# Engage Psychotherapy to Promote Connectedness in Caregivers

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Study Protocol

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**Healthy Aging Research Program (HARP): Engage Coaching Project**

Study Protocol for: Engage Psychotherapy to Promote Connectedness in Caregivers
A Pilot Study for Year One of the Rochester Roybal Center for Social Ties and Aging Research (P30AG064103) and the UR Healthy Aging Research Program (HARP)

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## I. RATIONALE FOR THE STUDY AND SPECIFIC AIMS

**Purpose:** This study asks: "what behavioral strategies are needed to help socially disconnected caregivers with significant barriers to increasing connectedness?" This study uses a mixed methods approach to adapt a brief behavioral intervention—Social Engage psychotherapy—for use with socially disconnected caregivers. The ultimate goal is for Social Engage psychotherapy to be offered as a second step in a stepped care approach for caregivers who do not demonstrate an adequate response to a discussion prioritization tool alone.

**Background:** Older caregivers for family members with Alzheimer's disease or related dementia (ADRD) are at risk for social disconnectedness that impacts health and quality of life. Social connectedness represents an untapped intervention target to improve caregiver well-being and health. Caregivers who report high social connectedness appear to be buffered from high caregiving burden because they perceive more positive aspects of caregiving. Barriers to connectedness among caregivers are numerous, varied, and dynamic. Current caregiver interventions effectively improve outcomes for the family member with dementia and reduce caregiver burden, but do not improve connectedness for the caregiver. Other interventions (e.g., caregiver support groups) have not been tested with regards to connectedness. The evidence base for strategies to promote connectedness is extremely limited. Promising interventions are multifaceted, intensive, and/or involve significant time out of the home, rendering them infeasible for most caregivers. There are no evidence-based interventions for promoting connectedness in older caregivers for individuals with ADRD.

**Overview of the Design:** The current study involves adapting a behavioral intervention for social connectedness —Social Engage part of the Rochester Roybal Center for Social Ties and Aging Research, which is a research center funded by the National Institute on Aging (NIA). This pilot study has been approved by NIA. This study is part of the Healthy Aging Research Program (HARP) of the University of Rochester and will use HARP recruitment infrastructure and procedures. This study is a single-arm clinical trial of Social Engage psychotherapy. We propose to enroll 30 participants for up to 8 weekly individual Social Engage psychotherapy sessions, over up to 3 months. Subjects will be aged 50 and older, and be caregivers for a community-dwelling family member with ADRD, living with (or in close proximity to) the family member with dementia, and experiencing elevated caregiving distress and social disconnectedness.

**Specific Aims & Hypotheses:**
**Aim 1:** *To examine feasibility: are socially disconnected caregivers willing and able to complete Social Engage psychotherapy?*

**H1a:** We expect at least 80% of caregivers screened will report willingness to enroll in Social Engage psychotherapy (based on our previous study of Social Engage with isolated older adults).

**H1b:** We expect at least 75% of participants will complete Social Engage psychotherapy (at least 80% of expected sessions).

**Aim 2:** *To address specific needs of caregivers: what strategies are best suited to addressing barriers to social engagement for caregivers?*

**H2a:** We will systematically track strategies that caregivers and Social Engage therapists utilize to address both structural barriers to social engagement (e.g., lack of time, difficulties leaving the care receiver home alone) and relational barriers (e.g., decreased relationship satisfaction). We will also conduct qualitative interviews with participants at 3 months to learn which strategies they perceive as most helpful.

**Aim 3:** *To examine potential efficacy of Engage by examining satisfaction with the intervention and changes*

*in social connectedness over the course of therapy.*

**H3a:** We will obtain qualitative and quantitative feedback from participants about ways in which Engage helped (or did not help) them increase social connectedness, including assessments of Self-Determination mechanisms of change—autonomy, competence, and relatedness.

