SAFE at Home: A Service to Provide Social Engagement to Community-Dwelling Persons With Dementia

Study Protocol

NCT05516147

12/1/23

1.0 STUDY OVERVIEW

Study Title:
SAFE at Home: A Service to Provide Social Engagement to Community-Dwelling Persons with Dementia

The proposed Phase 1 study will involve initial development and evaluation of a new service called Social Activities For Engagement at Home or SAFE at Home (SaH). SaH will enable PWD to participate in videoconference-based group activities with their peers—i.e., other PWD.

The SAFE at Home app will consist of five main components:

(1) Get to Know You Portal
(2) Social Engagement Portal
(3) Peer-to-Peer Interaction Portal (To Be Developed in Future Phase II Study)
(4) Self-Study Portal (To Be Developed in Future Phase II Study)
(5) Staff Training Portal
(6) Scheduling Portal (To Be Developed in Future Phase II Study)

The study will be conducted by two teams over the course of 12 months. The Development Team (DT) will be responsible for providing the overall vision for the app, as well as website / app development, training creation, and content creation. The Experimental Team (ET) will be tasked with all investigatory work on the project.

Participants
A total of 12 PWD living at home are expected to complete the quasi-experiment. We plan to oversample by 25% to accommodate attrition.

Inclusion / Exclusion Criteria
PWD must be at least 65 years old, speak and read conversational English, and be diagnosed with dementia (any type). PWD will be excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last six months, as evidenced by medical records.

Baseline Period/Measures

During the 4-week baseline period, the ET will collect the following data. PWD Demographics, medications, diagnoses, and type of dementia will be collected via proxy (family member) interview. The following assessments will be administered directly: The Short Portable Mental Status Questionnaire (SPMSQ-T; Roccaforte et al., 1994), the Dementia Quality of Life Scale (DEMQOL; Smith et al., 2005), the Geriatric Depression Scale-Short Form (GDS-SF; Yesavage & Sheikh, 1986; Yesavage et al., 1983), and the UCLA Loneliness Scale (ULS; Wongpakaran et al, 2020). Researchers will interview family members (FMs) using the Neuropsychiatric Inventory-Nursing Home (NPI-NH; Cummings, 1997; Wood et al., 2001). Using the Menorah Park Engagement Scale (MPES; Camp, Skrajner, & Gorzelle, 2015), researchers will observe PWD engagement and affect via videoconference on four days.

Intervention Period/Measures

During the 8-week intervention period, PWD will participate in SaH sessions through the Social Engagement Portal. Data on engagement and affect will be collected during SAFE at Home sessions using the MPES. In addition, PWD will answer questions related to satisfaction at the end of each session.

Post-Treatment/Distal Measures:

The DEMQOL, GDS-SF, ULS, and NPI-NH will be re-administered at Post-Intervention, allowing us to investigate possible long-term effects. Changes on these longer-term measures are not expected in this Phase 1 study.

