Title: Intelligent Personal Assistant for Managing Depression in Homebound Older Adults

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PROTOCOL TITLE: Intelligent Personal Assistant for Managing Depression in Homebound Older Adults

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STUDY SUMMARY:

Investigational Agent(s) (Drugs or Devices)	N/A
IND / IDE / HDE #	N/A
Indicate Special Population(s)	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners (or other detained/paroled individuals) ☐ Students/Employees
Sample Size	50 stakeholders & 40 older adults
Funding Source	Northwestern Older Americans Independence Center Pilot/Exploratory Studies Core
Indicate the type of consent to be obtained	☐ Written ☒ Verbal/Waiver of Documentation of Informed Consent ☒ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☐ Lead Site (For A Multiple Site Research Study) ☐ Data Coordinating Center (DCC)
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

OBJECTIVES:
The objective of this pilot study is to design a companion booklet and pilot test it with a voice-controlled intelligent personal assistant (VIPA), Google Home or Amazon Alexa, to provide patients with skills and tools to help manage their social isolation. The companion booklet is a document that will be created using feedback obtained from a panel of geriatric experts, highlighting features of the VIPA that may be most beneficial to socially-isolated older adults. It will be submitted to the IRB for approval once finalized. The specific aims of this project are to:

Aim 1: Design a companion booklet to be used in conjunction with a VIPA (Google Home/Amazon Alexa) for improving social isolation and communication among homebound older adults, defined as someone who is unable to leave the home without assistance of a device or another person, due to a physical or cognitive condition.

Aim 2: Assess the feasibility and implementation of the VIPA (Google Home/Amazon Alexa) and the companion booklet and its impact on clinical and functional outcomes for older adults with social isolation.

BACKGROUND:

Loneliness and social isolation are both common in older adults in the US. In a prospective survey of a US population based cohort, 17.6% of adults over 65 years of age endorsed feeling lonely “much of the time” (Donovan et al.). And, according to Landerio and colleagues, up to 50% of those aged over 60 are at risk of social isolation.

Social distancing, which may necessitate increased isolation, is an essential public health strategy during a pandemic such as COVID-19, especially for those at increased risk of morbidity and mortality (Centers for Disease Control). Older adults are one such group facing an increased risk from COVID-19; in the United States, between 31-70% of adults aged 65 and older with confirmed COVID-19 infection have required hospitalization and 8/10 reported deaths due to COVID-19 have been in adults older than 65 years of age (Centers for Disease Control). According to Armitage and Nellums however, self-isolation will have a disproportionate impact on elderly individuals, who may not have close friends and family, and whose social contact can be dependent on activities taking place outside the home (ex: at places of worship).

In a population-based Swiss cohort, independent of age, socially isolated individuals had increased risk of poor health, including poor self-rated health and presence of musculoskeletal disorders, moderate-severe depression, and multiple other comorbidities (Hammig). The same cohort also demonstrated an increased risk of unhealthy behaviors, such as physical inactivity, poor diet, and psychotropic drug use in socially isolated individuals (Hammig). In a population-based cohort in the US, loneliness was associated with a 20% increased rate of cognitive decline in adults over 65 years, independent of socio-demographic factors, social network, poor health, and baseline depression (Donovan et al.).

The impact of COVID-19 necessitated social distancing and consequent loneliness on the health of older adults is an acute public health concern. First, COVID-19 related changes in the health system may impair the physical and mental health of older adults--especially those who are frail, very old, or with multiple comorbidities--due to changes in diet, exercise, social stimulation, and accessibility of functional supports (Steinman et. al.). Furthermore, based on lessons learned from previous pandemics such as SARS and MERS, social distancing and the loneliness and/or social isolation that could accompany it may have a negative impact on mental health (Venkatesh and Edirappuli). Factors such as maintaining a healthy lifestyle and hobbies, virtual social interactions,

and mindfulness may help to mitigate these effects (Venkatesh and Edirappuli). Thus, strategies ought to be implemented to mitigate the risk of increased morbidity and of infection from COVID-19 due to the effects of isolation on the mental and physical health of the elderly (Armitage and Nellums) (Landerio et al).

Chen and Schulz found that information and communication technology strategies show promise in reducing social isolation in the elderly, but recognize that more information is needed regarding the efficacy of different interventions for different individuals (Chen and Schulz). Online technologies can be used to help provide a stronger sense of belonging and support for elderly individuals (Armitage and Nellums).

