomitant therapy, study-related procedures, accidents, and other external factors.

All adverse events (AEs) must have their relationship to study intervention assessed by a qualified medical professional who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- Related – There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out. The clinical event, including an abnormal laboratory test result, occurs in a plausible time relationship to study intervention administration and cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the study intervention (dechallenge) should be clinically plausible. The event must be pharmacologically or phenomenologically definitive, with use of a satisfactory rechallenge procedure if necessary.
- Not Related – The AE is completely independent of study intervention administration, and/or evidence exists that the event is definitely related to another etiology. There must be an alternative, definitive etiology documented by a qualified medical professional.]

Follow-up for Adverse Events

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, qualified medical professional's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

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

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

Unanticipated Problems

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

1. The Experimental Team Leader will immediately notify the Principal Investigator.
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 Principal Investigator will determine the study's status and notify the Study Team.

STUDY COMPLIANCE

The PI will maintain a Protocol Deviation / Violation Log, in which he will report of all protocol deviations/violations. All such deviations / violations will be reported to the SO, including but not limited to the following:

- Enrollment of an ineligible participant
- Failure to obtain Informed Consent
- Visits or procedures conducted outside of the protocol specified window
- 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.

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 (1-7 days after consent/assent)

1. Chart Review Form for PWD Inclusion Criteria
2. NPI-NH

Baseline Assessments / Observations Documents (8-30 days after consent/assent)

1. BIMS
2. DEMQOL
3. Chart Review Form for Diagnoses, Type of Dementia, Meds, and Demographics
4. MPES
5. EPWDS

Intervention Period Data Collection (31-60 days after consent/assent)

1. Session Summary Form
2. MPES
3. EPWDS
4. PWD Satisfaction Question Form

Post-Treatment Assessment Documents (61-74 days after consent/assent)

1. DEMQOL

2. NPI-NH

Staff Members

Screening Documents (1-7 days after consent)

1. Interview Form for Staff Inclusion Criteria
2. NPI-NH

Baseline Assessments / Observations Documents (8-30 days after consent)

1. QCPR
2. Pre-Training Quizzes for Training Modules

Intervention Period Data Collection (31-60 days after consent)

1. Learning Management Basic Training Data Form
2. Post-Training Quizzes for Training Modules
3. Session Summary Form
4. Staff Satisfaction Question Form

Post-Treatment Assessment Documents (61-74 days after consent)

1. QCPR

Family Members

Screening Documents (1-7 days after consent/assent)

1. Interview Form for Family Member Inclusion Criteria

Baseline Assessments / Observations Documents (8-30 days after consent/assent)

1. Life Story Questionnaire

ALL FORMS ARE INCLUDED IN THE APPENDIX.

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 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
- Signed informed consent forms

- Questionnaires completed by the participant
- Questionnaires completed by the proxy interviews
- Case Report Forms (CRFs)
- Data correction forms
- Applicable *Notes to File*

At conclusion of study, all source documents, CRPs, and other required documentation is kept with study records as required by protocol and IRB guidelines.

Forms Maintenance

All forms will be stored in electronic participant "binders" (file folders on the Hopeful Aging server). 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 binder.

General Instructions for Completing Forms

For All forms:

- All forms should filled out electronically, unless internet is unavailable.
- Completed forms should be saved in the participant's digital binder (file folder with their ID number)
    - Naming Convention should be as follows:
    - MM/DD/YYYY/ ID# Name of File
- All forms need to be reviewed by the Experimental Team Leader before being entered into SPSS.
- After being reviewed the Experimental Team Leader should initial the form, indicate the date, and make the file read only.
    - Reviewed by GJG on 7/1/2022 at 4:30pm
- The Experimental Team Leader is responsible for updating forms, as needed.
- The PI will review and approve all changes to forms.
- During the weekly meeting, issues with data collection, including possible problems with forms should be discussed by study team members.
- Be sure to completely fill out all forms.
- Participants must not be identified by name on any study document submitted with the forms. Replace the participant's name with the participant initials and/or identification (ID) number.
- Header: Complete the header information on EVERY page, including pages for which no study data are recorded.
- Participant ID: 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.
- Dates: 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).

