Official Title: ‘Connect for Caregivers’ – Developing a Brief Intervention for Social Connectedness

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Study Protocol
'Connect for Caregivers' – Developing a Brief Intervention for Social Connectedness
Principal Investigator –Sally Norton

A Pilot Study for Year One of the
Rochester Roybal Center for Social Ties and Aging Research (P30AG064103)
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## 1. PURPOSE OF STUDY

*Connect for Caregivers* is a mixed method intervention development pilot study. The purpose of the study is to develop and pilot test a single session behavioral intervention to help caregivers gain understanding of the importance of increasing social connectedness, awareness of their personal barriers to connectedness, and knowledge of local resources for promoting connectedness. The specific aims of this mixed method study are:

**Aim 1** To characterize caregivers' understanding of their experiences of social connectedness and of their perceptions of barriers to social connectedness, including which barriers are most common, most problematic, and most difficult to change.

**Aim 2** To use information provided by caregivers (in Aim 1) to develop a card sort discussion prioritization tool (*Connect for Caregivers*) that will systematize and routinize a process whereby caregivers and interventionists can collaboratively identify and prioritize personalized intervention targets for promoting connectedness.

**Aim 3** To investigate whether *Connect for Caregivers* (a card sort discussion prioritization tool combined with personalized education and resources) is associated with a signal for efficacy for changing connectedness.

This submission is for conducting Aim SA3, the final phase of the study, as approved in the original study Protocol.

## 2. BACKGROUND AND RATIONALE

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.

## 3. ADMINISTRATION ORGANIZATION

Caregiver interviews will be conducted in the subject's home or convenient location identified by the subject. Due to the COVID-19 pandemic, part SA2 will be conducted by ZOOM and since we will use video and audio, caregiver subjects will need to have a stable internet connection to participate. The focus group will be conducted via ZOOM.

## 4. STUDY DESIGN

This is a mixed method intervention development study using semi structured interviews (SA 1a and 2) and a focus group (SA 1b) to develop and refine a psycho-behavioral intervention that we will then pilot test (SA 3) using a non-randomized single arm pre-post approach.

**Study outcomes/endpoints**

*Aim 3: To investigate whether Connect for Caregivers—a card sort discussion prioritization tool combined with personalized education and resources—is associated with a signal for efficacy for changing connectedness. We will be conducting AIM SA3 in this phase of the study, as approved in the original study Protocol.*

- Outcome 3a: A **non-random sample of caregivers (n=5)** will complete the Connect for Caregivers tool with a research assessor, including discussing psychoeducational materials on the benefits of social connectedness, completing the card sort to identify personal barriers to connectedness, and reviewing personalized community resources to address those barriers. Using semi-structured interviews, they will provide feedback on the experience of the intervention, including ease of completing it and potential utility as well as the extent to which they experienced the SDT mechanisms of: autonomy, competence, and relatedness while completing the tool and after completing it.
- Outcome 3b: Participants will also complete quantitative measures of their motivation to increase social connectedness via self-report measures that assess mechanisms posited by Self-Determination Theory (i.e., autonomy, competence, relatedness). Participants will complete these measures at their initial screening interview and again after completing the Connect for Caregiver intervention.

## 5. SUBJECT POPULATION

We will enroll approximately **5 subjects**, who are **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. Caregivers will be recruited from the IRB approved

Health Aging Research Program (HARP) Population Study (RSRB00068059) (see III-d Recruitment Procedures). Care managers will be recruited from Lifespan of Rochester.

**Gender, Age, Racial, and Ethnic Origin of Subjects:**
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.

Procedures for assignment to a study group: Specific Aims 1 and 2 are descriptive. For Aim 3, all subjects will receive the intervention. Aim 3 is a single-arm pilot of the newly developed intervention, *Connect for Caregivers*. For Aim SA3, the originally approved N of 5 subjects will be enrolled. No additional subjects will be enrolled.

## 6. INCLUSION AND EXCLUSION CRITERIA

Caregiver Inclusion criteria (**assessed at the HARP Population Study RSRB00068059, screening assessment**):
1) Caregiver (age 50 or older) for a community-dwelling family member with ADRD, living with (or in close proximity to) family member with dementia.
2) 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).
3) Social connectedness: **UCLA Loneliness Scale: Short Form score of equal to or greater than 6 (n=10; Short Form score of 3-5, n=10)**.
4) Able to provide informed consent to participate in the research study.
5) For phase SA2, a stable internet connection for using Zoom video and audio.