Older adults have often been on the fringe of benefitting from technology. However, VIPAs (e.g. Google Home, Amazon Echo) may be useful to homebound older adults with social isolation, connecting them to caregivers and primary care; providing functional, cognitive, and social stimulation.

STUDY ENDPOINTS:
For Aim 1, the study endpoint will be the finalized VIPA companion booklet for use in the pilot.
For Aim 2, the study endpoint will be the completion of the 16 week pilot program.

STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):
The VIPA accompanying instructional booklet focused on social-isolation in older adults that will be designed for this project will assist older adults with socialization, goal setting, monitoring, feedback and reminders.

PROCEDURES INVOLVED:

In Aim 1, a panel of geriatric experts and patients (n=15-50) will be recruited to help identify which applications available on the VIPA (Google Home/Amazon Alexa) may be the most useful for homebound older adults who may be socially isolated. Stakeholders will include geriatricians (attending physicians), nurses, social workers, patients, and caregivers of older adults. Stakeholders (geriatric experts) will independently use the Google Home or Amazon Alexa Assistant as a trial themselves for 2-4 weeks, and then select those VIPA features that they think may be the most relevant and useful for older adults to help minimize social isolation.

Or, in the case of older adults and caregivers, they will be given the device, and either the study PI or Research Study Coordinator (RSC) will visit the participant's home, or assist the patient virtually, to set up the Google Home or Amazon Alexa device. Participants will then provide feedback about the device after 2-4 weeks of use. This feedback will be collected over the phone with the Research Study Coordinator or online. Once responses are collected, the feedback will be implemented into an updated iteration of the companion booklet, which will be used for Aim 2.

Based on the collective feedback from the geriatric expert and patient panel, we will design a finalized companion booklet to go along with the VIPA, highlighting the list of applications that may benefit older adults with social isolation. Once the VIPA companion booklet is updated, the stakeholders will review the booklet and provide feedback via a second online survey (or via telephone if unable to complete online) before it is finalized and is ready to be used in Aim 2 in the pilot study. The goal is a VIPA companion booklet along with the VIPA that will assist older adults with socialization, goal setting, monitoring, feedback and reminders.

For Aim 2, we will recruit a total of 20-40 older adult homebound patients who are likely to be socially isolated to use the VIPA and accompanying instructional booklet focused on social-isolation. Either the study PI or Research Study Coordinator (RSC) will visit the participant's home, or assist the patient virtually, once consented, to set up the Google Home or Amazon Alexa device for them and review the companion VIPA booklet with them. For Aim 2, participants will be asked to use the VIPA and accompanying second iteration of the instructional booklet focused on social-isolation. These participants will be surveyed over the phone, online, or in-person for 16 weeks (baseline, 4 weeks, 8 weeks, and 16 weeks) with outcomes measured at each time point. These outcomes include: VIPA use and acceptability (Acceptability, Feasibility, and Appropriateness Scale); Social Isolation (PROMIS-Short Form 8a); Anxiety (GAD-7); Self Efficacy for Managing Social Interactions (PROMIS-Short Form 4a); Ability to Participate in Social Roles and Activities (PROMIS-Short Form 4a); Companionship (PROMIS-Short Form 4a); Geriatric Depression Scale (GDS – Short Form)functional status (PROMIS-Physical function); Cognitive Function (Brief MOCA); and Quality of Life/Well-being (Neuro-QOL Positive Affect & Well-Being). Demographics will be collected at baseline, and technology use data (adapted from Teacher Technology Integration Survey (TTIS)) will be collected at baseline and 16 weeks. We will also continue to collect feedback to iteratively optimize the technology, protocol, and implementation.

DATA AND SPECIMEN BANKING
Upon completion of all study activities, a final de-identified dataset will be created. This dataset will be stored indefinitely on the GIM server for secondary analyses. Only authorized personnel will have access to the dataset.

SHARING RESULTS WITH PARTICIPANTS
Study results will not be shared with participants or anyone else.

STUDY TIMELINES
Aim 1 will be conducted during months 1-7 and Aim 2 will be conducted during months 8-24.

INCLUSION AND EXCLUSION CRITERIA
No subjects will be excluded on the basis of race or ethnicity.

