Mindfulness to Reduce Loneliness in Family Caregivers

NCT04560088

8/29/2022

MINDFULNESS TRAINING TO REDUCE SOCIAL ISOLATION AND FEELINGS OF LONELINESS IN OLDER CAREGIVERS FOR FAMILY MEMBERS WITH ALZHEIMER'S DISEASE AND RELATED DEMENTIAS

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RSRB#00005296

I. RATIONALE FOR THE STUDY AND SPECIFIC AIMS

Purpose: The current objective of this pilot study is to provide initial evidence of the role of mindfulness training in improving social disconnectedness – including social isolation and feelings of loneliness – in older caregivers for family members with ADRD.

Background: Social isolation and feelings of loneliness are risk factors for older caregivers for family members with Alzheimer's Disease and Related Dementias (ADRD).[1] Further, social isolation and loneliness place older caregivers at risk of poor health, including increased inflammation, cardiovascular disease, depression, and premature mortality.[2] Interventions to promote social connectedness in older caregivers have the potential to reduce elevated morbidity and premature mortality and buffer the high caregiving burden in this growing but understudied population. Thus, developing effective treatments to reduce social disconnectedness in older adults is essential, but previous behavioral treatment efforts have had limited success.[3] Mindfulness-based interventions may reduce loneliness in older adults, as demonstrated in a randomized controlled trial of an 8-week mindfulness-based stress reduction program.[4] Another recent study demonstrated the efficacy of a smartphone-based mindfulness training for reducing loneliness and increasing social contact in daily life among adults reporting above average stress;[5] however, smartphone-based mindfulness training interventions have not been tested with older adults, nor have they been tested with caregivers of family members with ADRD. Specifically, prior studies were conducted with healthy adults not necessarily burdened by caregiving; it remains unknown how caregiver stress -- related to competing demands on time and significant loneliness -- may impact the ability to comply with the intervention as well as indicate barriers to efficacy. The current study will follow a similar protocol as the aforementioned randomized controlled trial that used a smartphone-based mindfulness training to address loneliness and social contact.[5]

Overview of the Design: We propose a two-arm RCT: participants will be randomized to (a) smartphone-based MBSR app (Headspace) or (b) active control (breathing app) for 14 days. Loneliness and quality of social interactions will be assessed using end-of-day diary surveys at baseline (T1) and 14-days after randomization (T2).

Specific Aims and Hypotheses:

Aim 1. *To examine the feasibility and acceptability of providing a mobile health mindfulness meditation training intervention to caregivers with significant caregiving stress and loneliness.*

H1a-b: We expect 80% of caregivers screened will report willingness to use the mindfulness app and at least 75% of participants will complete mindfulness training (at least 80% of expected engagements with the app).

Aim 2. *To examine whether a mobile health mindfulness meditation training intervention reduces loneliness and improves quality of social interactions***.**

H2a-b: Participants randomized to mindfulness will demonstrate greater improvements (vs. control) in loneliness (3-item UCLA Loneliness Scale) and quality of social interactions (level of intimacy, involvement and enjoyment during/immediately following a social interaction) via end-of-day diary surveys on REDCap.

Aim 3. *To examine mechanisms whereby mindfulness meditation training reduces loneliness* and improves quality of social interactions.

H3a-b. Participants randomized to mindfulness will demonstrate greater improvements (vs. control) in the mindfulness skills of acceptance through nonjudgment and non-reactivity (Five-Facet Mindfulness Questionnaire [FFMQ]), emotion regulation (Difficulties in Emotion Regulation Scale [DERS]), and self-compassion (Self-Compassion Scale) at follow-up.

H3c (exploratory): Effects of mindfulness skills on loneliness and quality of social interactions will be mediated by improvements in emotion regulation.

II. CHARACTERISTICS OF THE RESEARCH POPULATION

A. Number of subjects. We propose a sample size of 50 older adults, enrolling a total of 63 participants over 13 months, using a 20% attrition rate for enrollment estimates.