- Abbreviations: Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.
- Extraneous Writing: Comments written extraneously on forms cannot be captured in the database; thus, write only in the spaces indicated.
- Correcting errors: 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.
- Skipping items: Do not skip any items. Some items may carry "Unknown" or "Not Applicable" response choices which should be checked when necessary.
- Incomplete data: 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.

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 internet is unavailable. If used, hard copy forms must be scanned immediately after collection and uploaded to the participant binder. Hard copy will then be stored in a locked cabinet. When completing hard copy study forms, print using dark ink.

Data Flow

Completed forms (whether electronic or hard copy) will be reviewed by the Experimental Team Leader to ensure completeness and accuracy. Any errors will be crossed out, corrected, and then initialed. Once the form has been reviewed and corrected (if needed), the form will be initialed on the bottom in the following way: form reviewed [and corrected] by DW on 7/30/21. This form is ready for data entry." If any accidental references to the person by name is included on the data form, such references will be redacted and initialed. Data from the form will then be entered into the study's master database by the research assistant.

Administrative Forms

The following administrative forms will be used: Screening and Enrollment Log and Staff Training Log. Screenshots of these forms are included in the Appendix.

Retention of Study Documentation

After the study ends, study staff shall maintain participant forms in a secure location for 3 years, as indicated by the protocol, federal regulations, and IRB guidance.

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 completed and which data will need to be completed (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 worksheets will be maintained for each type of participant (PWD, Staff Members, and Family Members).

Study Form Review will be conducted in the following way:

- Completed forms (whether electronic or hard copy) will be reviewed by the Experimental Team Leader to ensure completeness and accuracy. Any errors will be crossed out, corrected, and then initialed. Once the form has been reviewed and corrected (if needed), the form will be initialed on the bottom in the following way: form reviewed [and corrected] by XX on 7/30/21. This form is ready for data entry." If any accidental references to the person by name is included on the data form, such references will be redacted and initialed.

Data Entry will be conducted in the following way:

- The Research Assistant will enter data directly into SPSS by reviewing the forms. Once entered, the Experimental Team Leader will double check the entered data to ensure accuracy.

Data Analyses will be conducted in the following way:

- The PI, with the assistance of the Statistical Consultant (Dr. Saunders) will conduct data analyses with SPSS.

Quality Control Procedures

All study staff responsible for data collection and management 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.

Data and Form Checks

Before data is entered into SPSS by the Research Assistant, the Experimental Team Leader 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

Site Monitoring

This is a single-site clinical trial, since there is one investigational site (Hopeful Aging Alzheimer are)

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.

In addition, before the Research Assistant enters data into SPSS, the Experimental Team Leader review all source documents to ensure:

- Informed consent has been obtained and documented in accordance with IRB regulations
- Information recorded on the forms is complete and accurate
- There are no omissions in the reports of specific data elements
- Missing assessments / interviews / observations are indicated on the forms
- Participant disposition when exiting the study is accurately recorded

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. The type of safety monitoring is determined by the size and/or nature of the study and is specified in the Notice of Grant Award. Small, single-site studies usually have a Safety Officer, while multi-center studies require an independent (of the study, investigators, and participating institutions) Data and Safety Monitoring Board (DSMB) that is advisory to the NIA Director. However, if a small, single site study is determined to pose a significant risk to participants, a DSMB may be required.

9.2 Reports

The following reports will be produced for this study:

Enrollment Reports

- Delivered to Safety Officer within 7 days after 1st enrollment and then every seven days until Enrollment is completed
- Produced by Research Assistant

Data Tracking Reports

- Delivered to PI once per week once data collection commences
- Produced by Research Assistant

Safety Reports

- Delivered to the SO at least twice a year and will include a detailed analysis of study progress, AEs, and SAEs.

- Produced by the Experimental Team Leader

Final Report

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

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.

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.

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.

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 Hopeful Aging, Ltd., 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.

MOP MAINTENANCE

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

- The version date on the cover page and footer will be updated with the latest date.
- The new version date will be added to the Versions Page, along with the name of the person who made the changes (usually the PI), and a list of the key changes / additions that were made to the MOP.
- Previous versions of the MOP will be maintained and saved in an archive folder on the Hopeful Aging server