In Aim 1, stakeholders will be eligible if they are:

1. Adults aged 21 or older;
2. English-speaking; and
3. Currently provide at least 2 hours of weekly clinical support (e.g. emotional, social, physical, task-related) to an older adult (>65 yrs.) who may be socially isolated

Or

1. Adults aged 65 years or older;
2. Patients of the Northwestern Medicine Geriatrics Program;
3. English-speaking;
4. Able to verbally consent

In Aim 2, participants will be eligible if they are:

1. Adults aged 65 years or older;
2. Homebound patients;
3. Able to access the internet;
4. English-speaking; and

5. Able to verbally consent

VULNERABLE POPULATIONS – N/A

PARTICIPANT POPULATION(S)

Accrual Number:	Category/Group: (Adults/Children Special/Vulnerable Populations)	Consented: Maximum Number to be Consented or Reviewed/Collected/Screened	Enrolled: Number to Complete the Study or Needed to Address the Research Question
Local	Stakeholders (Aim 1)	50	50
	Older Adults (Aim 2)	40	40
Study-wide	Stakeholders (Aim 1)	50	50
	Older Adults (Aim 2)	40	40
Total:		90	90

RECRUITMENT METHODS

Aim 1: Recruitment of Stakeholders

The PI will send out an email invitation to relevant listservs including healthcare providers and caregivers who care for older adult patients to recruit stakeholders. Older adults will be identified by clinicians.

After receiving the email invitation, interested individuals will click on the online REDCAP survey link to complete the online screener to determine their study eligibility, or they will be contacted via telephone to complete the screener to determine their study eligibility. Eligible participants will then be able to access the consent form online to provide consent, or they will provide verbal consent via telephone. Once a participant consents to be in the study, they will receive an email from the research study team within two weeks which includes a link to a brief online survey for them to complete once they complete their 2-4 week trial period of the VIPA. Those who cannot access the online survey will receive a phone call from the study team, and they will complete the survey over the phone. The survey will include some demographic questions and will include questions for them regarding their experience/use of the Google Home/Amazon Alexa device which will help inform the design of the companion VIPA booklet.

An online or verbal consent will be obtained prior to the telephone survey.

Aim 2: Recruitment of Patients

This study will be presented to providers in the Northwestern Medicine Geriatrics Program and other Chicago-based clinics, and they will be asked to pass along study information flyers to potential patient/caregiver subjects. In addition, clinic staff can provide the research study coordinator (RSC) with the names and phone numbers of potential participants via encrypted email. Potential participants may also be approached in-person at senior events or by posting

flyers at senior facilities. Potential subjects who are interested in learning more about the study will then contact the research staff by phone, or the research coordinator will contact potential participants. Potential participants will learn more about the study and, if interested, be screened for eligibility. To supplement the patient pool for recruitment, potential participants will also be identified through reports generated by the Enterprise Data Warehouse (EDW). This list of patient names, medical record numbers, phone numbers, address, and date of birth will be compiled in a report that can be securely accessed and reviewed by study staff. The PI or trained research study coordinators (RSCs) will review the charts of identified patients to confirm eligibility that cannot be ascertained via the EDW. Among the remaining eligible patients, research staff will send the patient's clinician an Epic message with a list of their patients to review and remove any patients that should not be contacted within 3 days. The study staff will then contact identified patients and if they are interested in participating or learning more about the study, the RC will obtain verbal permission to ask the patient a brief series of questions to verify eligibility. If patients are eligible, the PI or RSC will engage patients in the verbal informed consent process, or patients will be able to access the consent form online to provide consent when appropriate. The first phone survey, the baseline survey, will then be conducted over the phone or in-person by the PI or RSC with the patient, or online for those who are comfortable.

COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES

Aim 1: For their participation as a stakeholder, each geriatrics expert panelist or patient will be provided a Google Home or Amazon Alexa (VIPA) which has a value of approximately $40, or a $20 gift card if they already have a device. Stakeholders will use this Google Home or Amazon Alexa device as part of their study engagement, and they will be able to keep the VIPA after study completion.

Aim 2: For their use of the Google Home or Amazon Alexa device and companion booklet as well as completion of study interviews, each older adult patient will be provided a Google Home or Amazon Alexa (VIPA) which has a value of approximately $40. This VIPA will be used throughout the study and they will be able to keep the VIPA after study completion. Patients will also receive a $20 gift card after completion of the study. Patients will receive the gift card compensation by mail.