Caregiver Exclusion criteria (**assessed at the HARP screening assessment**):
1) Non English speakers because our primary community partner agency (Lifespan) cannot currently accommodate non-English speaking clients.
2) Current problem drinking on the AUDIT-C (score of 5 or greater indicating exclusion).
3) Current non-alcohol psychoactive substance abuse (MINI Neuropsychiatric Interview), psychotic disorders (current and lifetime, MINI), bipolar disorder (MINI), and current mood disorder with psychotic features (MINI).
4) Significant cognitive impairment (MOCA <22) and those with hearing problems that preclude completion of interviews will be excluded.

**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.

## 7. RECRUITMENT METHODS

**Caregiver** 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, at their in-person screening visit and given information about the study.

## 8. CONSENT PROCESS

**Caregiver Consent**: Eligible subjects who have agreed to have their contact information shared will be contacted by the project coordinator and then scheduled for their semi-structured interview. We are requesting a waiver of documentation of consent for the caregivers because the research is no greater than minimal risk and the semi-structured interview questions will be addressing a topic where written consent is not normally required. The waiver won't affect the rights and welfare of the subjects. Eligible subjects will have an opportunity to review the information letter with the interviewer and ask questions and have their questions answered to their satisfaction prior to the start of their semi-structured interview. The process of reviewing the information letter 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 the interviewer initiating the semi-structured interview. All subjects will receive a copy of the study information letter. No subjects will be involved in research activities unless an investigator or a designated study staff member has completed a thorough review of the information letter with the subject.

The information that is given to the subject shall be in language understandable to the subject. Potential study subjects will be given ample time to read and consider the information letter. All subjects will be reminded of the voluntary nature of study participation. Research personnel will explain the study, the voluntary nature of participation, the study's potential benefits and risks, and alternatives. An explanation of risks will include information that questions asked may cause subjects to feel uncomfortable or upset. They will be informed that they may withdraw from the study at any time for any reason without negative consequences and receive full reimbursement for the study. Consent will be obtained during Aim SA3 in the same manner as was done under previously approved Aims SA1 and SA2. We are requesting a waiver of documentation of consent for caregivers who enroll in SA3 because the research is no greater than minimal risk and the interview questions will be addressing a topic where written consent is not normally required. The waiver won't affect the rights and welfare of the subjects.

## 9. STUDY PROCEDURES

**Caregiver Subjects:** The card sort intervention will be conducted by a trained research assistant (RA). The intervention will be conducted via ZOOM, audio-recorded, and typically last between 45-60 minutes. Interview questions will focus on (1) how participants characterize social connectedness and activities they use to connect, (2) social connections that are important/meaningful to them, (3) what makes social connections easier and more difficult (including barriers), (4) how their social connections may have changed with the caregiver role, (5) how or whether they prioritize social connectedness in their day to day lives, and (6) the advice they would give to new caregivers about maintaining or improving social connections. We will use a laddered technique with early questions designed to be minimally intrusive and deliberately broad to allow participants to focus on the experiences of social connection important to them. Later questions will be built off the earlier questions and probe for detail and specific examples of participants' unique experiences with social connectedness. The semi-structured interviews will be audio recorded so that the full conversation can be transcribed for later analysis, and subjects will be informed of this before discussion begins. No identifying information (for example, subject names, or other details shared during the discussion) will be included in the transcript. The audio recording will be transferred from the recording device to a secure computer in the School of Nursing, after which the recording will be deleted from the recording device. The de-identified electronic version of the transcript will remain on the School of Nursing's secure computer where it will be accessible only to the study PI and project team members. For Aim SA3, new measures will be used and are based on the work completed in AIMS SA1 and SA2.

**Caregiver subjects participating in SA3:** Questions included in the last few slides of the Power Point presentation of the card sort tool will be read to the participants, and individual semi structured interviews will also be conducted. The questions in the Power Point presentation of the card sort tool and the semi-structured interviews will be conducted by a research assistant (RA) trained in qualitative interviewing techniques. A second research assistant may also join the call for training purposes. Because the interviews will be recorded using Zoom video and audio, subjects will need to have a stable internet connection to participate.