B. Gender of subjects. Women will be well-represented in this study. Caregivers in the US are more likely to be women (67%); Caregivers are also more likely to be white, non-Hispanic (67%), while 10% are African American and 8% are Hispanic. Using the 2018 Alzheimer's Disease Facts and Figures along with our local demographic distributions, we plan to target 25% minority and 67% women enrollment. We will use the extensive resources in place to meet our minority recruitment goals (including targeting men for enrollment, as they represent the gender minority in the caregiver population).

C. Age of subjects. All subjects will be 50 years of age or older.

D. Racial and ethnic origin. Subjects will represent the demographics of the local population of subjects at the community organization, as shown in the following table:

Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	2	1	0	0	3
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	4	2	1	1	8
White	30	14	2	1	47
More than One Race	2	1	1	1	5
Total	38	18	4	3	63

E. Inclusion Criteria (assessed at the HARP screening assessment)

1. Age ≥50 years old.
2. English speaking.
3. Caregiver for a community-dwelling family member with ADRD, living with (or in close proximity to) family member with dementia.
4. Elevated caregiving distress: above population mean (>11) on 10-item Perceived Stress Scale (PSS-10) and/or at least moderate caregiver strain (score ≥ 5) on the Modified Caregiver Strain Index (MCSI).
5. Social disconnectedness: UCLA Loneliness Scale: Short Form score of ≥ 5.
6. Access to e-mail in order to complete the e-consent module in REDCap which will be used in this study.

F. Exclusion Criteria (assessed at the HARP screening assessment)

1. Non-English speaking because our primary community partner agency (Lifespan) cannot currently accommodate non-English speaking clients.
2. Those with significant cognitive impairment on a cognitive screening measure at the HARP screening assessment.
3. In order to test the effects of developing mindfulness skills in a novice population, those with a regular systematic mindfulness meditation or related mind-body practice (>2 times per week) will be excluded.

G. Vulnerable Subjects. Individuals who are 50 years of age and older with social risk factors for poor mental and physical health outcomes will be included. The results of this study will inform

future research and clinical interventions aimed at improving mental health treatment for older caregivers.

III. METHODS AND PROCEDURES

A. Design. This study is a two-arm RCT: participants will be randomized to (a) smartphone-based MBSR app (Headspace) or (b) active control (breathing app) for 14 days. Loneliness and quality of social interactions will be assessed using end-of-day diary surveys at baseline (T1) and 14-days after randomization (T2).

The study team will remain vigilant about any further changes that need to be made to study procedures if there are changes to the research reboot guidance found here: https://www.urmc.rochester.edu/coronavirus/coronavirus-research/guidance-for-researchers/human-subjectsresearch.aspx

B. Recruitment. Subjects will be recruited via the IRB approved HARP Population Study (RSRB00068059), a research registry run by the current study's Investigators. In compliance with procedures of the Population Study protocol, subjects of the Population Study consent to allow HARP Population Study researchers to share subjects' identifiable data (both name and contact information) with investigators conducting HARP research at the University of Rochester; in addition, they consent to allow their data collected as part of the Population Study to be included in their research record for subsequent HARP studies they participate in, including the current study. All eligible participants will be given information about this study at their HARP phone screen assessment. Contact information is collected and maintained via the IRB approved HARP Database Study. A brochure describing the study will be given to participants in the HARP Population study (brochure is uploaded in the RSRB online application). Information about the study will also be posted on the webpage of a community organization for older adults, www.beyondthenest.com (content to be displayed is uploaded in the RSRB online application) and the URMC Clinical Trials website. Information about this study will also be provided in the ResearchMatch registry. RSRB-approved study brochures describing the study will be posted at clinics and community organizations serving older adults.

