The Getting Active Project/HOPE Project (R01AG054457)

NCT03343483

Study Protocol

4/4/2019

Study Protocol Addendum

2/9/2022

HELPING OLDER PEOPLE ENGAGE (HOPE):
A Randomized Trial of Volunteering to Reduce Loneliness in Later Life
Study Protocol for R01AG054457
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I. RATIONALE FOR THE STUDY AND SPECIFIC AIMS

Purpose: With the long-term goal of improving quality of life and health in later life, the purpose of this study is to examine whether a social volunteering program reduces loneliness and improves quality of life among lonely older adults (age 60 and older).

Background: Older adults who are lonely carry increased risk for reduced quality of life,[1] morbidity,[2-16] and mortality.[2,7,8,17,18] The risk of premature mortality related to loneliness is at least as large as the risks arising from such factors as obesity, physical inactivity, alcohol misuse, and smoking.[17] Volunteering is a promising intervention for reducing loneliness, in part because it is associated with improvements in three correlates of loneliness—perceptions of usefulness,[19] social engagement,[20-22] and social support.[23-26] These three constructs may function as mechanisms whereby volunteering reduces loneliness in later life. Although volunteering has numerous documented health benefits for older adults, it has never been examined as an intervention to improve social well-being. The Helping Older People Engage (HOPE) project will address this limitation of the literature.

Overview of the Design: We propose to compare the effect of a Senior Corps volunteering intervention versus self-guided life review control on loneliness in older adults. We will randomly assign lonely older adults (150 women, 150 men) to 12 months of either: a *flexible social volunteering program*, or an *active control intervention with a self-guided program of life review*. Life review is a reasonable active control because it is intellectually stimulating (also true of volunteering) but its social component is negligible (unlike volunteering). Subjects will be aged 60 and older and have sufficient cognitive and physical capacity to function as volunteers, consistent with Senior Corps requirements.

Specific Aims & Hypotheses:

Aim 1: *To examine the effect of volunteering on loneliness and quality of life.*

H1: Older adults randomized to volunteering (vs. control) will report lower loneliness (H1a; UCLA Loneliness Scale)[27] and greater quality of life (H1b; WHOQOL Scale)[28] at 3, 6, 9, and 12 months.

Aim 2: *To examine increased social engagement, perceived usefulness, and perceived social support as mechanisms for reducing loneliness.*

H2: Older adults randomized to volunteering (vs. control) will report greater social engagement (H2a), perceived usefulness (H2b), and perceived social support (H2c) at 6 months, which will account for the effects on reduced loneliness at 12 months.

Aim 3: *To examine conditions under which volunteering is most effective at reducing loneliness.*

H3: The effect of volunteering vs. control on loneliness will increase with greater *quantity* (H3a; hours per month) and *satisfaction* (H3b).

H4 (exploratory): Given that functional impairment impacts all proposed mechanisms, the effect of volunteering vs. control on loneliness will be strongest for those with less functional impairment at baseline.

IMPACT: *National infrastructure for volunteering programs for older adults—The Senior Corps—ensures that volunteering is* ***highly scalable****. Dissemination and scaling up efforts will involve connecting primary care patients and aging services clients who are lonely with The Senior Corps, which we have shown to be feasible in our companion study, The Senior Connection. Existing infrastructure will make it possible to engage a large proportion of lonely older adults in volunteering, thereby reducing loneliness, improving well-being, and promoting health.*

II. CHARACTERISTICS OF THE RESEARCH POPULATION

a) Number of Subjects: The study will recruit and enroll 330 subjects into the study using the procedures described below. The target number of randomized subjects is n=150 in each group; in our experience recruiting for similar studies, thus far, 10% of those enrolled are either not eligible or not willing to be randomized, thus we must enroll up to 330 subjects to reach our target number of randomized subjects. After providing informed consent and completing a baseline assessment, subjects will be randomized to receive either the volunteering intervention (n=approximately 150), or the control life review intervention (n= approximately 150.) Subjects will be community dwelling older adults (age 60 or older) and will be recruited from primary care practices enrolled in the Greater Rochester Practice-Based Research Network (GR-PBRN). Recruitment will also be conducted via in-person in PCP offices and direct referral as well as through advertisements, flyers, informational sessions and referrals from the HARP database study (RSRB 67245).

b) Gender, Age, Racial, and Ethnic Origin of Subjects: The GR-PBRN serves approximately 30% of adults in Monroe County and is generally representative of the population of Monroe County. Although we propose to recruit subjects from within the Greater Rochester Practice-Based Research Network (as well as outside sources if needed), we anticipate that our study will include subjects representative of the current Greater Rochester Practice-Based Research Network (GR-PBRN) client mix. That distribution is provided in the Targeted/Planned Enrollment Table below. We intend to purposefully select practices, rather than approach them in a random order, so that we can assure the sample is generally representative of the race/ethnicity of the entire network (i.e., 78% White, 14% African American, 3% Hispanic). We plan to enroll an equal number of men and women. All subjects will be 60 years or older.