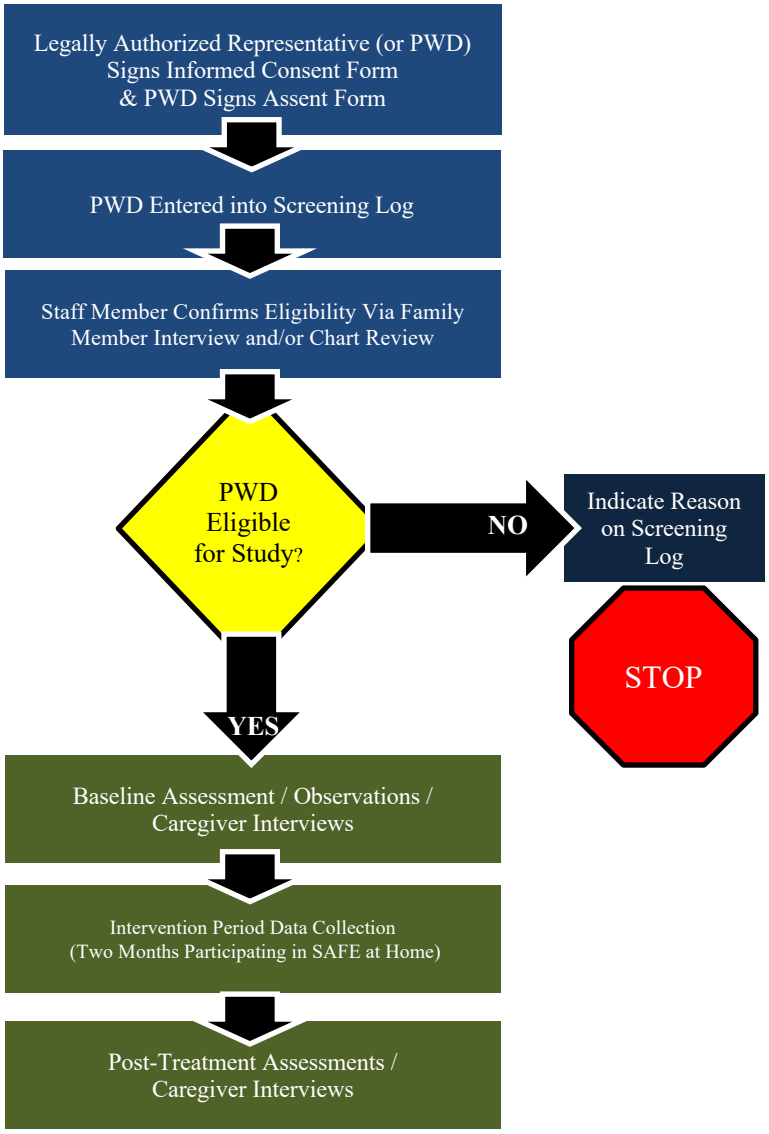
This App will be considered successful if (1) At least 85% of PWD agree to take part in 80% of the sessions; (2) mean session length is at least 25 minutes; (3) PWD exhibit higher levels of positive engagement/affect and lower levels of negative engagement during SaH sessions, as compared to baseline (based upon the MPES); and (4) PWD report high satisfaction with the app, defined as 85% being satisfied or very satisfied.

2.0 STUDY ORGANIZATION AND RESPONSIBILITIES

REDACTED FOR PRIVACY

3.0 STUDY FLOW

Study Flow Diagram



4.0 RECRUITMENT AND RETENTION

PWD

Please note: The approaches used for recruitment have been approved by an external Institutional Review Board (Heartland Institutional Review Board-- IORG0006400) prior to the commencement of the study.

Community-dwelling PWD will be recruited by contacting one or more of the Recruitment Sites listed in the grant proposal all of which have senior independent living apartments and/or housing:

After contacting each site, Mr. Skrajner will conduct an in-person and/or videoconference-based presentation about the project. A separate, personalized presentation will be used for each site. The presentation will be delivered to PWD themselves (in cases where PWD still provide their own consent) and/or family members of PWD (in cases where PWD who no longer provide their own consent). At the end of the presentation, Mr. Skrajner will hand out flyers (an aesthetically-pleasing summary of the key aspects of the project) and consent forms (if the presentation is done in person) and/or recommend that persons interested in enrolling in the study go to the study website. The study flyer and consent form will be included on the study website in PDF format. Interested PWD and/or family members will be able to sign up for the study by digitally signing the consent form on any device by using Adobe Sign, which is HIPAA compliant. Or they will be able to download and print the consent form, sign the hard copy, and mail it to Hearthstone.

In addition, after conducting each recruitment presentation, Mr. Skrajner will ask the organization to send a (a) recruitment email and/or (b) hard copy recruitment packet to PWD (in cases where PWD still provide their own consent) and/or family members of PWD (in cases where PWD who no longer provide their own consent).

(a) The Recruitment Email will include a cover letter (in the body of the email), an attached study flyer (in PDF format), and an attached consent form (in PDF format).
   - The PWD and/or family member will be encouraged to contact Hearthstone and/or the IRB to discuss any questions about the study.
   - PWD and/or family members will be able to enroll their loved on in the study by signing the consent form digitally on any device (by using Adobe Sign) or by signing a hard copy and sending to Hearthstone.