C. Screening. We will utilize a REDCap eligibility screening survey given the relatively low base rate of loneliness, which is our key inclusion criteria, to increase the efficiency of our screening/enrollment process. Information about the study will be provided at the beginning of the survey. Individuals who complete this survey and endorse loneliness (UCLA Loneliness Scale) and at least mild stress will have the option to provide their contact information to share with the Healthy Aging Research Program (HARP) staff to complete the HARP Database (RSRB00067245) and Population Study (RSRB00068059) assessments, which will provide information needed to determine final eligibility for this Mindfulness study, which is part of the Rochester Roybal Center for Social Ties & Aging Research. The link to the eligibility screen will be available via ResearchMatch, the URMC Clinical Trials website, and the URMC website with information about the study.

D. Process of Consent. Eligible participants who are scheduled for a baseline interview (after phone screening) will provide informed consent prior to start of the interview. Consent will be done via telephone or Zoom. E-consent will be done through the REDCap module. An agreed upon security question will be used for the subject to access the E-consent. The informed consent process will be conducted in a manner to facilitate questions from potential study subjects. If a study team member is unable to answer a question, an investigator will be contacted. All questions from potential subjects should be answered prior to signature. Subjects will certify that the information

in the document is correct (which includes their name), and that electronically signing is the equivalent of signing a physical document. Subjects will sign using finger, mouse or stylus. The study coordinator's name and timestamp will be saved in REDCap as their signature. Consents will be stored within REDCap, and a copy will be e-mailed to the subject. No subjects will be involved in research activities unless an investigator or a designated study staff has obtained documentation of legally effective informed consent of the subject. The collection of protected health information (PHI) and questionnaires are considered to be research activities requiring prior documentation of informed consent.

Consent will only be sought under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject. Potential study subjects will be given ample time to read and consider the consent form. All subjects will be reminded of the voluntary nature of study participation. Using the consent form to structure discussion, research personnel will explain the study, its potential benefits and risks, and alternatives, and document the consent process by signature of the subject and the person obtaining consent.

During informed consent procedures, individuals will be told about possible risks and benefits of participation. This will include information that questions asked may cause them to feel uncomfortable or upset. They will be informed that: they may withdraw from an assessment at any time for any reason and receive full reimbursement for that assessment; and, they may withdraw from the research study at any time without negative consequences. Subjects are further informed that we will perform an immediate evaluation of their dangerousness towards self or others should safety concerns arise during assessments or treatment sessions. As well, they will be informed that we will contact their primary care physicians should concerns arise about medical or psychological risk. The staff will assess the participant's understanding of the study using an IRB-approved adapted version of the San Diego Brief Assessment of Capacity to Consent (UBACC), that we have implemented successfully in all of our studies with older adults. If a participant fails to answer all questions correctly, the staff will re-explain the study and then test the participant again. The consent will be an ongoing process during the study. Explanations of the study and verbal consent will be conducted at each data collection. Participants will be reminded that their participation is voluntary and that they can withdraw at any time for any reasons.

E. Randomization. The Center statistician will be responsible for randomizing all participants. To ensure treatment balance, new participants will be sequentially assigned to receive (a) smartphone-based MBSR app (Headspace) or (b) active control (breathing app) using covariate adaptive randomization, which will take into account covariates (i.e., age and gender) and previous assignment of participants. The statistician will then inform the project coordinator of study condition. In all instances, members of the research team responsible for data collection will remain blind to study condition and the statistician will be the only one with access to the randomization schedule.

F. Assessments. Data obtained during the assessments will be obtained specifically for research purposes. Participants will complete the standard STAR baseline and follow-up assessments, with the addition of mindfulness (using the Five-Facet Mindfulness Questionnaire [FFMQ]), emotion regulation (using the Difficulties in Emotion Regulation Scale [DERS]), and Self-Compassion Scale

questionnaires. Loneliness (using the 3-item UCLA Loneliness Scale) and quality of social interactions will be assessed daily using end-of-day diary surveys and all baseline measures will be repeated 3 days after the 14-day intervention.