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
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	23	9		2	1					35
White	135	154		2	0					291
More than One Race	1	0		0	0					1
Unknown or Not Reported										
Total	161	164		4	1					330

c) Inclusion Criteria: age ≥ 60 yrs; English speaking; endorse clinically significant loneliness, as measured by a score of 6 or greater on the 3-item UCLA Loneliness Scale during an initial phone screen; a score of 2 errors or fewer on the 6-item screener (a brief cognitive functioning scale) in the initial phone screen; ability to supply their own transportation (or have alternate transportation services, including the city bus or services such as Liftline), which are Senior Corps and Lifespan requirements for participation. Subjects will have sufficient cognitive functioning to provide informed consent and to understand the study requirements and procedures (additional details below).

d) Exclusion Criteria: presentation at screening and the baseline interview with any of the following: currently volunteering through Lifespan's Retired & Senior Volunteer Program (RSVP), current problem drinking, psychosis, significant cognitive impairment (MOCA<22), illiteracy, felony conviction (via self-

report, as this a requirement of Lifespan, which runs the volunteering intervention), and hearing or other problems that preclude engagement as a volunteer.

Other inclusion/exclusion considerations are as follows: 1) We will restrict subjects to those who can speak *English* because the agency that offers the volunteer program (Lifespan) cannot accommodate non-English speaking volunteers at this time due to training and supervision needs; 2) given that our active control condition involves reading and writing, illiteracy is an exclusion criterion; 3) subjects will **not** be required to cease on-going *volunteer activities* (for ethical reasons). Subjects will be asked to refrain from initiating *new* long-term volunteer activities during their 12 months of involvement with the study (one-time only activities are allowed as these are unlikely to foster social connections). We believe this constraint is ethically sound because subjects are permitted to continue current volunteer roles and combined with the fact that abstaining from new volunteering will not expose subjects to risk. Further, subjects assigned to control will be told they will be connected with our community's Senior Corps program at the end of their study involvement if they choose. Throughout the study, we will assess for "dose" of both study and out-of-study volunteer and informal caregiving activities, and co-vary for this factor in the unlikely event that differences emerge across conditions.

e) Vulnerable Subjects: Individuals who are 60 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 and improving mental health treatment for older adults.

III. METHODS AND PROCEDURES

a) Design: The design is a randomized controlled trial. Community dwelling older adults (n=300) will be randomly assigned to either the volunteering condition (volunteering) or self-guided life review condition (life-review). Those subjects assigned to volunteering will volunteer through Senior Corps by participating in social volunteer assignments offered by RSVP as part of their standard process for placing volunteers. Those subjects assigned to life review will complete a series of self-guided (with minimal email support) life review writing experiences over 12 months. All subjects will receive repeated assessments over the course of the study (baseline, 3, 6, 9, 12 months). The 3 and 9 month assessments will be online/mail at home or in-person.

b) Intervention Setting: Those randomly assigned to the volunteering condition will receive the intervention at Lifespan as well as Lifespan volunteer placements in the community per standard RSVP policy and procedures. Those randomly assigned to the life review condition will receive the intervention via the phone (for training) and their homes via email/mail.

c) Recruitment Setting: Subjects will be recruited from the Greater Rochester Practice Based Research Network. The GR-PBRN is a network of primary care practices coordinated by the University of Rochester's Clinical Translational Science Institute to provide access to subjects and community-based practices for research. The 31 family medicine and internal medicine practices that constitute the network care for approximately 217,000 patients, of which approximately 50,000 are over age 60 and therefore eligible for initial screening for the study.