**H3b:** We will measure a behavioral indicator of connectedness (quality and quantity of positive social interactions), a psychological indicator of connectedness (loneliness), and indicators of well-being over the course of treatment and at 6-month follow-up to estimate the length of treatment needed for improvement; to estimate the proportion of participants who respond to treatment; and the proportion who maintain gains after treatment (to inform a fully powered, randomized efficacy trial).

## II. CHARACTERISTICS OF THE RESEARCH POPULATION

**a) Number of Subjects:** We will enroll approximately =30 participants, anticipating n=24 will begin the intervention (considering exclusion criteria, interest in the intervention) and n=20 participants will provide follow-up data and complete a full course of Social Engage. Subjects will be caregivers (age 50 or older) for a community-dwelling family member with ADRD, living with (or in close proximity to) the family member with dementia. They will be recruited from the IRB approved Health Aging Research Program (HARP) Population Study (RSRB00068059) (see III-d Recruitment Procedures) and Research Match.

**b) Gender, Age, Racial, and Ethnic Origin 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 proactively recruit minority participants (including targeting men for enrollment, as they represent the gender minority in the caregiver population) using best practices for minority recruitment, including working with providers serving minorities; collaborating with community gatekeepers; tailoring the recruitment materials to the culture and education level in inner city populations.

Our planned recruitment is as follows:

| Racial Categories | Ethnic Categories | | | | Total |
|---|---|---|---|---|---|
| | Not Hispanic or Latino | | Hispanic or Latino | | |
| | Female | Male | Female | Male | |
| American Indian/ Alaska Native | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 4 | 1 | 0 | 0 | 5 |
| White | 13 | 9 | 2 | 0 | 24 |
| More than One Race | 1 | 0 | 0 | 0 | 1 |
| **Total** | 18 | 10 | 2 | 0 | 30 |

**c) Inclusion Criteria** (assessed at the HARP screening assessment):

1. Age ≥ 50 yrs;
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. Endorse elevated caregiving distress as measured by a score of greater than 11 on the 10-item Perceived Stress Scale (PSS-10) and/or a score of 5 or greater on the Modified Caregiver Strain Index (MCSI);
5. Endorse clinically significant loneliness as measured by a score of greater than 6 on the UCLA Loneliness Scale: Short Form.
6. Has access to e-mail in order to complete the e-consent module in REDCap which will be used in this study.

**d) Exclusion Criteria** (assessed at the HARP screening assessment)**:**

1. Primary language is not English;
2. Recent or current psychosis;
3. Significant cognitive impairment on a cognitive screening measure at the HARP screening assessment;
4. Hearing problems that preclude completion of the intervention.

**e) 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 single-arm clinical trial of Social Engage psychotherapy. We will enroll n=30 participants. Participants will complete up to 8 weekly individual Social Engage psychotherapy sessions by Zoom. Participants will be allotted up to 3 months to complete all sessions, a time-frame that allows for two weeks without meeting to address life stressors such as illnesses that may pop up. The first and last session are longer – up to 60 minutes if needed. Middle sessions are shorter (20-45 minutes). Participants will complete follow-up assessments at 3-months (phone/Zoom and online via REDCap) and 6-months (online via REDCap or by phone).

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-subjects-research.aspx

**b) Intervention Setting**: The assessments and intervention will be remote by phone/Zoom/online.

**c) Recruitment Setting and Procedures:** 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 in-person 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 PI's URMC lab webpage (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. 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 Engage Coaching study, which is

part of the Rochester Roybal Center for Social Ties & Aging Research. The link to the eligibility screen will be available via research match, the URMC Clinical Trials website, and the URMC website with information about the study.

**e) Assessment Measures & Administration Schedule:** All baseline measures will be administered as part of screening through the HARP studies (described above). The following list specifies the assessment measures we propose to collect at follow-up assessments, with assessments conducted at both 3 and 6 month follow-up unless otherwise specified:

**Domain 1, Social connectedness**: Loneliness scales (UCLA Loneliness Scale and DeJong Loneliness Scale);;Berkman-Syme Social Network, Unidimensional Relationship Closeness Scale, *PROMIS social functioning* computerized adaptive tests (satisfaction with roles/activities, social isolation, meaning/purpose, companionship, emotional support, instrumental support.

