The Loneliness Epidemic Tailoring Interventions to Reduce Loneliness and Pain

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Protocol

Setting and Recruitment

We will recruit participants: 1) direct referral from those with ethical access in independent or assisted and independent living facilities and 2) community and social media marketing. A copy of a letter of support will be uploaded from each senior retirement apartment. We will host informational sessions (PI, Co-Is, and study personnel) with question-and-answer periods at the facilities (in Omaha and Lincoln) to inform participants about the study. We will obtain permission from these facilities prior to placing flyers at any locations in the community and hosting study informational presentations. Interested individuals will undergo screening and enrollment.

The sites where the study will be conducted are the *participant's place of residence at the following locations*: Aksarben Village Senior Apartments Trinity Courtyard Senior Apartments (both in Omaha, NE) Eastmont Senior Living Apartments and The Legacy Senior Living (all in Lincoln, NE).

Screening

Study personnel (Omaha and Lincoln) will screen interested potential subjects according to inclusion and exclusion criteria in the private residence. Those meeting eligibility will undergo informed consent.

Inclusion: 1) men and women 60 years of age; 2) live alone (single-family home, independent, or assisted living); 3) self-report have experienced or currently experiencing musculoskeletal pain; and 4) wireless internet access via a broadband Internet connection.

Exclusion: 1) memory loss as evidenced by poor performance on the Mini Cog; 2) inability to speak English; 3) prior study participation; 4) prior use or current use of a conversational voice assistant; and 5) not willing to engage with the voice assistant.

Both UNMC and UNL personnel will conduct screening, enrollment, Alexa set-up with instructions and training, data collection, data analysis and interpretation.

Enrollment and Randomization

Once all participants are recruited and enrolled, participants will be randomly assigned with equal distribution to the conversational voice assistant-standard group (CVA-S) or the conversational voice assistant-enhanced loneliness routine treatment group (CVA-E). The study will be a 12-week randomized pilot trial.

Study Groups

Group 1. Conversational Voice Assistant Standard Loneliness Routine (CVA-S) Participants in the CVA-S group will receive an a priori set of evidence-based interactions to perform with the conversational voice assistant. The interaction dose will be 15 minutes performed once in the morning and once in the evening, at pre-set times. The participants will 1) do a meditation activity, 2) play an interactive trivia game, and 3) ask the assistant to tell a joke.

Group 2. Conversational Voice Assistant Enhanced Loneliness Routine (CVA-ELR) Participants in the CVA-ELR group will receive personalized intervention activities based on individual preferences and personality. The interaction dose will be 15 minutes performed once in the morning and once in the evening, at pre-set times and as needed. After collection of post-intervention data, participants will be compensated for their time.

Procedures

An appointment will be scheduled to set up Alexa, review instructions, and perform data collection by study personnel (Omaha and Lincoln). The instructions for both groups will include basic training by study personnel (Omaha and Lincoln) on how to use the conversational voice assistant. Then review of the loneliness routine based on group assignment. Data will be collected at pre (baseline) and post intervention (after 12-weeks).

Data

Pain Severity and Pain Interference: Subjective pain will be measured using the Brief Pain Inventory Short form (BPI-SF). The instrument has nine questions that measure pain severity and pain interference with function. The severity questions assess pain numerically ranging from 0 no pain to 10 pain as bad as you can imagine; interference questions assess interference from 0 no interference to 10 completely interferes. Higher scores indicate higher severity or interference with 0 being none, 1-3 mild, 4-6 moderate, 7-10 severe. The BPI-SF has Cronbach alphas ranging from 0.86-0.96.

Loneliness: Subjective social isolation and loneliness will be measured using the University of California Los Angeles, UCLA Loneliness Scale Version 3, a 20-item instrument with responses of never, rarely, sometimes, and always. There is no standard accepted score for identifying loneliness; higher scores reflect greater reported loneliness. The scale has established validity and reliability with Cronbach's alphas ranging from 0.85 to 0.94.

Depression: Will be measured as it may interfere with pain and loneliness. We will use the Geriatric Depression Scale Short form. The instrument has 15 questions with higher scored indicating depression.

Self-management of Pain: PROMIS Self-Efficacy for Managing Symptoms-SF-8: an eight-item tool that allows the subjects to report the level of confidence to manage/control their symptoms, to manage their symptoms in different settings (home, public place, an unfamiliar place), and to keep their symptoms from interfering with work, sleep, relationships, or recreational activities.

Objective Use: We will securely access the participants voice assistant profiles and document the time stamps of intervention activities to assess frequency and length of use, type of uses, and routine completion rates with the standard and enhanced loneliness routines.

Usability: Usability will be measured using the System Usability Scale. The 10 question 5-point Likert scale scores range from 0-100 and scores above 68 are above average.

Personality Inventory: The Big Five Inventory is a 40-item assessment of general personality using the five-factor model Neuroticism (N), Extraversion (E), Openness to Experience (O), Agreeableness (A), and Conscientiousness (C).

Statistical Analysis

Descriptive statistics to calculate inferential results such as percentages, mean and standard deviations on demographic, health history, BPI-SF, UCLA Loneliness Scale, Geriatric Depression, and PROMIS Self-efficacy scores at baseline and after the 12-week intervention.

We will compare the average questionnaire scores within and between the CVA-S and CVA-E groups. The Shapiro-Wilk test used to assess the normality of distributions for these variables. Given the significant results, indicating non-normal distributions from the Shapiro-Wilk test for these variables except baseline pain severity and post-study severity, Wilcoxon Signed-Rank non-parametric test was chosen for hypothesis testing of all variables except baseline pain severity and post-study severity, which were tested by paired-samples t-test. In addition, ANOVA tests were performed to compare the baseline scores of self-reported pain severity, pain interference, loneliness, depression, and self-efficacy between the CVA-S and the CVA-E groups.

Mann-Whitney U test was employed to test differences between the standard and enhanced conditions in terms of routine initiation rates and SUS scores. Multiple regression analyses were conducted to explore the relationships between participants' SUS scores, objective use of the routines with personality.