PROTOCOL

Protocol Title:	**Social Assistive Robot Interface for People with Alzheimer's and Other Dementias to Aid in Care Management**
Study C Title:	**SimpleC Wellness Platform With Social Robot Interaction**
NCT:	NCT05296239
Document Date:	Approved IRB Protocol version 2.4 from June 07, 2022. Extract created August, 07, 2025 to include section relevant for Study C

Abbreviations

LAR	Legally Authorized Representative
PWD	Person living with MCI, dementia, or other care needs
SAR system	Social Assistive Robot system, consisting of Robot, Avatar, Tablet with SimpleC digital interventions
SHC	Senior Housing Community

1. INTRODUCTION

A. Purpose/Objective of the Study.

The overarching goal is to develop a SAR system to engage a PWD (Resident) in a natural language conversation as psychosocial support (enhancing mood, mitigating the effects of loneliness, and enhancing social connection and communication) and provide value to the organization and its staff.

The purpose of Study C is to gather in-market feedback: Assess the installation procedure, develop training, assess user materials, and identify any barriers and concerns during implementation. New features and design will be validated.

Research questions include:

- How should the SAR system be introduced to the users and their environment?
- What are facilitators and barriers to installation
- Will users accept the SAR system in their environment?
- What are facilitators and barriers to SAR system acceptance?
- What are the desired parameters that the SAR system should have?
    - What social behaviors do user expect?
    - What tasks would be acceptable that the SAR system tablet do?
    - How should the SAR system's perception, competence, and awareness be presented to the PWD and their partners in care?
    - What is most valuable to users and why?
- If the answer depends, then what does it depend on (user, task, environment)?

Primary Outcomes:

- Barriers and facilitators to successful implementation [interview, usage data, observation, and/or questionnaire]

Secondary Outcomes:

- Technology acceptance and adoption [questionnaire, interview]
- Robot Social Ability [questionnaire, interview]
- Usability and usefulness [questionnaire, interview]
- Engagement and satisfaction [questionnaire interview]
- Conversation quality [interview]
- Value proposition / Economic impact [interview]
- Requirements, training, and communication around the product (interview, observation, usage data)

TABLE 1. OVERVIEW OF STUDY OBJECTIVES AND PARTICIPANTS

STUDY	# PARTICIPANTS
Study C: Beta testing (in-market): Install & usability test ***Objectives:*** - Technology Acceptance - Usability testing - Concept testing	**10 groups** (i.e., 10 Residents, 10 Family members) 10 care providers Experience: Novice or current user of SimpleC Conditions: All groups assigned to SAR intervention Duration: 3 weeks

TABLE 2. PRIMARY OUTCOMES – STUDY C

Objective	Measure	Baseline			Reassessment			Reference
		RES	FAM	STAFF	RES	FAM	STAFF	
Descriptives	MMSE	x						Folstein et al. (1975)
	Demographics, Health, & Technology Questionnaire	x	x	x				
Engagement	Robot Social Attributes Scale (RoSAS)				x	x	x	Carpinella et al (2017)
	Interview				x	x	x	
Health & behavioral outcomes	~~Affect Survey~~	~~x~~			~~x~~			~~Diener et al. (2009)~~
	~~Loneliness Survey~~	~~x~~						~~de Jong-Gierveld (1987)~~
	~~Domains of Wellbeing (Connectedness, Community Integration)~~	~~x~~			~~X~~			
	Caregiver Guilt		x			x		Wells and Jorm (1987)
	Interview				x	x	x	
Technology Adoption	Usage Pattern	Throughout						
	Tech Acceptance Survey (short)				x	x	x	Davis et al. (1989)
	Interview				x	x	x	

B. Background of the Study.

The goals of this project are that a Socially-Assistive Robot (SAR) will help to 1) facilitate the transition into an SHC, 2) engage PWD to address behavior problems (e.g., agitation, anxiety), improve mood, support Activities of Daily Living (ADL), and 3) reduce loneliness, improve social connections and experience while at the SHC extending their time in SHC before escalating to the next more expensive level of care. The SAR will facilitate the transition into SHC by fostering relationships (among residents and with staff) and conveying schedules. Because the SAR has access of PWD's hobbies and interests, it will initiate conversation for residents to discover what they have in common, thereby facilitating serendipity. The SAR will also engage PWD through activities (e.g., storytelling, simple games). Although PWD prefer to stay in SHC (once acclimated) than move to a more expensive nursing home, several challenges must be overcome. The proposed SAR system will address these challenges by relieving problem behaviors and caregiver burden; and reducing depression, and social isolation.