**Domain 2, Caregiving:** *Montgomery Borgatta Caregiver Burden Scale,* Modified Caregiver Strain Index (MCSI), Caregiver Reaction Scale

**Domain 3, Health indicators**: WHODAS, PROMIS computerized adaptive tests of depression, anxiety, fatigue and pain interference; ;Modified Cornell Services Index (only 3 month); Neuropsychiatric Inventory (only 3 month), FAST (only 3 month) Modified Barthel Index (only 3 month), Columbia Suicide Severity Rating Scale (only 3-month).

**Domain 4, Well-being indicators**: *WHOQOL-BREF* is a 36-item measure of several domains of health related quality of life

**Domain 5, Mechanisms of behavior/social connectedness change.** *Interpersonal Needs Questionnaire (INQ)*; the *PSS-10* measures perceived stress.

**Domain 6, Feedback about intervention** Participations will be provided an opportunity to discuss what they liked and did not like about the intervention, including what aspects they found helpful. This part of the 3 month interview will be recorded on Zoom. A short self-administered feedback questionnaire will be completed at 6 month follow-up.

| Session | Objective 1 | Objective 2 | Objective 3 |
|---|---|---|---|
| 1 | Orient to Engage: structure of therapy, session frequency, rationale. | Gather info: Current social network, relationship with person caring for, typical social contact—now and before caregiving; exploration of a "valued life." | Begin first action plan: Brainstorm Social Activity List; teach action plan process with a relatively easy goal |
| 2 | Set agenda & mood/ stress check | Review homework; begin discussion of barriers to social engagement via any barriers experienced completing homework; create barrier list | Create action plan & review expectation for homework |
| 3 | Set agenda & mood/ stress check-in | Review homework; introduce Barrier Strategy 1 (if needed) | Create action plan; discuss doing an extra action plan on own (or use time for integrating barrier strategy) |
| 4 | Set agenda & mood/ stress check-in | Review homework | Create action plan |
| 5 | Set agenda & mood/ stress check-in | Review homework; add Barrier Strategy 2 (if needed) | Create action plan |
| 6 | Set agenda & mood/ stress check-in | Review homework; begin discussion of termination | Create action plan |
| 7 | Set agenda & mood/ stress check-in | Review homework; continue discussion of termination | Create action plan; homework to consider changes made & ways to maintain gains |
| 8 | Set agenda & mood/ stress check-in | Wrapping up: Accomplishments regarding "valued life"; areas to continue to work on, concrete steps to take going forward | Saying goodbye |

Figure 1. Social Engage psychotherapy for caregivers objectives and tasks.

**f) Study Conditions:** This study is a single-arm clinical trial of Social Engage psychotherapy. Dr. Van Orden conducted a study at URMC (K23MH096936) using Social Engage psychotherapy that demonstrated increases in well-being and social engagement for lonely older adults. Social Engage psychotherapy involves psychoeducation on the importance of social connections for health as well as structured goal setting for increasing social connectedness. The study PI will train and supervise study therapists as done in the prior study. Therapists and the PI will work together to devise caregiver specific barrier strategies as needed, such as brief communication skills coaching or education on behavioral issues in dementia. The development and piloting of these new caregiver specific barrier strategies is a key objective of this pilot study. Figure 1 describes the content, objectives, and tasks of each Engage session.