(b) The Hard Copy Recruitment Packet will include a cover letter, study flyer, two copies of the consent form (one to sign and send back to Hearthstone and one to keep for their records), and a postage-paid, pre-addressed return envelope (for sending the signed consent form to Hearthstone).
   - The PWD and/or family member will be encouraged to contact Hearthstone and/or the IRB to discuss any questions about the study.
   - PWD and/or family members will be able to enroll their loved on in the study by going to the study website and digitally signing the consent form on any device (by using Adobe Sign) or by signing a hard copy and sending to Hearthstone.

The cover letter, consent form, and flyer will have phone numbers, addresses, and email addresses for the PIs and Heartland IRB. The person will be encouraged to contact the PI or IRB if he/she has any questions. The consent form will include detailed information about what participation in the study entails. 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 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 PWD 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 PWD to participate in the study, the PWD 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, an ID number will be assigned to the participant. They will then speak with the PWD 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 PWD might have and then ask the PWD if he or she is interested in participating in the study. If so, the PWD will sign the assent form. Note: a copy of the full consent form will also be available to the PWD, in case he or she would like to review the full consent form.

4.1 Retention

In terms of retention, study staff will be in regular contact with all participants. Researchers will assist them 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 PIs at any point. Please also note that we will oversample to accommodate a reasonable level of attrition.

4.2 HIPAA Authorization

PWD

Included with the consent packet will be a HIPAA authorization form, which will inform the legally authorized representative (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, and 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.

5.0 SCREENING AND ELIGIBILITY CRITERIA

5.1 Screening

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

A researcher will confirm that the participant meets the following inclusion/exclusion criteria by interviewing a family member or obtaining medical records for the person:

Inclusion: PWD must be at least 65 years old, speak and read conversational English, and be diagnosed with dementia (any type).

Exclusion: PWD will be excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last six months, as evidenced by medical records.
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5.2 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) and include all relevant screening data (as listed above).

5.3 Eligibility Criteria

Inclusion: PWD must be at least 65 years old, speak and read conversational English, and be diagnosed with dementia (any type).

Exclusion: PWD will be excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last six months, as evidenced by medical records.

6.0 STUDY INTERVENTION

Description of SAFE at Home

The SaH Service will be made available to consumers via the SaH Member Website (for computers) and the SaH App (for tablets). The same content and functionality will exist on the website and the app. The tablet-based app will be offered to ensure a high-quality experience on tablets. The Member website/app will consist of six different components. There will be four user types: Members (PWD/Family Members), Engagement Professionals (staff who facilitate SaH sessions), and Engagement Coaches (staff who are more extensively trained). Users will access the website by entering a username/ password. After logging in, they will be directed to the SaH Dashboard, which will be dynamic based on user type.

(1) Get to Know You Portal (For All User Types) [Phases 1 & 2] **Engagement Coaches** will access this portion of the app to conduct the Get to Know You Session with the PWD and family member. The Get to Know You Session will last approximately 45 minutes and be split into three main parts: (1) the Cognitive/Communication Assessment, (2) the Full Interest Inventory, and (3) Account Creation /

Orientation. The first two parts of the session will be facilitated one-on-one with the PWD; however, the family member should be nearby to help with any technical issues that the PWD may experience. The final part of the session will be conducted privately with the family member. The purpose of the Cognitive/Communication assessment will be to determine whether the PWD is appropriate for a high cognitive / communication ability group or a middle cognitive / communication ability group. Persons who have low cognitive / communication abilities will have been be previously deemed ineligible for SaH (during the Trial Session). The assessment will use Hearthstone's I'm Still Here Skills Inventory (ISH-SI). The ISH-SI has been successfully used with for over 10 years to place people in appropriate activity programming for their particular ability level. This 5-10 minute assessment is an adapted version of the MMP/MAS, which was developed and tested in an NIH-funded study (R01AG021508). The ISH-SI assesses cognitive/communication skills by inviting the PWD to participate in three brief activities (Hearthside Book Club, Sort It Out, and Critic's Corner). These activities determine the extent to which the person can read, look at pictures/videos, and engage in conversation. Participants who score similarly on the ISH-SI will be identified as potential group peers. Further determination as to whether they show be assigned to the same group will be based upon their specific background / interests. **Engagement Professionals** will access this component to learn about PWD who will be taking part in sessions that they will be facilitating. To maintain privacy, they will only have access to information for PWD assigned to their groups. **Members** (PWD and family members) will have access to this portal to confirm/adjust information gathered about his/her interests and background. It should be noted that members do not need to access this portion of the app/website during the Get to Know You Session. In fact, we do not expect members to access this part of the app/website very often (it is possible that they will never do so). However, since information about the PWD will be saved here (in way that is HIPAA-compliant), it is important for us to provide access to this information, so that we are transparent about the data we collect.