1. Initial eligibility phone screen: verbal informed consent will be conducted; demographics data will be collected (age, gender, race/ethnicity, education, marital status, living arrangements, caregiver status); and screening instruments will be administered (4-item Perceived Stress Scale, cognitive assessment [Telephone Interview for Cognitive Status; TICS], AUDIT-C, and UCLA Loneliness 3-item scale). Those who do not endorse exclusion criteria for cognition and alcohol abuse will be invited for an initial assessment for further assessment for participation in the study.
2. Initial assessment: A Clinical Research Coordinator (CRC) will conduct the interview via telephone or Zoom. The CRC will explain the study purpose and procedures as well as potential eligibility for pilot studies. The process of obtaining informed consent involves completing procedures to ensure the potential subject has the capacity to provide informed consent (see **C. Process of Consent** for more detail regarding the informed consent). The CRC will obtain E-consent for participation via REDCAP. Subjects will also receive a brief orientation to the end-of-day diary surveys via REDCap. Next, the CRC will administer the STAR Core Battery that assesses domains central to the Center's scientific mission (see below):
    a. Social connectedness: the *UCLA Loneliness Scale*, version 3, has demonstrated excellent internal consistency, test re-test reliability, and construct validity (associations with social support, social network size),[6] including with older adults[6,7] and is sensitive to change;[8] the *Berkman-Syme Social Network Index*[9] measures social integration and has strong predictive validity for morbidity, mortality;[10-12] the *Interpersonal Support Evaluation List*[13] assesses three components of social support: tangible, belonging, and self-esteem; *Unidimensional Relationship Closeness Scale*[14] assesses quality of relationship between participant and family member and has demonstrated valid scores across several relationship types, including spouses and other family members; *PROMIS Social Functioning Computerized Adaptive Tests*[15] which provide age-normed scores of social functioning.
    b. Caregiving: *Montgomery Borgatta Caregiver Burden Scale*[16] assess objective burden, subjective burden and subjective stress burden; *Modified Cornell Services Index* [17] assesses formal & informal health/ social services usage, including caregiver support services; Objective Caregiver Burden subscale of the Caregiver Burden Scale [18] will assess type and extent of current caregiving activities.
    c. Health indicators: *WHO Disability Assessment Schedule* (WHODAS 2.0)[19] measures functioning in 6 domains (cognition, mobility, ADLs, IADLs, social functioning, social participation); *Medical conditions and medications*[20] will be assessed with a checklist of self-reported medical conditions derived from the Minimum Data Set Version 2.0.; *Pittsburgh Sleep Quality Index* (PSQI)[21] differentiates poor from good sleep by assessing domains of sleep quality and disruptions; *Fatigue and pain* will be assessed with PROMIS computer adaptive tests;[15] the *Montreal Cognitive Assessment* (MOCA)[22] has alternate forms to prevent practice effects with repeat administration to assess changes in cognition over time.

d. Well-being indicators: *WHOQOL-BREF*[23] is a 36-item measure of several domains of health related quality of life; *PROMIS Depression and Anxiety Computerized Adaptive Tests* are sensitive to detecting clinical levels of psychological distress;

e. Mechanisms of behavior/social connectedness change. *Interpersonal Needs Questionnaire (INQ)* [24,25] measures unmet psychological needs for belonging and relatedness (as conceptualized by Self-Determination Theory) and has strong construct and predictive validity for negative health outcomes;[24] the *Perceived Competence Scale* and *Perceived Autonomy Scale*[26,27] measure the other psychological needs posited by Self-Determination Theory (autonomy, competence); the *PSS-10*[28] for perceived stress.

f. In addition to STAR Core Battery assessments, participants will also be assessed for mindfulness skills and emotion dysregulation. The *Five-Facet Mindfulness Questionnaire (FFMQ)* measures five factors that represent mindfulness as it is currently conceptualized: observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience; the *Self-Compassion Scale* measures self-compassion in six domains: self-kindness, self-judgment, common humanity, isolation, mindfulness, and over-identified; the *Difficulties in Emotion Regulation Scale (DERS)* measures emotion dysregulation in six domains: nonacceptance of emotional responses, difficulties engaging in goal directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity.

