NCT06179225

Reducing Loneliness of Older Adults in Long Term Care Facilities Through Collaborative Augmented Realities

Study Protocol and Analysis Plan

July 23, 2023

VU IRB Protocol #221150

Specific Aims

The primary aim of this pilot study was to examine the feasibility and acceptability of cocreated collaborative HMD-AR activities using photorealistic avatars. To evaluate the feasibility and acceptability of the study procedures for a future RCT comparing HMD-AR with photorealistic avatars versus 2D ICT (eg, Zoom), we used an RCT design.

Study Design

This study was a feasibility and acceptability evaluation of older adults' use of HMD-AR compared with 2D ICT (ClinicalTrials.gov NCT06179225). To inform a future RCT, we designed the pilot as a nonblinded 2-arm RCT.

Participants were recruited from April 2024 through May 2025. The primary aim was to examine the feasibility and acceptability of the 2 ICTs. We enrolled 8 pairs of older adults and their designated companions (ie, designated family members or friends). After completing baseline assessments, 2 to 4 pairs were enrolled at a time because of logistical constraints. Randomization was conducted at a 1:1 ratio. The intervention consisted of 8 sessions delivered over 4 weeks (2 sessions per week). Baseline evaluations were conducted at week 0. Social presence was evaluated after the second and eighth sessions. Feasibility and acceptability outcomes were evaluated at completion of the study.

Study Design Rationale

We targeted older adults, with and without cognitive impairment, who resided at home or in LTC settings because of the high prevalence of loneliness or social isolation in these populations, resulting in further cognitive and physical decline. Reviews have yielded mixed findings on whether men or women are more likely to report loneliness. Age does not appear to have an association with levels of social presence in ICT; however, women tend to report higher levels of social presence when using ICT.

We used a 2D audio-visual intervention as the comparator because it has been extensively used since the COVID-19 pandemic. Although it provides audio and visual communication, it limits the quality of the interaction and has produced mixed results among older adults residing in the community. Our focus is on known family members or close friends because of older adults' desire to maintain meaningful long-term relationships.

We examined feasibility and acceptability because these factors are highly salient for adoption and intervention success. An RCT design was chosen for its robustness in conducting future intervention studies. We chose 2 visits per week for a 4-week duration to allow sufficient exposure to assess feasibility and acceptability. There are several HMD products; at the time of this study, we chose HoloLens 2 (Microsoft Corporation) because of its robustness, widespread use (eg, US Army with >80,000 hours of soldier feedback) [51], usability among older adults, and ability to fit over eyeglasses.

Ethical Considerations

This study protocol was approved by the Vanderbilt University Medical Center Institutional Review Board (IRB; 221150). Written informed consent was obtained in person from all participants before data collection and study procedures. To ensure that potential participants

understood the study purpose, risks, and benefits, we administered the University of San Diego Brief Protection of Human Subjects Capacity to Consent instrument.

Research assistants (RAs) underwent training to recognize signs of frustration, anxiety, or stress displayed by participants; any sign of discomfort resulted in termination of the session. RAs were trained in procedures to protect privacy and confidentiality. Participants were assigned unique study ID numbers, and all deidentified data were stored in a secure password-protected database.

Participants received financial compensation for study activities, including the interactive sessions and data collection procedures, to acknowledge their time and reduce attrition. An external safety officer, designated by the National Institute on Aging (NIA), reviewed and approved the study protocol and informed consent documents before the start of the study. Biannual reports were provided to both the safety officer and the NIA program officer to review progress and any untoward events.

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Conceptual Framework

Several frameworks guided the study. First, social presence theory postulates that the ICT properties and the persons' perceptions, behaviors, or attitudes regarding the physical presence of other people within the ICT environment affect the quality of the interaction. We compared 2 ICTs, HMD-AR and 2D audio-video communication. Second, we applied the engagement framework proposed by Cohen-Mansfield, which emphasizes the role of social interactions, activities, and environment in shaping engagement. Third, the social connection framework by Holt-Lunstad et al guided our focus on the functional and qualitative aspects of ICT visits. Finally, we adapted the unified theory of acceptance and use of technology framework to guide the evaluation of users' acceptance and use of the ICTs. Individual characteristics such as age, gender, cognition, relationship with designated companion, and social network can impact acceptance and use of ICT, the type and quality of engagement, and loneliness—our future condition of interest.

Participants and Setting

Overview

This study took place in the greater Nashville, Tennessee area. Eligibility criteria for older adults included being aged 60 years or older and living within a 1-hour drive from the principal investigator's office. If the older adults resided in LTC settings, they must have been residents for 3 months or more. Exclusion criteria included severe cognitive, sensory, or physical impairments that impeded participation; major psychiatric disorders; inability to provide assent; inability to understand or speak English; and acute or terminal illness.

Each older adult recruited 1 companion (family member or close friend). Companions had to be aged 18 years or older and willing to participate in both HMD-AR and 2D audio-video visits and related study procedures. For both older adults and their companions, adequate internet bandwidth was necessary. Eligible older adult–companion pairs were randomized at a 1:1 ratio to ICT type using a computer-generated randomization scheme after baseline measures were completed.