(2) Social Engagement Portal (For All User Types) [Phases 1 and 2] This will allow for Engagement Professional-led social engagement of multiple Members simultaneously and is the central component of the product. **Members** (PWD, likely with the help of a family member) will access this portion of the app to participate in social engagement sessions. A list of upcoming sessions will be shown when accessing this portion of the website. To join a session, they will simply click "Start Now" to be connected via videoconference to an Engagement Professional and up to five other PWD. Members will be able to go to the Social Engagement Portal to start each session or they will be able to click on a link included in the reminder email that will be sent. **Engagement Professionals** will facilitate a session by interacting with participants via the webcam but will also share their screen with participants to show the activity content. As mentioned earlier, activities that have been shown to be effective in prior research will be used. Everything an Engagement Professional needs to facilitate a session will be included in the Social Engagement Portal, including access to the activities. **Engagement Coaches** will also have access to the Social Engagement Portal. They will drop in unannounced to audit sessions, but not appear on video. The goal is for the Engagement Coach to make certain that high quality sessions are being offered to members and that fidelity to the procedures is being maintained in order to ensure a high quality intervention. Please note: Mr. Skrajner [PI] conducted six proof of concept activity sessions with 18 PWD via videoconference to determine whether conducting sessions using this methodology would be successful. In all cases, PWD were able to engage in the activities and generally seemed to enjoy participating. In a few cases, PWD spoke very quietly, which made it hard for Mr. Skrajner to hear their responses. But this was due to the fact that they were too far away from their tablet. So, we will instruct family members to place the device very close to their loved one for sessions, and to encourage PWD use headsets with mics, to avoid such issues in the future.

(3) Peer-to-Peer Interaction Portal (For Members) [Phase 2] In order to maximize the potential for social engagement, **Members** (PWD) will be encouraged to participate in "breakout sessions" with 1-2 other PWD when they are not participating in staff-facilitated Social Engagement Sessions. To do so, they would log in to the Peer-to-Peer Study Portal at the same time as others. It is likely that family members will need to help to arrange Peer-to-Peer Study Sessions. Within this component of the website/app, PWD

would have options to engage with each other in meaningful ways ranging from simply chatting informally to having access to small group assignments / conversation starters that they can work on or discuss together (e.g., "talk about what it was like to go to the movies years ago")

(4) Self-Study Portal (For Members) [Phase 2] Members (PWD) will also be encouraged to participate in Self-Study when they are not participating in the Social Engagement or Peer-to-Peer Study Portals. Distinct versions of Hearthstone's proprietary, evidence-based activities formatted and structured for private use will be available in this portal.