3. End-of-day diary surveys via REDCap: Subjects will complete end-of-day dairy surveys for 3 days pre-intervention and 3 days post-intervention. The diaries will be completed in REDCap and will ask about subjective experience of loneliness (using the 3-item UCLA Loneliness Scale) and quality of social interactions.

4. Follow-up assessments: 3-days after the 14-day intervention, participants will complete assessment measures from the baseline interview and an evaluation regarding their experience of the study via telephone or Zoom with a Clinical Research Coordinator.

G. Description of Interventions

Mindfulness Intervention. Participants randomized to the mindfulness intervention will complete up to 14 days of an individual mobile health mindfulness-based intervention training (dose based on a recent study of smartphone-based mindfulness training that demonstrated efficacy in reducing loneliness). Participants will be allotted up to 2 weeks to complete all sessions. The mindfulness intervention will be delivered via Headspace, a mindfulness-based smartphone app. Subjects will be instructed to engage with the app's first 10 introductory sessions. These sessions are intended to act as a general introduction to mindfulness meditation and incorporate techniques such as breath awareness and body scanning. Each session will be completed daily, has a duration of approximately 10 minutes, and is guided by a former Buddhist monk. Upon completion of the introductory sessions, additional content for the four final sessions will be accessible, including sessions from the Reframing Loneliness course, which teaches on connectivity, and the Kindness course, which teaches compassion toward self and others. Note: The study team is not evaluating the safety or effectiveness of the app, nor is the app FDA approved.

Breathing Control. Participants randomized to the breathing app control intervention will complete up to 14 days of an individual breathing app. Participants will be allotted up to 2 weeks to complete all sessions. The breathing control intervention will be delivered via Headspace. The intervention is designed to be structurally equivalent to the mindfulness-based study intervention on key common

factors of psychosocial interventions: (a) the number of sessions, (b) the length of sessions, and (c) delivery format. Unlike the mindfulness-based intervention, there will be no attempt to teach the participants mindfulness meditation skills. Note: The study team is not evaluating the safety or effectiveness of the app, nor is the app FDA approved.

3. **Subject capacity/comprehension.** The staff will assess the participant's understanding of the study using an IRB-approved adapted version of the San Diego Brief Assessment of Capacity to Consent (UBACC), that we have implemented successfully in all of our studies with older adults. If a participant fails to answer all questions correctly, the staff will re-explain the study and then test the participant again. The consent will be an ongoing process during the study. Explanations of the study and verbal consent will be conducted at each data collection. Participants will be reminded that their participation is voluntary and that they can withdraw at any time for any reasons. Decisionally impaired individuals will not be eligible to participate in this study.
4. **Debriefing procedures.** Not applicable.
5. **Consent forms.** See electronic application.
6. **Documentation of consent.** All signed consent forms will be stored in a locked file in a locked office, separate from other non-identifying subject data. Only study staff will have access to these files. All subjects will receive a signed copy of the consent form for their records.
7. **Costs to the subject.** All study procedures including participation in the mindfulness intervention and control condition are provided at no cost to subjects.
8. **Payment for participation.** Participants will be informed that they will receive $40 per assessment for a total of $80 for study completion. Payment for participation is based on a pro-rated system; thus, partial payment will be given if they do not complete the entire study. Study payments will be made as follows:

- Initial Assessment: $40
- Final Assessment: $40

Total: $80

IV. DATA ANALYSIS

Participants will be characterized at baseline with regards to demographic characteristics, degree of social disconnectedness, caregiver distress, well-being (depressive symptoms, quality of life), cognitive function, and relationship satisfaction with the person they care for. A baseline check of randomness will be conducted for each demographic and outcome variable collected. Mixed-effect linear models (MLMs) will focus on time × condition interactions using end-of-day diary surveys and baseline to follow-up data.