## 10. AUDIO/VIDEO RECORDINGS

We will use audio recorders and Zoom which are HIPPA-compliant and URMC-approved. The audio files will be uploaded onto a secure database within the School of Nursing usually within 24 hours (occasionally interviews occurring off site on a Friday afternoon will be uploaded on Monday morning). The audio recordings will be transcribed and the transcripts deidentified. Audio recordings will then be used to verify the transcription accuracy. Audio recordings will be archived with a unique identifier for linkage to the other data and will be kept for 3 years. It is occasionally helpful during data analysis to listen to the original audio recording to verify the intent of the speaker

(e.g., para linguistic cues of humor, sarcasm, or emotion that are not contained in the transcription). The archived recordings will be housed on a University of Rochester School of Nursing firewalled, password-protected, and HIPAA compliant server and in BOX which is URMC-approved. Unique identifiers will be used to maintain future linkage between the archived conversations and the Analytic File.

## 11. RISKS TO SUBJECTS

**Potential risks to subjects: minimal risk for all procedures.**
For research assessments—self-report questionnaires and semi-structured interviews—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. For Aim SA3, we will minimize potential risks to subjects by having the trained interventionists report to the PI any concerns that may arise during administration of any of the measures.

Private identifiable information collection: Study coordinators and research team members will have access to individually identifiable private information about human subjects.

**For the intervention,** Connect for Caregivers, 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 interventionist for such experiences. No sustained negative effects are expected, but negative outcomes from behavioral interventions cannot be ruled out. The study PI (Dr. Norton) will provide weekly (and as needed) supervision. In addition, Dr. Van Orden (Co-I) is a clinical geropsychologist and is experienced in working with older adults, including those experiencing emotional distress and will available as needed.

Regarding alternative interventions, subjects will not be prohibited from seeking out supportive social services, or mental health services (for ethical reasons).

## 12. POTENTIAL BENEFITS TO SUBJECTS

Caregiver subjects *might* find identifying their own barriers and facilitators to social connection helpful. 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. There are no other anticipated benefits.

## 13. COSTS FOR PARTICIPATION

None anticipated. The location of the caregiver interviews will be by ZOOM due to COVID-19 safety guidelines. The location for the care manager focus group will be via ZOOM.

## 14. PAYMENT FOR PARTICIPATION

Each subject will be paid $20 by check for their participation in each of the three parts of SA3, for a maximum total of $60 per subject..

## 15. SUBJECT WITHDRAWALS

We do not anticipate any circumstances under which participants will be withdrawn by the investigator. Subjects are free to withdraw at any time without negative consequences. Subjects may also refuse to answer any individual questions.

If a subject voluntarily withdraws from the study we will note the reason. We will use the data already collected unless the subject indicates they want the data destroyed. In the event of the latter, subjects who withdraw from the study will be replaced.

## 16. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

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 subject. Information pertaining to individual subjects will be released with the subject's informed and written consent only, except in unusual cases where withholding the information might pose a serious risk or danger to the subject or others. All data will be identified by a uniquely coded study number assigned to each subject. Access to the master list of study numbers will be restricted to Dr. Norton 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. Norton. 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. Audio recording devices will be kept on the person of the study interviewer who will return immediately to the School of Nursing with audio recorder after the interview has been completed. The audio recording will be immediately uploaded to the School of Nursing secure server, and once the upload is complete, the recording will immediately be deleted from the recording device. Since two recording devices are used to insure protection from any unexpected technical problems, both recording devices will have the recordings deleted as soon as uploads are complete after each interview. 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 recordings of semi-structured interviews will be transcribed and then kept for three years

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 the semi-structured interviews, the researcher 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.

## 17. DATA / SAMPLE STORAGE FOR FUTURE USE

Not applicable

## 18. DATA AND SAFETY MONITORING PLAN

Attached

## 19. STATISTICAL ANALYSIS PLAN

Testing the 'Connect for Caregivers' discussion prioritization tool: Aim 3 involves a pilot test of the Connect for Caregivers discussion prioritization tool with a sample of caregivers who report disconnectedness (n=5). Caregivers will receive the psychoeducation materials on connectedness (delivered by research staff), complete the card sort task to identify personal barriers to connectedness, and received personalized community resources to address their identified barriers to connectedness. Using the methodology described in Aim 1 for semi-structured interviews, caregivers will provide feedback on the experience of the intervention, including ease of completing it and potential utility. Participants will also complete quantitative measures of their motivation to increase social connectedness via self-report measures that were developed to test mechanisms posited by Self-Determination Theory that we have used with success in prior studies with social connectedness interventions (i.e., Perceived Competence Scale and Perceived Autonomy Scale). Participants will complete these measures at their initial screening interview (as described in the STAR Core Battery above) and again after completing the Connect for Caregiver intervention. We will use descriptive statistics to compare changes in mean scores pre and post completion of the tool.