(5) Staff Training Portal (For Engagement Professionals and Engagement Coaches) [Phases 1 and 2] Engagement Professionals will access this portion to take video-based, SCORM-compliant training modules. In order to be eligible to be an Engagement Professional, the person must have experience in recreation therapy, life enrichment, physical therapy, occupational therapy, speech therapy, or a related field. The person must have at least one year of experience working with PWD. So, we expect our engagement professionals to have most of the basic qualifications needed to work effectively with PWD. That being said, our training will be designed to ensure that the person has the appropriate knowledge and skills to facilitate a videoconference-based session with PWD. More specifically, there will be five main training modules. (1) Video Conferencing Best Practices, (2) Overview of the 10 SaH Activities, (3) Communicating with PWD, (4) Tips for Facilitating Activities with PWD via Videoconference, and (5) Using the SaH Website and App. After completing the self-study online training courses and taking a test that shows that he/she has acquired the necessary knowledge to implement SaH sessions, each Engagement Professional will schedule a Mock Session with an Engagement Coach. The Mock Session will be scheduled within the Staff Training Portal. During the Mock Session, the Engagement Professional will connect with two Engagement Coaches, who will participate in a simulated SaH session, which will be led by the trainee. If the Engagement Professional shows competence at facilitating the mock session (based upon a 20-item checklist of key processes for leading SaH), he/she will become a certified SaH Engagement Professional. He/she will then be able to facilitate sessions as they are needed. **Engagement Coaches** will also have access to this portion of the app, so they can check progress trainees have made on the self-study online courses, review test results, and also start the Mock Sessions. Please note that Engagement Coaches will be trained initially by taking the Online Training courses and then doing the Mock Session (like Engagement Professionals). However, in addition, in order to become a certified Engagement Coach, the person will need to facilitate 30 SaH sessions (receiving good reviews from Members), pass a knowledge test, and receive further individualized training.

(6) Scheduling Portal (For All User Types) [Phase 2] Members (Family Members) will access this component to schedule sessions. They will be asked to indicate all available time slots, as well as the number of sessions they wish to participate in per week. Once a session is scheduled, based upon availability of all PWD, they will be able to approve/deny the session request. If an insufficient number of PWD approve a requested session day/time, a new session time will be proposed (Please note: in order to achieve the goal of social engagement, sessions will only occur if at least three PWD can participate.) However, even if a session is unavailable, family members can opt to log their loved one in for a Self-Study session, allowing them to benefit from being personally engaged even if social engagement isn't available at that time. **Engagement Professionals** will access this component of the app to see all requests for engagement sessions. They can then accept or reject such requests. A calendar showing all requests and future engagements will be available. They will only be invited to facilitate a session if the calendar determines that they are available. **Engagement Coaches** will access this component to determine which sessions he/she might view for auditing purposes.

7.0 STUDY MEASUREMENTS AND PROCEDURES

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. Diagnoses
        iii. Type of dementia
        iv. Medications
2. **Short Portable Mental Status Questionnaire (SPMSQ-T)**
    a. A researcher will conduct a direct interview with the PWD to administer the DEMQOL
    b. The Short Portable Mental Status Questionnaire (SPMSQ-T) by Roccaforte et al. (1994) is a brief, validated tool used to screen for cognitive impairment in older adults. It consists of 10 simple questions assessing orientation, memory, and basic arithmetic, providing a quick evaluation of mental functioning in clinical and research settings.
3. **Dementia Quality of Life (DEMQOL)**
    a. A researcher will conduct a direct interview with the PWD to administer the DEMQOL. However, if the PWD is unable to respond to questions on the DEMQOL, this measure will be administered 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 administered to 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 administered, the total score is calculated and scaled to fit the same scoring range as the DEMQOL. If DEMQOL-Proxy total score = **X**, then $(^{X}/_{30}) \times 28$ = 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)

4. Geriatric Depression Scale – Short Form (GDS-SF)

a. A researcher will conduct a direct interview with the PWD to administer the GDS-SF.
b. The Geriatric Depression Scale-Short Form (GDS-SF) is a 15-item screening tool designed to assess depressive symptoms in older adults. It uses a simple yes/no format to evaluate mood, energy, and outlook, making it quick and easy to administer in clinical and community settings.

5. UCLA Loneliness Scale (ULS)

a. A researcher will conduct a direct interview with the PWD to administer the ULS.
b. The UCLA Loneliness Scale is a widely used instrument designed to measure subjective feelings of loneliness and social isolation. It consists of 20 items that assess the frequency of loneliness-related thoughts and feelings, providing insight into an individual's perceived social connectedness.

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

a. A researcher will administer 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.