The innovation of this project is the use of a SAR to engage a PWD in a detailed natural language conversation as psychosocial support. The robot will have access to knowledge on a vast number of topics. SimpleC's currently provides non-drug interventions for PWD in the form of personalized programs of audio-visually media delivered via a touchscreen device. This is driven by a data base for each PWD that SimpleC creates from information and media supplied by family and friends of the PWD. By accessing backgrounds and interests, the SAR will be able to have an engaging natural language conversation with the PWD. The SAR will convey body language motions to match the conversation and make the conversation more interactive and engaging. The SAR can be used for both personalized individual and group conversation.

The use of SARs will be a new tool to add to and deliver SimpleC's behavioral intervention programs. SimpleC's programs help address behavioral symptoms, and reminders and motivational programs support a healthy routine as well as reconnect with and enjoy one's personal story. SimpleC's programs cue and remind, calm and relax, and engage and energize. SimpleC has now installed its Dementia Intervention product, the SimpleC platform, in a variety of living environments across 10 states.

In phase I, we determined what kind of SAR-delivered natural language interventions and engagements work for PWD in terms of technology acceptance, usability, and ultimately outcomes. In phase II, we will iteratively develop the SAR system and integrate it with the SimpleC platform; performing usability tests between iterations and evaluate it.

2. PARTICIPANT SELECTION

Human subjects will be recruited for participation. For all studies we will recruit a person living with dementia or care needs (PWD) in an Assisted Living Facility and their partner in care, who may live with the PWD or separately. The goal is to enroll groups; however, this may not always be possible. Enrollment of the family caregiver is desired but not required for the PWD to enroll, and vice versa. Employees of the SHC who are expected to interact with the SAR system will be recruited as well. Research participation will be entirely voluntary.

Inclusion and Exclusion criteria.

TABLE 3. INCLUSION CRITERIA

Inclusion Criterion	PWD (RESIDENT)	Family Caregiver (FAMILY)	Care Provider (STAFF)
Age	50+ years	18+ years	18+ years
Gender	Male or Female	Male or Female	Male or Female
Language	Fluent in English	Fluent in English	Fluent in English
Relationship	Self	Family or friend.	Works for SHC
SimpleC experience	New or current user of SimpleC	New or current user of SimpleC	New or current user of SimpleC
Cognitive Ability	At risk for MCI; MCI; moderate/ cognitive impairment (MMSE score of 13 and higher)	No diagnosis of dementia or related disorder	

TABLE 4. EXCLUSION CRITERIA

Exclusion Criterion	PWD (RESIDENT)	Family Caregiver (FAMILY)	Care Provider (STAFF)
Co-morbidity or psychiatric history	Co-morbidities or psychiatric history that would preclude study participation	Co-morbidities or psychiatric history that would preclude study participation	n/a
Availability	Expecting to move during the study	Expecting to move during the study	Expecting to move during the study
Sensory capabilities	Both legally deaf and blind	*Both legally deaf and blind	*Both legally deaf and blind
Physical capabilities*	Not able to press tablet buttons	Not able to press tablet buttons	n/a
Speech capabilities*	Not able to verbally answer questionnaires	n/a	n/a
Pregnancy	Pregnant	Pregnant	Pregnant

*Study D

Vulnerable Populations.

Seniors with dementia are the focus of this research, and therefore, will be explicitly recruited and included. Their ability to give consent will be evaluated, and their participation is entirely voluntary. For participants who are willing to take part but unable to consent we will 1: seek to obtain assent where possible and also 2: obtain consent from a Legally Authorized Representative. Enrollment of the family caregiver/friend is desired but not required for the PWD to enroll.

There is no specific reason to include pregnant women. Therefore, pregnant women will be excluded from participation.

3. STUDY DESIGN / METHOD / PROCEDURES: Study C

Design: This is a continuation of the CBPR approach and mixed-method design. As soon as the beta version of the SAR system is available, it will be rolled out for Study C. One SHC will receive the new SAR system. For Study C, participants will experience the SAR system for three weeks.

Sample: Thirty individuals will participate in Study C: 10 residents, 10 family, and 10 staff, likely from the same SHCs from Study B. Participants will continue their participation in this study. We will recruit new participants to account for attrition. We will stop enrollment when we reach saturation.