**g) Analytic Procedures:** Participants will be characterized 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. For Aim 1 the number of

subjects and the number of sessions completed by each will be examined to determine if at least 80% of subjects will be willing to start Social Engage and at least 75% complete a full dose of the intervention. Aim 2 is to determine the most useful barrier strategies to use with caregivers. We will tabulate how often each strategy is used within and across participants. Qualitative analyses of interview data from participants at follow-up regarding their perceptions of effective barrier strategies (Aim 2) and effective/ineffective aspects of the therapy in general (Aim 3) will be led by Dr. Norton and follow these procedures: The feedback portion of the 3 month interview will be transcribed verbatim using the method described by Easton and colleagues. A research assistant will review the accuracy of each transcript and correct any errors, note any extended pauses, emotional displays, and/or disruptions (e.g. people leaving the room, telephone calls). The corrected transcript will be de-identified, dated, timed, and entered into the Atlas.ti8.01a data management software program. We will use a phased approach to data analysis. During phase 1 we will use an inductive technique called open coding. Open coding is a process of identifying and labeling emergent ideas in the text, often using the participants' own language. We will then code for pre-specified domains of social connectedness including the structure, function, and quality of caregivers' social connections and their barriers and facilitators. Subsequently, we will develop a coding scheme reflecting both emergent and pre-specified domains. During phase 2 we will code all transcripts with our coding scheme. Finally, during phase 3 we will examine for patterned variation based on high or low scores of social connectedness, first within each group and then across the two groups.

Aim 3 is to obtain evidence for a signal for efficacy with regards to social connectedness. Baseline data from the assessment battery will be used: a behavioral indicator of social connectedness (quality and quantity of positive social interactions), a psychological indicator of connectedness (loneliness), mechanisms of change (autonomy, competence, and relatedness), and indicators of well-being (psychological distress and quality of life). Assessments will be completed at the end of intervention (3 months), and 6-month follow-up. Follow-up data will be used to estimate the length of treatment needed to demonstrate improvement and to estimate the proportion of participants who demonstrate increases in social connectedness by the end of the intervention and the proportion who maintain gains after the intervention. Our hypotheses will be tested with repeated measures ANOVAs with the Stata software package; significant increases support a signal for efficacy.

**h) Data and Safety Monitoring Plan:** See Data and Safety Monitoring Plan document.

**i) Data Storage & Confidentiality:** 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 Dr. Van Orden 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 Dr. Van Orden. 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. Audio-visual recordings of semi-structured interviews will be transcribed and then destroyed to protect the security and confidentiality of identifiable information. In order to protect subjects' **privacy**, audio-visual recordings will only be made 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. If a subject only wants to have audio recordings done, the subject can choose to disable the video function in Zoom or call into Zoom by telephone only. Engage sessions will be recorded for supervision of therapists and to identify strategies that are best suited to addressing barriers to social engagement for caregivers. The data on the recording will be identified only by an ID number. Recordings for the ENGAGE sessions will be uploaded onto UR Box.

## IV. RISK BENEFIT ASSESSMENT

**1. Risk Category:** Minimal risk for all procedures.

**2. Potential Risks:**

- For research assessments—self-report questionnaires and semi-structured interviews—the primary risk is invasion of **privacy** (including because study staff may send email reminders of assessment visits), breach of **confidentiality** (if safety issues are detected), or **mild reactions of distress or fatigue**. Given that assessments and intervention are conducted/provided in the subjects' homes through Zoom/phone/online, others could be present, which risks revealing the subject's participation in the study; subjects will have full discretion in having others present. 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.
- For the intervention, Social Engage psychotherapy, the primary risk of is **emotional distress or fatigue**. Subjects may think about stressors, negative life events, and caregiving burden/distress; they will receive support from the Engage therapist for such experiences. No sustained negative effects are expected, but negative outcomes from behavioral interventions cannot be ruled out. The study PI (Dr. Van Orden) is a licensed clinical psychologist and will provide weekly (and as needed) clinical supervision for Engage psychotherapists. Dr. Van Orden is a clinical geropsychologist and is experienced in working with older adults, including those experiencing emotional distress and will be on-call at all times to support therapists and participants as needed.