7. Baseline Comparison for Engagement

a. This study will use the MPES in this study to examine engagement and affect of PWD. 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.

b. For the Phase I study, we will use a large database of participants engaging in activities as the baseline MPES scores. An independent samples t-test will be conducted to examine differences.

~~0. If a person has not been seen in group activities after three visits and/or if a staff member has told us the person does not attend group activities, we will consider the person a "chronic non-activity attender."~~

~~1. We will then target this person in particular in future visits.~~

~~2. We will ask staff to invite up to three non-attenders per activity.~~

~~3. If the person attends, we will observe them in the activity.~~

~~4. If they do not attend, we will go to the person's room during the session and find out if they are awake or asleep (knock on the door).~~

~~0. If they are awake, it will be coded as DID OTHER for more than half.~~

~~1. If they are asleep, it will be coded as SLEPT/CLOSE EYES for more than half.~~

c. Please note: all MPES observations will be conducted via a HIPAA compliant Google Form. Submitted responses will automatically be sent to a database. As such, there will be no need to save a corresponding PDF file in each participant's digital binder for each MPES observation. To prevent changing of data in the database, there will be a lock on the database preventing changing of data, except by the PI or Experimental Team Leader. Although each MPES observation will not have a corresponding PDF file in the participant's digital binder, a PDF will be generated for each observation for auditing purposes. The PDFs will be placed in a single folder. MPES observations will be spot checked for accuracy by comparing database data to PDF form data.

Intervention Period Data Collection

PWD will participate in SAFE at Home for two months during the Intervention Period of the Study. A variety of data will be collected during and/or after the session.

1. **Ease of Use and Satisfaction Measure**

After each session, the PWDs will be asked simple questions related to ease of use and

satisfaction (e.g., Did you find the activity easy to use? Did you enjoy the activity? Would you recommend it to others?)

2. **Observations of PWD in SAFE AT HOME Sessions w/ MPES**
    a. Researchers will observe PWD's engagement and affect during SAFE AT HOME 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 SAFE AT HOME 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

The following measures will be collected again at post-treatment:

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

8.0 TIMELINE AND VISIT SCHEDULE

Assessment / Interview / Data to Collect	Screening	Baseline	Intervention Period	Post-Treatment
Informed Consent Form (Legally Authorized Representative or PWD)	X			
Assent (PWD)	X			
Confirm That the PWD Meets Eligibility Criteria	X			
Enrollment (if person meets basic eligibility criteria)	X			
SPMSQ (Baseline)		X		
DEMQOL (Baseline)		X		
GDS-SF (Baseline)		X		
ULS (Baseline)		X		
NPI-NH (Baseline)		X		
MPES (Baseline Database of Existing Means / SD)		X		
MPES (Intervention Period)			X	
Satisfaction / Ease of Use Questions			X	
DEMQOL (Post-Treatment)				X
GDS-SF (Post-Treatment)				X
ULS (Post-Treatment)				X
NPI-NH (Post-Treatment)				
DEMQOL (Post-Treatment)				X
NPI-NH (Post-Treatment)				X

9.0 VISIT PROCEDURES

PWD

Screening Procedures

A researcher will confirm that the participant meets the following inclusion/exclusion criteria by interviewing a family member or obtaining medical records for the person:

Inclusion: PWD must be at least 65 years old, speak and read conversational English, and be diagnosed with dementia (any type).

Exclusion: PWD will be excluded from the study if they show signs of rapid cognitive decline or physical deterioration over the last six months, as evidenced by medical records.

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 administer the SPMSQ, DEMQOL, GDS-SF, and ULS.

Caregiver Interview
Researchers will interview a caregiver to collect 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-SF questions), a researcher will interview the caregiver to administer the proxy version of the DEMQOL and/or GDS-SF.

Observations of Standard Activities
For the Phase I study, we will use a large database of participants engaging in activities as the baseline MPES scores. An independent samples t-test will be conducted to examine differences.

Intervention Period Procedures

PWD will be invited to participate in SAFE at Home sessions via videoconference twice per week for two months. The sessions will led by a Life Enrichment Professional.