Procedure: All staff, residents, and family will be invited to use the SAR system, independent of their study participation. Resident profiles on the SimpleC Platform will be created as part of the standard SimpleC enrollment process. Residents and family will be invited to personalize and may choose to invite other family members. Residents and SHC will receive the new SAR system (or upgrades). Installation will be followed by training.

The research will follow established SimpleC procedures for recruitment, screening, and assessment. Participants will provide informed consent, which will be followed by a baseline assessment. Participants will be screened to ascertain inclusion and exclusion criteria. Participants will engage with the SAR system as they are willing. At the end of the study, assessments will be administered, which is followed by a brief interview.

TABLE 5. OVERVIEW OF TASKS AND TIME SPENT BY EACH PARTICIPANT GROUP IN STUDY C

TASKS	RESIDENT	FAMILY	STAFF
Step 1a. Informed consent	.25 hour	.25 hour	.25 hour
Step 1b. Baseline assessment	.5 hour	.5 hour	.5 hour
Step 2. Install & Initial Instructions	.5 hour	.25 hour	n/a
Step 3a. Use SARv system	as willing	as willing	as willing
Step 3b. Monitor remotely	n/a	n/a	n/a
Step 3c. Check-Ins	as available	as available	as available
1. Initial follow-up: 1-3 days	.25 hour	.25 hour	.25 hour
2. Week 1	.25 hour	.25 hour	.25 hour
3. Week 2	.25 hour	.25 hour	.25 hour
Step 3d: Install robot & instruct	n/a	n/a	.25 hour
TASKS	RESIDENT	FAMILY	STAFF

Step 3e: Use SAR system	as willing	as willing	as willing
Step 4. Reassessment	.5 hour	.5 hour	.5 hour
Step 5. Final Interview	.5-1.0 hour	.5-1.0 hour	.5-1.0 hour

Step 1: Once IRB-approved consent procedures are completed, a baseline assessment will follow. Depending on availability and method, consent and baseline may occur in one or two sessions. Some self-report data will be gathered via SimpleC applications as part of the enrollment process or online assessments and analyzed as research data. A trained research assistant will administer assessments and take notes on first impressions. We will collect additional data as available and authorized to share from SHC.

Step 2: Once respondents enroll, they will receive the SimpleC Wellness application, including introduction training on the SAR system. Families will personalize their resident's application via Family Connect (either by downloading or using via proxy). Residents will receive a tablet.

Step 3: During the study period, participants and others will receive instructions for the SAR system and use it as part of scheduled interactions. This includes interactions as part of the general schedule. In the third week, the social robot will be installed, and staff trained in group sessions as available. As feasible, we will attend and observe the scheduled interactions and record interactions and conversations with the robot. During those scheduled interactions, non-study residents may be present along with study-residents. We will also record observations for non-study residents; however, only in a de-identified manner.

Participants may use the full SAR system as they are willing. We will track and monitor usage and content of the SAR system interactions and document any user issues and successes. We will regularly check-in with participants to gather feedback, answer questions, and adjust programs as needed. Some updates to programs can also be initiated by staff and family at any time and are immediately available.

Step 4: At the end of the study, assessments will be repeated.

Step 5: At the end of the study (if feasible, in the same session with Step 4), an unstructured interview is aimed to elicit qualitative data to complement quantitative measures. Topics will address: a) individual likes and dislikes of the technology; b) a review of usage data, including the most or least liked shows and features; c) an overall rating of the technology adoption; d) as a proxy of usability success, participants will be asked if they want to keep the new SAR system, and at what monthly cost; e) what additional functions or features would be desirable with an eye to care events, behavior management, QOL, independence, and cost. If feasible, interactions and conversation will be video recorded. Participants will be compensated for their participation. Tablets will be collected.

Criteria to Stop

- The risks associated with the proposed studies are minimal. This research involves the implementation of an assistive technology that relies on psychosocial care interventions which are typically considered "do-no-harm solutions". The only risk is emotional upset, which is minimized by our personalized approach and regular validation of media content with the individual to assure positive engagement. In a worst-case scenario, emotional upset is simply remediated by disengaging or removing the upsetting media content (a particular photo, piece of music, or entire show). To date, we have had few cases where the *Companion* was not accepted by the PWD in their room, which led to removing the device without any further incident. The vast majority of users accept the interventions (care shows) and the *Companion* in their living environments.