**3. Protection Against Risks**

**Informed Consent:** Once a protocol is approved by the IRB, all study team members must read and understand the study protocol, the informed consent form, and the case report forms prior to being involved in the informed consent process. The PI of the protocol will practice the consent process with the consent designee(s) prior to the enrollment of the first subject. PIs will train the study staff to conduct consent by explaining, demonstrating, and observing the consent process until they master the consent process. PIs will randomly check the consent process quarterly and re-train staff as needed.

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 Dr. Van Orden 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 Dr. Van Orden. 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. Audio (or audiovisual) recordings of semi-structured interviews will be transcribed and then destroyed to protect the security and confidentiality of identifiable information. Audio (or audio-visual) recordings of the Engage sessions will be saved and stored on UR Box.

In order to protect subjects' **privacy**, audio-visual recordings will only be made 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. If a subject only wants to have audio recordings done, the subject can disable the video function in Zoom or call into zoom by telephone only.

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 the PI and Co-I's past research involving older adult populations.

- 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.
- 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. Van Orden (or the person covering for her), who will maintain a cell phone for this purpose. If neither is available, or if otherwise necessary, study staff will connect the subject with supports from: the nation-wide area agencies on aging, which provide social services for older adults (via Eldercare Locator, a public service of the U.S. Administration on Aging at 1-800-677-1116 or https://eldercare.acl.gov/), the National Suicide Prevention Hotline (1-800-273-TALK), or by calling 9-1-1 (as the subject's physical location will be confirmed at the beginning of the session).

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. Van Orden for review of risk and protective factors and consideration of emergency psychiatric services. Dr. Van Orden has expertise in suicide in later life and regularly conducts research studies with distressed and suicidal older adults. 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. Van Orden 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, or a similar program in their area, as the nationwide Eldercare Locator provides a national listing of such programs, which are available in every state through the nationwide Area Agencies on Aging—these programs. A phone call may 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 per discussion above. This safety protocol has been used successfully in Dr. Van Orden's prior and on-ongoing studies.

**4. Informed Consent Procedures:**

Informed consent for the study. Eligible participants will provide informed consent prior to entering the study and beginning the intervention. Consent will be done over the phone or through Zoom. Prior to the consent, the study coordinator will call the subject and ask the subject whether they want to use phone or Zoom. E-consent will be done through the REDCap module. The study team will obtain verbal permission to send the eConsent via email. Verbal permission will state: "Because URMC can't control the security of email

messages once we send them, we need your permission to email you. Do you want to receive the link to the eConsent via email?" The permission will be documented. The email will not include PHI.

To verify the subject's identity - the study team will add a security question to answer at the time of accessing the survey/eConsent. This question will be a pre-established security question such as "What is your favorite color?" that is needed to access the eConsent. The responses will be agreed upon by both the study team and the subject during the initial call. The answer will be saved in the subject record for verification later.

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. 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 may 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.

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.

**5. *Confidentiality: Limits and Precautions***: The present study includes a documented plan for the collection, storage, protection and analysis of research data. The key components of this plan include a Certificate of Confidentiality from the Department of Health and Human Services (DHHS), restriction from unauthorized access to identifiable subject data, storage of data to protect against inadvertent loss, and use of appropriate database software tools to maintain integrity of data for subsequent analyses. All research files will be coded using a study identification number. Subject identifying information and PHI will be stored separately from other data collected for this study and will only be accessible by those investigators or staff who have a need to know this information for the purpose of conducting the study. All identifying data will be stored in locked cabinets and locked offices or in password-encrypted files. Access to these files is limited to investigators and support personnel with the need to enter or analyze data.

All research and clinical information obtained is kept confidential unless the subject is an immediate danger to him or herself or to others (Note: clinically relevant but not life threatening information may be shared with outside personnel with subject permission). During crisis situations, this clinical information may be provided to other clinicians (or family members) in order to facilitate appropriate treatment and minimize the risks of self-harm or harm to others. This information may include the subject's clinical diagnosis, psychiatric and medical history, current medication and treatment status, response to psychiatric or substance abuse treatment, financial and social resources, and history of suicidal behavior, if known.