Recruitment

Using IRB-approved communication scripts, flyers were posted in public areas, including Vanderbilt University parking garages, local community and older adult centers, churches, and libraries. RAs provided several in-person demonstrations at local centers. Emails were sent to several assisted living facilities located near Vanderbilt University. Interested older adults and family members contacted the investigator team directly. RAs followed the IRB-approved informed consent document to explain the study either in person or by telephone. A standardized screening checklist was completed to ensure eligibility.

Sample Size

There is no precise sample size for an early-stage proof-of-concept technology feasibility study. Nielsen and Landauer found that 5 users uncovered 85% of usability problems with the technology. Our target was to enroll 12 pairs of older adults and designated companions for a sample size of 24, as the recommended sample size for pilot studies is 20 to 30. Our final sample of 8 pairs (16 participants) with 8 sessions per pair (64 sessions) was judged sufficient to address the primary aim of feasibility and acceptability of ICT in the home setting. HMD-AR and 2D Audio-Visual Interventions

For both interventions, the internet bandwidth within the homes of older adults and family members was measured, and a hot spot was used when necessary to facilitate data streaming. A minimum download speed of 80 Mbps was required for data communication. For each session, a trained RA engineer was physically present in both the older adults' and companions' homes to troubleshoot for technological issues during the sessions. The RA trained the participants in establishing the ICT (HMD-AR or 2D audio-visual intervention) connection and assisted participants as needed. The RA remained in the room to monitor for technological issues and maintain field notes. Session duration was at the discretion of the older adult and family member or close friend, but it did not exceed 60 minutes.

HMD-AR Intervention

Creation of Photorealistic Avatars

We created photorealistic avatars for all participants randomized to the HMD-AR study arm. A mobile app, Polycam, was used to take multiple photos of the participant's face using a 360° view. Polycam constructed a 3D model from these photos that was then used to create a MetaHuman on Unreal Engine, matching the facial geometry and the facial features of the participant. However, MetaHuman Creator is limited in its ability to match the features exactly; therefore, the RAs added manual touch-ups to ensure the avatar looked similar to the participant. After creating the first version of the avatar, a video call was arranged with the participants to share their avatar with them and receive feedback. Participants were able to pick

their avatar's clothing, hair, body shape, and accessories, and apply makeup. If a participant was not satisfied with the likeness of their avatar, the process was repeated, and more manual touch-ups were added. A second meeting was arranged with the participants to share the new version. For most participants, it took 1 meeting to finalize their avatars.

Experimental Setup

Participants, in consultation with the RAs, determined the physical space for conducting the sessions. General criteria for physical space were that it was free from clutter, furniture, and objects to allow for clear overlays of virtual objects and photorealistic avatars and located in an area of low traffic to minimize session interruptions. For each participant, equipment included a Kinect camera (Microsoft Corporation), a microphone, an HMD, and a laptop on which the data sharing and the activity ran and were remotely displayed on each participant's HMD. An Alienware (Dell Technologies Inc) laptop with a 3060 Graphics Processing Unit was used due to the high-performance demand of the AR activity. The RAs ensured that both the older adult and their family members or close friends were connected before moving to an unobtrusive viewing area. Upon completion of the session, the RA dismantled all equipment and cleaned the HMD-AR with disinfectant wipes. Collaborative AR Activity Sessions

Before the start of the experimental sessions, RAs provided one-on-one training and orientation to the HMD-AR to ensure that the participants were able to navigate the system. In addition, a hard-copy, 1-page quick reference guide was provided to each participant. Each older adult–companion pair participated in 2 sessions per week for 4 weeks (total of 8 sessions). Two collaborative AR activities were available to the participants: fireplace decoration and checkers. If the fireplace activity was selected, participants could choose from a variety of virtual objects to decorate the fireplace mantel, hearth, or nearby wall. For the checkers activity, each participant sat at a table, and the checkerboard and checkers appeared as a virtual object in space. Participants were able to see each other's photorealistic avatars during both activities. Upon completion of each session, the participants would let the RAs know who turned off the AR display and stopped the data communication.

2D Audio-Visual Intervention

Experimental Setup

Participants, in consultation with the RAs, determined the physical space for conducting the sessions, preferably in an area of low traffic to minimize session interruptions. If the participants were placed in the 2D ICT group, they could use their PC. In the event that participants did not own a device, a laptop was provided for each session. The RAs ensured that both the older adult and their companion were connected before moving to an unobtrusive viewing area. Upon completion of the session, the RAs recovered any loaned devices.

Collaborative 2D Audio-Video Sessions

For this study, we used the Zoom videoconferencing application for all sessions. Before the start of the experimental sessions, RAs provided 1:1 training and orientation to using the laptop device, if needed, especially for older adults unaccustomed to tablets or computers and logging in to Zoom. Participants were provided with links to an online checkers game and an online room decoration activity that they could engage in during the session. A 1-page quick reference guide was provided to each participant.