- In the case of participant distress caused by the technology or interventions, the PI will be notified immediately and make a determination to seek emergency medical assistance, consult with the SimpleC professional team, and/or consult with the caregiver on ways to reduce distress. Our team includes experts in gerontology, social work, human-technology interaction, communication, and dementia care If the PI cannot be reached or in case of a medical emergency, caregivers and PWD will be instructed to contact collaborating community partners to activate established plans for emergency services.

- Participation will be stopped upon the explicit request of participants (revocation of participation); if the PI and research team deems continuation unsafe or undesirable; in case of a serious adverse event that clearly relates to the *Companion, the Social Assistive Robot system, Family Connect, Community Connect, Clinical Connect*, the interventions or the research. Incidents will be reviewed on a case-by-case basis and reported to Sterling IRB.

Analysis of Study Results

Quantitative measures will be analyzed via intervention time series analyses and t-tests, using repeated measures as applicable. Qualitative measures (e.g., diaries, interviews), will be coded to gather details about the intervention, likes and dislikes, barriers and facilitators to success, as well as value and success stories.

Study C Planned Analyses

- Quantitative data will be used to assess the installation process. Ratings of the SAR system, the interactions, and technology acceptance will help determine success and prioritize additional requirements.

- Qualitative data will be categorized into sets of issues to be translated into design requirements to be implemented in subsequent design iterations. The discourse with SAR system will be analyzed.
- We will compile a summary of user needs and recommendations, from which the team will update operational procedure and additional training needs.

Monitoring

Data and Safety Monitoring. This research does not have a data safety monitoring board. This research is low-risk, not a multiple site trial, and not an NIH Phase III Clinical Trial. Instead, Dr. Madeleine Hackney has accepted the role as Safety Officer (SO). The Principal Investigator (Adams, PI) will be responsible for ensuring participants' safety on a daily basis, along with study staff, specifically Drs. Beer (co-I) and Komsky (co-I). All members of the study team will undergo basic and clinical trial human subjects training and will sign an understanding of agreement on data storage and sharing procedures. The Safety Officer (SO), will also monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses. The Principal Investigator (PI) is responsible for distributing adverse event reports to the SO and coordination across the SO, IRB, SimpleC, and University of Georgia.

Frequency of Data and Safety Monitoring. Over the course of data collection, the research team will complete data safety report logs. These logs will be completed continually (include a detailed overview of study progress and data) as each participant uses the technology (e.g., real time usage logs). The research team will hold regular (minimally bi-weekly) research meetings either in-person or by teleconference. At these meetings, we will review safety report logs, as well as review study progress, data quality, and participant safety. Regular meetings with the SO will occur every 6 months. At these meetings, data safety reports will be reviewed. Additionally, the SO will review study progress, data quality, and participant safety.

Content of Data and Safety Monitoring Report. The content of the data and safety monitoring report (reviewed at research team meetings outlined above) will include: Study status, participant descriptive information, safety information/assessment, enrollment updates/status, protocol deviations, projected timetable/schedule. The study team will prepare safety reports to be reviewed by the SO and NIA for recommendations for or against the trial's continuation, as well as any modifications to the study.

Conflict of Interest for SO. The SO will maintain independence from the study. Accordingly, the SO will not be directly involved in the design and conduct of the study, and does not have scientific, proprietary, financial, or other interests that may affect independent decision-making. In addition, the SO has signed a Conflict-of-Interest Statement prior to the appointment. The SO is not a current collaborator of the PI.

SO Responsibilities for Study C.

1. Review the entire IRB-approved study protocol and the MOP regarding participant safety, recruitment and retention milestones, randomization, intervention, data management, quality control and analysis as well as the informed consent document regarding applicability and readability.
2. Recommend changes to the protocol and the informed consent form, when applicable**.** Review proposed protocol changes or proposed new protocols and recommendations and approve if indicated.
3. Recommend participant recruitment be initiated after receipt of a satisfactory protocol.
4. Review recruitment and retention rates and whether delayed recruitment raises concerns of futility and ethical considerations.
5. Identify the relevant data parameters and the format of the information to be regularly reported.
6. Review data. These data can be related to safety, recruitment, randomization, retention, protocol adherence, trial operations, data completeness, form completion, intervention effects, gender and minority inclusion.
7. Identify needs for additional data relevant to safety issues.
8. Provide advice on issues regarding data discrepancies found by the data auditing system or other sources.
9. Provide advice to the study on trial protocol and safety issues arising during the study. Review ongoing adverse event reports.
10. Propose additional analyses and periodically review developing data on safety and endpoints.
11. At each meeting, consider the rationale for continuation of the study, with respect to progress of randomization, retention, protocol adherence, data management, safety issues, and outcome data (if relevant) and make a recommendation for or against the trial's continuation.
12. During biannual data safety meetings, either approve study continuation or recommend to NIA Director early discontinuation of the intervention and/or the study due to inadequate recruitment, retention, compliance, excessive risk or low likelihood of the study meeting its objectives.
13. Review manuscripts reporting major outcomes prior to submission for publication, as appropriate.