Aim 1. To examine the feasibility and acceptability of providing a mobile health mindfulness meditation training intervention to caregivers with significant caregiving stress and loneliness.

H1a-b: We expect 80% of caregivers screened will report willingness to use the mindfulness app and at least 75% of participants will complete mindfulness training(at least 80% of expected engagements with the app).To assess hypothesis 1, the number of subjects and the number of sessions completed by each will be examined to determine if at least 80% of subjects engage with the app and at least 75% complete a full dose of the intervention.

Aim 2. To examine whether a mobile health mindfulness meditation training intervention reduces loneliness and improves quality of social interactions.

H2a-b: Participants randomized to mindfulness will demonstrate greater improvements (vs. control) in loneliness (3-item UCLA Loneliness Scale) and quality of social interactions (level of intimacy, involvement

and enjoyment during/immediately following a social interaction) via end-of-day diary surveys following procedures by Mote et al.[29] To assess hypothesis 2, multilevel mixed-effect linear models (MLMs) will focus on time × condition interactions in end-of-day survey-sampled loneliness and quality of social interactions outcomes (using all available data).

Aim 3. To examine mechanisms whereby mindfulness meditation training reduces loneliness and improves quality of social interactions. H3a-b. Participants randomized to mindfulness will demonstrate greater improvements (vs. control) in the mindfulness skills of acceptance through nonjudgment and non-reactivity (Five-Facet Mindfulness Questionnaire [FFMQ]), emotion regulation (Difficulties in Emotion Regulation Scale [DERS]), and Self-Compassion Scale at follow-up.

H3c (exploratory): Effects of mindfulness skills on loneliness and quality of social interactions will be mediated by improvements in emotion regulation. To assess hypothesis 3a-b, multilevel mixed-effect linear models (MLMs) will focus on time × condition interactions in mindfulness skills and emotion regulation at follow-up. Exploratory hypothesis 3c examines our belief that the effects of the mindfulness meditation training on loneliness and quality of social interactions are not only direct, but are also indirect, working through emotion regulation. To assess exploratory hypothesis 3c, we will use two simple path analyses using multiple regression, one assessing the link from intervention to emotion regulation to loneliness, and one assessing the link from intervention to emotion regulation quality of social interactions.

V. DATA SAFETY AND DATA MONITORING PLAN

A. Data and Safety Monitoring Plan. The purpose of the Data and Safety Monitoring Plan (DSMP) is to specify the procedures and rationales of the current study to ensure the safety of participants and the validity and integrity of the data. This specifies who will look at the data and review any adverse events, how often, and what they are authorized to do. The use of Data and Safety Monitoring Boards (DSMBs) may be indicated if studies have multiple clinical sites, are blinded (masked), and/or employ particularly high-risk interventions or vulnerable populations. This study on the other hand will be conducted utilizing a low risk intervention in a population of older adults residing independently in the community. Therefore, we have chosen to include a *Data Safety Monitoring Plan Committee* that, while constituted by individuals connected to the study/STAR Center, will systematize monitoring safety issues throughout its duration. The Committee will be led by a designated Safety Officer (SO).

The Principal Investigator (PI) will be responsible for ensuring participants' safety on a daily basis. The DSMP Committee will act in an advisory capacity to the NIA Director and to evaluate the progress of the study, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of trial sites, and other factors that can affect study outcome. The committee will make recommendations to NIA's Director concerning the continuation, modification, or conclusion of the trial.

The Data and Safety Monitoring Committee also provides a data processing, analysis and coordination function. This will be accomplished, in part, at the meetings of the committee with administrative reports by the PI that describe participants screened, enrolled, completed, and discontinued, as well as baseline characteristics of the study population. Given that this is a pilot study, further plans for data processing, analysis, and coordination are not warranted for this study. Interim analyses are not planned given the nature of this study.