Observations of SAFE AT HOME Sessions

Researchers will observe the PWD taking part in SAFE at Home sessions using the MPES. We will aim to conduct multiple observations for each activity type, so that an average score can be calculated for SAFE AT HOME activity programming. Researchers will follow the standard protocols for using the MPES and be extensively trained on how to properly use these measures.

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.

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 administer the DEMQOL, GDS-SF, and ULS.

Caregiver Interview
Researchers will interview a caregiver to collect 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 administer the proxy version of the DEMQOL and/or GDS-SF.

10.0 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.

11.0 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.

12.0 SAFETY REPORTING

For the purposes of this study, a participant is considered enrolled if they have successfully completed the screening procedure outlined above. The appointed Safety Officer provides safety oversight of the trial.

After being enrolled in the study, participant safety will be monitored regularly by the PI *and reported as needed to the Safety Officer.*

All adverse events that are both serious (SAE) and unexpected (i.e., have not been previously reported for the study's intervention), they should be reported to IRB, NIA PO and to the NIA-appointed Safety Officer (SO), within 48 hours of the study's knowledge of SAE.

The summary of all other SAEs should be reported to NIA Program Officer and to the DSMB (or a Safety Officer) quarterly (or biannually), unless otherwise requested by the DSMB or a Safety Officer.

Reports of death should be submitted to NIA Program Officer and to the Safety Officer within 24 hours of study's knowledge of death. AEs should be reported per IRB policies. They should also be reported the NIA Program Officer and the SO, at frequency requested by NIA and/or by the SO. At minimum, annual reports are required**.**

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, and in aggregate on an annual basis.*
- 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 of determination of AE/SAE.*
    - 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.

12.1 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 their participation in the programming will stop for that session. 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.

12.2 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.

12.3 Reporting Procedures

SAEs and 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.

12.4 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.

12.5 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.

12.6 Follow-up for Adverse Events

<u>Expected AEs</u>

Expected AEs associated with the study procedures include:

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

<u>AE Management</u>

- Only staff with proper experience in 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 SPs will receive training on how to recognize signs of frustration and embarrassment and what to do in such situations.
- SPs 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.

12.7 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.

13.0 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

14.0 DATA COLLECTION AND STUDY FORMS

The following documents are used in this study. Descriptions of measures are included above.

PWD

Screening Documents

1. PWD Initial Screening / Inclusion Form

Baseline Assessments / Observations Documents

1. Chart Review Form
2. SPMSQ
3. DEMQOL
4. GDS-SF
5. ULS
6. NPI-NH

Intervention Period Data Collection

1. Satisfaction Question Form
2. MPES

Post-Treatment Assessment Documents

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

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 administered to the participant
- Measures administered to 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.

Please note: all MPES observations will be conducted via a HIPAA compliant Google Form. Submitted responses will automatically be sent to a database. As such, there will be no need to save a corresponding PDF file in each participant's digital binder for each MPES observation. To prevent changing of data in the database, there will be a lock on the database preventing changing of data, except by the PI or Experimental Team Leader. Although each MPES observation will not have a corresponding PDF file in the participant's digital binder, a PDF will be generated for each observation for auditing purposes. The PDFs will be placed in a single folder. MPES observations will be spot checked for accuracy by comparing database data to PDF form data.

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.

Please note: all MPES observations will be conducted via a HIPAA compliant Google Form. Submitted responses will automatically be sent to a database. As such, there will be no need to save a

corresponding PDF file in each participant's digital binder for each MPES observation. To prevent changing of data in the database, there will be a lock on the database preventing changing of data, except by the PI or Experimental Team Leader. Although each MPES observation will not have a corresponding PDF file in the participant's digital binder, a PDF will be generated for each observation for auditing purposes. The PDFs will be placed in a single folder. MPES observations will be spot checked for accuracy by comparing database data to PDF form data.

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 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 Retention of Study Documentation

After the study ends, research 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:

- A data tracking spreadsheet will be used. 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, SPs, 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 research staff responsible for data collection and management will have received human subjects and, as applicable, 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 the separate Data and Safety and Monitoring Plan. 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 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*** – Research 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.

17.4 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.