Storage and Confidentiality of Data.

Data will be stored electronically and in paper files. The PI will manage data for SimpleC and overall data sharing, entry, processing, and reporting. Dr. Beer/UGA team will have access to data remotely via secure server. Data will be shared as necessary for UGA to accomplish the following tasks:

UGA approved for

a. Recruitment and Screening
b. Obtaining informed consent
c. Collecting identifiable data DURING the data collection process (e.g., collecting data, UGA obviously meets with participants in person or via Zoom, which means their identity is obvious)
d. Analysis of de-identified data. Once collected, data need to be de-identified. Only then can UGA assist with analysis of de-identified data.
e. Data cleaning

Measures taken to mitigate risk ***related to data collection*** are highly likely to be effective:

1. Paper files will have a numerical identifier.
2. Use a HIPAA cover sheet

Measures taken to mitigate risk ***related to data storage*** are highly likely to be effective:

1. Paper files will be stored in locked file cabinets in an office that can be locked.
2. To reduce the risk of breaches of confidentiality, all study data will be stored on password-protected, secure servers.
3. At SimpleC, the research databases will be housed on a dedicated Sharepoint site that will be accessible only to properly authorized members of the study team based at SimpleC.
4. SimpleC electronic databases (research and commercial) are HIPAA compliant with secure storage and encrypted data entry procedures.
5. Electronic databases will be created using Microsoft Excel and SPSS statistical software (IBM) for data entry and analysis using abstracted data whenever possible. Access to these databases will be password protected due to their storage location. Some specific databases (e.g., Master Key) will be protected with an additional password.
6. For data analysis purposes, all participants will receive a unique identifier that will be the only number that appears on data abstraction forms. Numerical identifiers will be used where possible.

Measures taken to mitigate risk ***related to data sharing*** are highly likely to be effective:

1. Password protected electronic databases will be accessible only to relevant members of the research team. Access to the data will require invitation to the database, access to a secure data network, knowledge of the appropriate passwords, appropriate software, and the database. Internet transmissions will be encrypted.
2. Dr. Beer/UGA team will have access to data remotely via secure server.
3. Personal information will only be shared with relevant team members as necessary to complete tasks. For all others, such as those involved in data review, data will be de-identified

where possible using random numerical identifiers that are assigned to studies and participants.

4. Upon completion of the study, all research data will be permanently de-identified.

General risk-reduction practices:

1. All members of the study team will undergo basic human subjects training, if not already completed, and sign an understanding of agreement on data storage and sharing procedures.
2. In the case of participant distress caused by SimpleC technology or programming, Dr. Adams will be notified immediately and make a determination whether to seek immediate medical assistance, consult with the SO, consult with our professional team, and/or consult with the caregiver on ways to reduce distress.
3. A fallback provision will be defined in study protocols in case Drs. Adams/Beer cannot respond immediately, which will include a role for collaborating community partners and their established plans for emergency services.
4. Participation is voluntary. Participants are free to disengage or withdraw at any time.
5. We recognize the progressive nature of dementia and will evaluate the safety of our intervention on a case-by-case basis. Our current model involves a Care Specialist who participates as a member of the care team in the assisted living facility making regular feedback to medical professionals fairly easy.
6. In the case that there is no professional care team: If any member of our staff is alerted to any serious medical problems (e.g., dehydration, psychosis, etc.) over the course of the study, Dr. Adams will be notified immediately, and we will work with the caregiver to identify appropriate medical intervention.
7. Other than alerting medical care when required, there will be no recommended alternative treatments.

4. BENEFIT / RISK ASSESSMENT

Risks and Prevention of Risk

The risks associated with the proposed studies are minimal. The proposed studies involve an assistive technology that relies on psycho-social care interventions, which are typically considered a "do-no-harm solution". Measures taken to mitigate the risk (described later) are highly likely to be effective.