WITHDRAWAL OF PARTICIPANTS

Participants can choose to withdraw from the study at any time. If a participant chooses to withdraw from the research, any data collected up until the point of withdrawal will still be utilized as it will not include identifying information.

RISKS TO PARTICIPANTS

The risks of harm from being in this study are minimal. The most significant risk is that both stakeholders and patients will be using a VIPA which may result in a loss of confidentiality if someone else were to access the information gathered by the Google Home or Amazon Alexa device. However, the research team will not have access to the any of the information that may be gathered/stored on the VIPAs. Patients in Aim 2 may additionally experience distress or psychological discomfort while completing the phone surveys, especially when answering questions related to social isolation.

POTENTIAL BENEFITS TO PARTICIPANTS

We cannot promise any benefits to stakeholders or patients taking part in this research. However, possible benefits for stakeholders (Aim 1) include that as a result of participating in this study,

they may gain a better understanding of how to incorporate the use of VIPAs with patients/older adults that may be socially isolated.

For patients (Aim 2), benefits may include learning helpful strategies using a VIPA to manage self-isolation and being able to access tools that might help them develop better socialization and communication habits while being homebound.

DATA MANAGEMENT AND CONFIDENTIALITY

Data collected includes consent forms (online and verbal) and data collected during the study surveys.

Data Access. The Data Custodian is the Principal Investigator, Dr. Katherine O'Brien. Only authorized personnel listed on the IRB will have access to the data. Any information that could allow identification of individual participants, including the master list, will be kept strictly confidential.

Local Data Storage. Data will be stored in REDCap, a secure, web-based application, and on the Northwestern secure server for the length of the study. The PI or research coordinator will download the de-identified data only from REDCap monthly and save it to the dedicated project folder on the FSM department servers which are located in a HIPAA compliant data center. These data files do not contain any identifiable information, and are identified by project staff by an assigned study ID. Upon completion of all study activities, a final de-identified dataset will be created and all identifiable information will be deleted. This dataset will be stored indefinitely on the GIM server for secondary analyses. Only authorized personnel will have access to the dataset. All identifiable information will be deleted upon completion of the study

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS

This study involves no greater than minimal risk. Due to this, we will not be convening a DSMB for this study.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS

In all research documentation, participants will be identified by a unique identification number ("Study ID"), not by name, and any other identifying information (e.g. personal and/or contact information) will be kept separate from the other data**;** all information will be kept in secure, password protected files. Further, subjects will be told that unless required by law, only the study investigators, members of the project staff, and representatives of Northwestern University will have the authority to review any study records. In such case, they too will be required to maintain confidentiality.

COMPENSATION FOR RESEARCH-RELATED INJURY – N/A

ECONOMIC BURDEN TO PARTICIPANTS – N/A

CONSENT PROCESS

Aim 1: Informed consent (online or verbal via telephone) will be collected for participants who are screened as eligible to participate in the study as stakeholders. The consent document is written in language that the potential participant can understand. A copy of the consent form will be accessed online or via telephone and can be downloaded and/or printed for their records, or can be mailed to the participant at their request.

Aim 2: Informed consent will be obtained by the PI or trained RSC verbally over the phone, or online when appropriate, for any participants that are screened as eligible to participate in the study. All interviewers will follow the SOP: Informed Consent Process for Research (HRP-090). Informed consent will be viewed as a process, i.e., at several times during review of the IRB approved consent document, the participant will be asked to explain in his/her own words his/her understanding of the consent. This will enable the research personnel to enter into a dialogue with the participant and ensure that the participant understands that he/she is free to withdraw at any time without penalty. Information will be provided to the participants in terms that they can fully understand. There will be no exertion of any overt or covert coercion. The consent document is written in language that the potential participant can understand, and they will be encouraged to ask questions prior to giving consent. A copy of the verbal or online consent form will be mailed or emailed to study participants in Aim 2 of the study, depending on their preferred modality of receiving the copy of the consent form.

Waiver of HIPAA Authorization are requested to identify subjects (patients) prior to enrollment into the study.

NON-ENGLISH SPEAKING PARTICIPANTS

Non-English speaking subjects will not be included in this research study.

WAIVER OR ALTERATION OF CONSENT PROCESS

The following groups will not be included in this research study.