B. Data storage and confidentiality. All patient data will be obtained with the written consent of the patient. Information pertaining to individual participants will be released with the patient's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the participant or others. All patient data will be identified by a uniquely coded study number assigned to each participant. Access to the master list of study numbers will be restricted to the PI and the study coordinator. Confidentiality will be further maintained by the storage of "hard copy" data in locked files in a locked office. Access to computerized data is restricted and subject to review by investigators and study coordinators. Publications or presentations will report only cumulative data or

descriptions certain to maintain participants' anonymity. We understand that the these data are subject to the Privacy Act, Freedom of Information Act, and other Federal government rules and regulations, and will comply with those rules and regulations.

IV. RISK/BENEFIT ASSESSMENT

A. Risk category/Potential risk.

1. For research assessments, the primary risk is invasion of **privacy**, breach of **confidentiality** (if safety issues are detected), or **mild reactions of distress or fatigue**. All assessment measures and procedures have been safely used previous research with older adults; no sustained negative effects from assessments are expected, but negative outcomes cannot be ruled out.
2. For the intervention, the primary risk of is **emotional distress or fatigue**. Subjects may think about stressors, negative life events, and caregiving burden/distress. No sustained negative effects are expected, but negative outcomes from behavioral interventions cannot be ruled out. The study PI (Dr. Gallegos) is a licensed clinical psychologist and will be on-call at all times to support participants as needed. Dr. Silva has expertise in suicide in later life and regularly conducts research studies with distressed and suicidal older adults, and will be available to consult with Dr. Gallegos as needed.
3. Regarding alternative interventions, subjects will not be prohibited from seeking out supportive social services, or mental health services (for ethical reasons). If subjects do engage these services, he/she will be followed for the full 3 weeks, with documentation of the nature and extent of that engagement, and evaluation of its impact on the outcomes of interest.

B. Protection against risks.

1. In order to protect the **confidentiality of subject information**, we will take a number of precautions. These include training research interviewers in confidentiality procedures; entry and storage of data using coded identification labels; maintenance of project computers in secure locations with restricted access by enforced password protection; use of HIPAA compliant data management software (REDCAP). Back-ups of all study files will be made daily to allow for recovery of data due to disk failure. All data, including assessment measures, will be obtained with the written consent of the patient. Information pertaining to individual participants will be released with the patient's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the participant or others. All data will be identified by a uniquely coded study number assigned to each participant. Access to the master list of study numbers will be restricted to the PI and the CRC. Confidentiality will be further maintained by the storage of "hard copy" data in locked files in a locked office. Access to computerized data is restricted and subject to review by the PI. Publications or presentations will report only cumulative data or descriptions certain to maintain participants' anonymity. All data collection involving human subjects will be HIPAA compliant. All data involving human subjects will be stripped of any identifiers; the data will be stored in a secure HIPAA compliant program called REDCAP, which manages protected health information in a HIPAA compliant manner.
2. In order to protect subjects' **privacy**, interviews will only be completed with subjects' written consent; subjects will be free to refuse to answer any questions they would prefer to not answer; interviews will be conducted in private settings.
3. Risks associated with **emotional distress or fatigue** will be minimized by employment of research personnel with appropriate backgrounds and experience and work with psychological factors and elderly subjects. The baseline research interview will last approximately two hours in total. Given the length of time involved for this assessment, and concerns regarding subject health and well-being, subjects will be reminded that if they become fatigued, they may terminate the interview at any time, and that the interview can be conducted over multiple sessions as

needed. Research personnel will further be trained to recognize potential signs of fatigue among elderly subjects, and to actively suggest alternative data collection strategies (including telephone-based and mail-in interviews), in order to reduce the possibility of overwhelming study subjects and to ensure completeness of data collection. These strategies have been employed effectively in our Center's current and past research involving older adult populations.

a. During the course of assessment interviews, the CRC will monitor subjects' reactions for signs of distress or fatigue. If necessary, subjects may take breaks from the interview, or complete the interview over several sessions if fatigue becomes a concern.