Intervention-related risk is low. There is minimal risk of PWD's emotional upset about content displayed or questions asked. To date, we have had very few cases where the PWD did not accept the Companion in their room, which led to removing the device without any further incident. The vast majority of users accept the interventions (care shows) and the Companion in their rooms.

Measures taken to mitigate risk are highly likely to be effective:

1. SimpleC's has a personalized approach and regular validation of content with individuals to assure positive engagement.
2. In a worst-case scenario, emotional upset is simply remediated by removing the upsetting content (e.g., a particular photo, piece of music, or entire program).
3. All participants may discontinue their participation at any time, without explanation or a loss of benefits or incentives to which they are entitled.

Equipment-related risk is low. Participants will be interacting with a SAR. The robot will be virtual on a tablet or physical as a Softbank robot. The NAO robot (Phase I) is about 2 feet tall and was utilized in a research study room. The Pepper robot (Phase II) is approximately 4 feet tall and will be utilized in a community room. The SAR will be placed in a fixed location where it does not pose a risk of bumping into or physically harming participants. The tablet is low weight and poses minimal risk if dropped. In rare instances, participants express a fear of robots or frustration interacting with new technology. We consider this a low risk because our approach of including participants in the design process has been successful to address concerns in advance.

Measures taken to mitigate risk are highly likely to be effective:

1. Including participants in the design process.
2. Describing the robot in detail , so participants are aware of the technology before the interaction.
3. If participants feel distress during the interaction, the robot can be immediately switched off and easily removed from the room.
4. A person will be available to answer questions, and we will provide training.
5. All participants may discontinue their participation at any time, without explanation or a loss of benefits or incentives to which they are entitled.

Data-protection related risk is low. Data will be collected via paper and electronically. Members of the research team will have access to individually identifiable information about human subjects. There is a low risk of inadvertent sharing of personal data, such as pretest and post test results. We consider this is low risk because of extensive security measures to protect data from unauthorized use, and experience managing data, data sharing, entry, processing, and reporting. Please see **Storage & Confidentiality of data** for risk management.

Participation is voluntary, and participants are free to disengage or withdraw at any time. We recognize the progressive nature of dementia and will evaluate the safety of our intervention on a case-by-case basis. Our current model involves a Care Specialist who participates as a member of the care team in the assisted living facility making regular feedback to medical professionals fairly easy. In the case that there is no professional care team: If any member of our staff is alerted to any serious medical problems (e.g., dehydration, psychosis, etc.) over the course of the study, the PI will be notified immediately, and we will work with the caregiver to identify appropriate medical intervention. Other than alerting medical care when required, there will be no recommended alternative treatments.

Adverse Events

An adverse event is determined as any untoward or unfavorable occurrence in a human study participant (such as distress), whether or not considered related to participation in the research.

In the case of participant distress caused by the technology or interventions, the PI will be notified immediately and make a determination whether to seek emergency medical assistance, consult with the SO, consult with the SimpleC professional team, and/or consult with the caregiver on ways to reduce distress within 24 hours. Our team includes experts in gerontology, social work, human-technology interaction, communication, and dementia care. If the PI cannot be reached or in case of a medical emergency, caregivers and PWD will be instructed to contact collaborating community partners to activate established plans for emergency services.

Additionally, participation will be stopped upon the explicit request of participants (revocation of participation); if the PI and research team deems continuation unsafe or undesirable; in case of a serious adverse event that clearly relates to the Companion, the Social Assistive Robot system, Family Connect, Community Connect, Clinical Connect, the interventions or the research. Incidents will be reviewed on a case-by-case basis and reported to Sterling IRB.

As outlined by NIH, classifications of adverse events include the following:

- **Mild**: Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient. This could include behavioral symptoms, such as increased stress.

- **Moderate**: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning. This could include behavioral symptoms such as inability to cope.
- **Severe**: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating. This could include behavioral symptoms such as hospitalization due to emotional factors.

There are no anticipated adverse events, aside from possible distress of using technology. While adverse events are rare, and the risks in our study are minimal, our population of interest (persons with dementia) may have non-study related events (unanticipated adverse events) that could be categorized by the classifications above.

Any serious or unexpected adverse event will be reported per IRB policies, as well as the NIA Program Officer within 24 hours.

Benefits

The potential benefit of the proposed research to the participants is great and represents the primary value of developing the SimpleC products.