Ensuring Intervention Fidelity

We incorporated recommendations from the National Institutes of Health Behavior Change Consortium to maximize treatment fidelity across RAs and over time. In brief, we used theoretical models to guide our study, conducted standardized training for RAs with ongoing reviews, and used standardized protocols. Issues were discussed at the weekly investigator-RA meetings. RAs completed field notes after each session, documenting the session date, start and end times, notes on issues encountered during the session, and quotes from participants, and evaluated the amount of effort the older adults exerted to accomplish tasks.

Data Collection Procedures

Data were collected throughout the experiment from the older adult and their companion, as detailed subsequently. A final interview was conducted at the experiment's conclusion. All data were collected in person using standardized assessment forms and entered into REDCap (Research Electronic Data Capture; Vanderbilt University), a secure, web-based software platform, and double checked for accuracy. During face-to-face interactions, participants read the questionnaire while the research staff read the questions aloud and documented the responses. Instruments were chosen with established validity and reliability. All data collection forms were scanned and uploaded into REDCap.

Measures

Feasibility and Acceptability Outcomes

Feasibility, defined as the practicality of conducting the study, was measured by observation and documentation of recruitment and retention rates, data completion, and session attendance (ie, intervention completion). Logistical, technological, and user issues were observed and documented after each session. We measured intervention implementation rates for both study arms as the proportion of successful connections. Feasibility was also measured by the participants' perceptions of the ease of using the technology using a valid and reliable 4-item questionnaire, the Feasibility Intervention Measure. Each item was rated on a 5-point Likert scale ranging from 1 (completely disagree) to 5 (completely agree). Data were collected during the final 2 weeks after the follow-up visit.

Acceptability, defined as the perception that the intervention (HMD-AR or 2D audio-visual intervention) was agreeable and palatable, was measured using a valid and reliable 4-item questionnaire—the Acceptability Intervention Measure. Each item was rated on a 5-point Likert scale ranging from 1 (completely disagree) to 5 (completely agree). Data were collected 2 weeks after the follow-up visit. Overall satisfaction with the ICT was ascertained at the final session via semistructured interviews.

Baseline Variables

For both older adults and companions, baseline data were collected on demographics (age, gender, and race), social network, and loneliness. Social network was assessed using the 12-item Lubben Social Network Scale, a self-report measure of social engagement with family and friends. Each item is rated using a 6-point Likert scale ranging from 0 (no monthly contact) to 5 (daily contact); scores range from 0 to 60, with higher scores indicating a greater social network.

For older adults residing in LTC, the Revised Lubben Social Network Scale–Long-Term Care Scale was used; this scale includes an additional 11 items that assess quality and frequency of interactions with other residents and staff members. Loneliness was assessed using the 6-item revised University of California, Los Angeles (UCLA) Loneliness Scale, a self-report measure consisting of 6 items rated using a 4-point Likert scale. The score ranges from 6 to 24, with higher scores indicating greater loneliness.

For older adults, cognition was assessed using the Self-Administered Gerocognitive Examination. The Self-Administered Gerocognitive Examination is a brief tool that assesses language, reasoning or computation, visuospatial, executive, memory, and orientation domains. Scores range from 0 to 22, with scores greater than 16 suggesting normal cognition. Physical function was assessed via self-report using the Barthel Index. Participants rate their degree of independence in performing 10 activities of daily living (eg, bathing and dressing); scores range from 0 to 100, with higher scores indicating greater independence.

ICT Sessions

Immediately after each session, RAs completed a modified Observational Measurement of Engagement instrument to note engagement behaviors, type of activity, level of noise, and lighting. Additional field notes provided contextual information for understanding the older adults' engagement with their family members across each type of ICT. Participants were asked to complete the 3-item UCLA Loneliness Scale.

The Mutual Awareness Subscale (MAS) of the Networked Minds Measure of Social Presence was completed after the second and eighth sessions. The MAS is an 8-item questionnaire rated using a 5-point Likert scale, ranging from 0 (never) to 4 (a great deal); scores range from 0 to 32, with higher scores indicating a greater sense of social presence with one's partner.

At the last session, participants completed the Networked Minds Measure of Social Presence instrument, consisting of several subscales: MAS (8 items), Perceived Attentional Engagement (6 items), Perceived Emotional Contagion (8 items), Perceived Comprehension (6 items), and Perceived Behavioral Interdependence (6 items). Higher scores indicated greater social presence. Loneliness is the targeted primary outcome for future studies; therefore, participants also completed the 6-item UCLA Loneliness Scale. Finally, the RAs conducted a brief interview using a semistructured questionnaire to elicit participants' perceptions of facilitators and barriers.

Analysis Plan

We will produce a CONSORT (Consolidated Standards of Reporting Trials) flowchart to track the progress through the phases of the trial (enrollment, intervention allocation, follow-up, and data analysis). Reasons for noneligibility, nonparticipation, and attrition will be documented and summarized. Feasibility and acceptability (eg, participant recruitment, enrollment, and retention rates) will be descriptively analyzed using frequency distributions and measures of central tendency and dispersion, as appropriate. For participant-completed instruments (eg, social presence, Feasibility Intervention Measure, and Acceptability Intervention Measure), we will examine the extent of missing data to inform the selection of future instruments.