- ***Participants who are not yet adults (infants, children, teenagers)***
- ***Cognitively Impaired Adults***
- ***Adults Unable to Consent***

Aim 1: Process to Document Consent Online

Since the recruitment, screening, enrollment, and completion of the surveys will take place online or by telephone for stakeholders, we are requesting a waiver of written documentation of consent. We are not obtaining HIPAA Authorization to access PHI from participants. Eligible participants will consent online or complete a verbal consent by telephone before they are able to proceed with the first survey. The Waiver of Written Documentation of Consent does not adversely affect the rights and welfare of participants given that various protections will be in place to keep data de-identified, to not use the data for any other purposes outside of the scope of this study, and involves no more than minimal risk to participants. A copy of the consent form will be accessible to participants online and can be downloaded and/or printed for their records, or can be mailed to the participant at their request.

Aim 2: Process to Document Consent Online or Verbally

A verbal consent, or a waiver of documentation of consent, is deemed appropriate because the nature of the study involves minimal risk. We will not be obtaining HIPAA Authorization to access protected health information (PHI) from the medical records of participants. The Waiver of Written Documentation of Consent does not adversely affect the rights and welfare of participants given that various protections will be in place to keep data de-identified, to not use the data for any other purposes outside of the scope of this study, and involves no more than minimal risk to participants. Eligible participants will consent online or complete a verbal consent by telephone before they are able to proceed with the first survey. For those who are able to engage online, eligible participants

will receive an email invitation to the online REDCAP survey link to complete the online screener and, if eligible, the online consent form. For those over the phone, once the study team has read the verbal consent over the phone and answered any questions the patient may have, the patient will be asked if they would like to participate in the study. If a patient agrees to participate after the consent is read, the PI/RSC will record the patient's name on the consent form and the PI/RSC will sign their own name on the form. These consent forms will be locked in a file cabinet only accessible to necessary research staff. Participants will be given the option to receive a copy of the consent form for reference if they request it either by mail or email.

Waiver of HIPAA Authorization are requested to identify subjects (patients) prior to enrollment into the study.

PROTECTED HEALTH INFORMATION (PHI AND HIPAA)

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In order to preserve participants' confidentiality rights, research subjects will be assigned code numbers that will be used to identify all the information collected. Using these codes, none of the collection forms will contain the names of the participants. All electronic data will be stored on a password-protected computer. A Microsoft Access master study tracking database will contain information linking participants to their study id numbers. This database will be encrypted and kept on a secure server and only accessible by study personnel.

Survey data will be stored in REDCap. Individual study identification numbers will be assigned to each participant and only this number will appear on the survey. Subjects will be told that unless required by law, only the study investigators, members of the project staff, the funding agency and representatives of Institutional Review Boards will have the authority to review any study records. In such cases, these parties too will be required to maintain confidentiality. The final data set will be stripped of identifiers. Data will be shared via presentations at national and international meetings and in peer reviewed publications. Furthermore, all results will be shared with the funding institute.

QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE

This project is being led by Dr. Katherine O'Brien, with Drs. Bradley, Lindquist, Mohr, and Kwasny as mentors. Dr. Lindquist has been a colleague and mentor to Dr. O'Brien since she joined the Northwestern faculty in 2018. Both Dr. Kwasny and Dr. Mohr have a longstanding collaborative relationship with regard to research involving healthcare design and technology use, and Dr. O'Brien will leverage this existing partnership. Northwestern University will be the lead administrative site and data collection and coordinating site. Staff at Northwestern will work under the primary direction of Dr. O'Brien to recruit and retain patients and collect data.

Dr. O'Brien, as the study PI, will personally train and supervise the research coordinator in the day-to-day execution of the study details. Although Dr. O'Brien will have executive decision-making over all final research decisions, the research coordinator will be the first point of contact "on the ground," with close access to and constant communication with Dr. O'Brien. Any IRB revisions or updates will be submitted by the research coordinator, in addition to any other administrative tasks (e.g. tracking of participant incentives, arranging for meeting space).

Team Meetings: The entire co-investigator team (O'Brien, Bradley, Lindquist, Mohr, Kwasny) and the research coordinator will meet every other week during the two years of the grant. Dr. O'Brien and the research coordinator will be responsible for presenting interim outcome data, including the number of patients screened/enrolled/refused and any anticipated or unanticipated

obstacles encountered. Dr. O'Brien will then lead a discussion on any proposed solutions to problems with study design, execution, or analysis.

MULTI-SITE RESEARCH – N/A