- PWD will potentially experience reduced distress associated with their illness, better healthcare outcomes, and increased QOL. We do not purport that any care interventions will ameliorate or improve the patient's disease.
- Caregivers have the potential to experience reduced stress, lower costs, and improved QOL.
- Normal volunteers who take part in the concept & usability testing will have no measurable benefit other than the personal gratification that comes from assisting researchers with the development of a product for PWD and their caregivers.

It is our opinion that the benefits of this project far outweigh the risks. The expected benefits address critical concerns, and risks are few, minimal, and highly likely to be mitigated through our measures to protect against those risks.

5. PARTICIPATION RECRUITMENT AND INFORMED CONSENT

Recruiting & Screening

Human subjects will be recruited for participation. Research participation will be entirely voluntary. All residents and staff are invited to use SimpleC Platform, regardless of their participation status.

We will collaborate with community networks and long-standing community partners. Collaborating sites have an executive-level point person responsible for the research collaboration who will identify and refer eligible persons or distribute research announcements.

Participants will receive a joint communication from Drs. Adams/Beer and/or community partner introducing the research and opportunity to take part. Interested candidates will be invited to learn more about the research and technology by calling the telephone number shown in the solicitation letter or joining a recruitment event in the community. Study C: Each site will contact family caregivers and obtain permission to share contact information with the study team.

Study staff will follow up on mailings and referrals. If parties are interested, the screening process will begin. Participation in the research will not affect the relationship with the referring partners in any way.

To the extent possible, we will protect the privacy and confidentiality of employees. Each site will be provided with documentation about the IRB approval for the study. Participation of employees in the study will be voluntary and not mandated by the organizations.

Because we are dealing with a vulnerable population (PWD), family members will often have the power of attorney (POA) over informed consent and similar issues. Therefore, the PWD and their spouse and/or caregivers and/or Legally Authorized Representative (LAR) will be approached jointly. If not feasible, we will contact the caregiver/LAR first. All participants will undergo screening, either via phone or in-person. The screening with the caregiver will be used to ascertain inclusion and exclusion criteria for themselves and the PWD. Verbal consent will be given to proceed with the screening.

Informed Consent / Assent

IRB approved informed consent procedures will follow the screening. Informed consent will be obtained prior to collecting any data. As applicable, separate informed consent forms will be used for the PWD and the caregivers, detailing the goals of the study, methods, assessments, and procedures. Participants who are willing to take part but unable to provide informed consent (as measured by the Evaluation to Sign Consent Tool for residents) will provide assent.

Study C: Consent will occur in-person, via an online session, and by accepting SimpleC's Terms and Conditions. The Verbal Consent Form will be read and agreed to by participants (or their Legally Authorized Representative) prior to the study. Verbal consent will be obtained and documented by study staff. Consent will not be documented (by participants) even for those who are consented in-

person. Written consent forms will be called *Participant Information Sheets* and shared with participants in person, through mail, or email.

Obtaining and Documenting Consent

An Informed Consent Form will be read and agreed to by participants (or their Legally Authorized Representative) prior to the study. Study C: Participants will receive the information sheet, and we will obtain verbal consent at the onset of the session. We request that documentation of consent will be waived.

Participation Comprehension and Capacity

There will be ample time for participants to ask questions at different points in the enrollment process and during the studies. They will be asked explicitly during enrollment if they have any questions or reservations, including the person with dementia. The PI will be available to any participant interested in obtaining additional information about the study. The PWD's capacity to understand the research and his or her involvement will be evaluated using the Evaluation to Sign Consent Tool. Participants will be reminded of the next steps and asked for their approval and understanding of procedures at each visit (as applicable).

Costs to Participants

SimpleC, LLC will cover the costs of all procedures associated with the studies. None of the procedures require insurance coverage. Emergency care will be made available to treat any injury incurred by participants as a direct result of the study procedures after following all instructions and guidelines. The cost of such care will be covered by SimpleC, LLC. Neither SimpleC, LLC nor the sponsor will be responsible for the cost of referrals or additional services requested by participants as a result of participation in this study (e.g., seeking further medical guidance or help).

Compensation to Participants.

Participants in Study C will receive the following amounts for their participant. Participants who choose to end the study early will receive an amount that is equivalent to the time committed to the study. We may sponsor a luncheon for staff in the area.

Table 6. Compensation

Study	**Resident**	**FAM**	**Staff**
Study C	$ 20	$ 20	Unpaid