b. If a subject's safety becomes a concern, the researcher will evaluate the subject's emotional state and safety. If the subject appears distressed, the CRC will briefly attempt to de-escalate the patient's distress. If these measures do not effectively reduce the patient's distress within 10-15 minutes and depending on the severity of the patient's distress, the CRC will call Dr. Gallegos (or the person covering for her), who will maintain a cell phone for this purpose. If neither is available, or if otherwise necessary, intervention will be provided by a clinician with Strong Behavioral Health's Older Adults Clinic, Lazos Fuertes, or by an on-call clinician in the University of Rochester Medical Center Community Mental Health Clinic (CMHC) or Psychiatric Emergency Department.

c. Given that we will be assessing depressive symptoms and subjects may report suicide ideation, the CRC's will be trained in the study's safety protocol for mental distress, suicide risk, and elder abuse, which involves items from the Columbia Suicide Severity Rating Scale and clinical interview. Subjects will be informed that study staff will perform an immediate evaluation of their dangerousness towards self or others should safety concerns arise during assessments or treatment sessions. Subjects will also be informed that their confidentiality may be breached should concerns arise about their dangerousness to self or others. Finally, they will be informed that suspected child abuse will be reported, as mandated by law. Any subject who endorses death or suicidal ideation will be asked additional questions to assess his/her safety. Any endorsements of active suicidal ideation will involve notifying Dr. Gallegos for review of risk and protective factors and consideration of emergency psychiatric services. Dr. Silva has expertise in suicide in later life and regularly conducts research studies with distressed and suicidal older adults, including Spanish speakers. While it is expected (based on prior research) that only a small minority of subjects for the current study will report significant distress (and even fewer suicide ideation or elder abuse), CRC's will be trained in the study's safety protocol and data from each assessment will be reviewed with Dr. Gallegos weekly, or more often if needed. A small minority of participants may experience elder abuse. In the case of suspected elder abuse, subjects will be given an immediate referral to the Elder Abuse Prevention Program (EAPP) of Rochester, which provides crisis intervention services. A phone call will be made to the primary care provider. Any suspected cases of elder abuse will be immediately reviewed with the PI before the CRC ends the assessment.

Situations involving potential imminent dangerousness may involve the use of emergency services and law enforcement authorities. This safety protocol has been used successfully in Dr. Gallegos's prior and on-ongoing studies.

d. The study PI (Dr. Gallegos), who is a licensed clinical psychologist, will be on-call at all times, and will provide weekly (and as needed) supervision to research staff. Dr. Van Orden (Center Co-PI) is a clinical geropsychologist and is experienced in working with older adults, including those experiencing emotional distress, and will be available to consult with Dr. Gallegos as needed.

C. Importance of the knowledge to be gained from the proposed research. There is a pressing public health need to find interventions that reduce loneliness in later life, which is associated with significant

morbidity and mortality among older adults who are caregivers. There are no evidence-based interventions for promoting social connectedness in older adult caregivers. Reducing loneliness and promoting connectedness would significantly improve the lives of older adults who are caregivers by improving well-being and promoting health and longevity. Given the minimal risks associated with the proposed research and the substantial gains both to the individual and older adults more broadly, benefits appear to outweigh the risks.

D. Potential benefits to the subjects. All study subjects will receive a behavioral intervention aimed to increase social connectedness and reduce loneliness – an intervention that targets a significant risk factor for reduced well-being, morbidity and mortality. Thus, the potential benefit to the individual may be significant. Subjects may additionally benefit from participating in research interviews and completing the questionnaire measures, as these assessments provide them with the opportunity to be carefully listened to and comprehensively evaluated. They may further benefit from feelings of altruism connected with participation in research designed to better understand the mental health needs and experiences of community-residing older adults.

E. Alternatives to participation. The alternative to participation in this study is not to participate.

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