If study personnel identify inappropriate treatment practices by an outside professional (e.g., inappropriate/ dangerous medication combinations given to a vulnerable elder) key study personnel will be consulted and a course of action will be planned that balances subject confidentiality with his or her safety. Normally, consent will be obtained from the subject to speak to the other treating professional and express concerns. If the subject refuses to provide consent to speak with the professional, the degree of danger to the subject will be the primary barometer to determine the appropriate steps.

**6. *Certification of Research Personnel in the Protection of Human Subjects***

In order to ensure appropriate human research knowledge, all study personnel interacting with subjects or with access to subject research will have completed mandatory training in the protection of human research participants per guidelines issued by the U. S. Department of Health and Human Services, Office for Human Research Protections (see http://ohrp.osophs.dhhs.gov/) and per guidelines of the University of Rochester Medical Center. Any additional personnel will complete this training before interacting with study subjects.

Consistent with University of Rochester Research Subjects Review Board (RSRB) policy, all investigators and research staff will complete certification by the RSRB—required completion of a course that contains seven modules dealing with topics such as “Ethics and Federal Regulations,” “Roles and Responsibilities of the Investigator and the Study process,” and “Roles and Responsibilities of Institutions in Human Subjects Research,” among others. The program provides a substantial resource to the investigator for understanding the ethics and regulations governing research with human subjects.

It is also University of Rochester policy that all research and clinical staff who may be in contact with protected health information (PHI) demonstrate a working understanding of the University of Rochester's Notification of Health Policies and Practices form. This information form describes to patients and research subjects the University's policies and procedures regarding PHI, consistent with the federal Health Insurance Portability and Accountability Act (HIPAA) and with other relevant university regulations and local, state, and national legislation. All investigators and research staff will complete an information and training session on HIPAA legislation, the University's Notification of Privacy Practices, and on ethical conduct of research in accordance with this legislation and with University regulations.

**7. 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.

**8. Importance of the Knowledge to be Gained:** 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 adults. 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.

**9. Alternatives to Participation:** 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 6 months, with documentation of the nature and extent of that engagement, and evaluation of its impact on the outcomes of interest.

**10. ClinicalTrials.gov Requirements:** This study will be registered at clinicaltrials.gov

## VII. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

**1. Method of Subject Identification And 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 provided with a study brochure (brochure is uploaded in the rsrb online application). Information about the study will also be posted on the PI's URMC lab webpage (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. 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 included 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 Engage Coaching study, which is part of the Rochester Roybal Center for Social Ties & Aging Research. The link to the eligibility screen will be available via research match, the URMC Clinical Trials website, and the URMC website with information about the study.

**2. Process of Consent:** Consent will be done over the phone or through Zoom. Eligible participants will provide informed consent prior to study start. 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. At the conclusion of the consent process and prior to requesting that they sign the form, all subjects are asked capacity questions prior to signing. 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 may contact their primary care physicians should concerns arise about medical or psychological risk.

**3. Subject Comprehension and Capacity to Consent:** 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. At follow-up assessments, study staff will review relevant parts of the consent form with subjects and will remind subjects that their participation is voluntary and that they can withdraw at any time for any reasons.

**4. Debriefing Procedures:** At the final interview, the CRC will answer any questions subjects have about the study. Given the lack of deception, more formal debriefing procedures are not indicated.

**5. Consent Forms:** See attached.

**6. Documentation of Consent:** Consents will be stored within REDCap, and a copy will be e-mailed to the subject.

**7. Costs to the Subject:** There are no costs to the subject. Parking at URMC will be paid for by the study.

**8. Payment for Participation:** Participants will be paid $60 for an internet-based/phone/Zoom survey follow-up at 3 months and $30 for an internet-based/phone follow-up at 6 months.