Having received prior approval for the study from the GR-PBRN executive committee (see attached Letter of Support), we will approach individual practices for their permission to contact patients on their rolls who are ages 60 years and over. **These recruitment procedures were used successfully for our prior studies—Social Connections and Healthy Aging (The Senior Connection) and Aging Well and Social Connections (Engage).** We intend to purposefully select practices, rather than approaching them in a random order, so that we can assure the sample is generally representative of the race/ethnicity of the entire network (i.e., 78% White, 14% African American, 3% Hispanic.) Practices will be added sequentially until sufficient subjects have been recruited into the study.

In addition, flyers, brochures, advertisements, Facebook and attendance at health fairs and information sessions will be used to recruit subjects from the community. We will also be recruiting through referrals from the HARP database study (RSRB 67245).

d) Recruitment Procedures:

- Stage 1 - Recruitment
- Strategy 1 - Informational letters:
  - 1.A. After obtaining approval from a given practice, the study coordinator will perform a (secure) data request for patient names, addresses, and phone numbers for those over age 60 in that practice. The data request will occur via the URMC CTSI Research Data Request procedures and will only involve patients within the covered entity. The research coordinator will review and clean the data on a secure device with enforced password protection. He or she will then give a designee from the practice the opportunity to review the list and exclude patients as needed. These letters, prepared by University Mail Services, will describe the study, indicate that the letter is sent on behalf of the research team, and invite those who may be interested to call research staff. These letters will state that participation in the study is entirely voluntary, and that participation or non-participation will not influence one's medical care. Letters may be sent to the same practices again after at least a year. Patients' interests and eligibility may change after a period of time as well as new patients may now be included. Interested patients will contact the research staff and Stage 2 Phone Screening will be completed (see below).
  - 1.B. The study coordinator will perform a (secure) data request for patient names, addresses, and phone numbers for those over age 60. The data request will occur via the URMC CTSI Research Data Request procedures and will only involve patients within the covered entity. The research coordinator will review and clean the data on a secure device with enforced password protection. These letters, prepared by University Mail Services, will introduce the study including a brochure. The letter will indicate it is sent by the PI, and invite those who may be interested to call research staff. These letters will state that participation in the study is entirely voluntary, and that participation or non-participation will not influence one's medical care. Letters may be sent again after at least a year. Patients' interests and eligibility may change after a period of time as well as new patients may now be included. Interested patients will contact the research staff and Stage 2 Phone Screening will be completed (see below).

- Strategy 2 - Flyers and advertisements: Approved flyers and advertisements will be used to recruit interested individuals. The flyers and advertisements invite interested individuals to call or e-mail the research staff. Individuals will contact the research staff and Stage 2 Phone Screening will be completed (see below). Advertisements will be used in a variety of places, including newspapers, community periodicals and magazines. Lifespan will also post the advertisement on their Facebook page.
- Strategy 3 - HARP database study (RSRB 67245): Those who are eligible and interested will be given a brochure regarding the HOPE project. They will be told research staff will contact them. The contact information will be given to the coordinator. The coordinator will contact interested individuals and complete Stage 2 Phone Screening.
- Strategy 4 : Primary care office recruitment:
  - A study staff member, identified by their UR name tag, will introduce him or herself to older adults in the waiting rooms of participating primary care practices, show them the study brochure and questionnaire, and ask if they have an appointment that day. For individuals who respond that they do indeed have an appointment, the study staff member will explain that we are approaching everyone who is 60 or older (and who has an appointment) with an opportunity to hear more about a study. The

staff member will say that "the office is cooperating with the study and your doctor has asked us to hand this information out about it directly to their patients who may qualify." The brochure will briefly explain the study. With assurances that participation is voluntary, it will include a brief questionnaire with initial screening questions, with instructions that if the subject is interested in completing the survey, he/she should approach the study personnel seating in the waiting room with a sign denoting, “HOPE Project.” Due to time constraints, the questionnaire does not contain all screening questions for the study.

- Individuals interested in participating will then be taken to a private part of the waiting room and provided with a brief description of the study, encouraged to ask questions, reminded that participation is voluntary, and asked to complete the form. We will ask them to only complete the survey once. The questionnaire will be completed with research staff in a quiet, private area of the waiting room. Those who screen positive to the screening questions (meet initial inclusion criteria), and who give verbal permission to have research staff call them with additional information about the study will then be invited to provide their name and contact information. They will be told that study personnel may contact them to provide additional information about the study and conduct the remaining screening questions to assess eligibility. Due to time constraints, we are not planning to assess all screening questions in-office. Participants will provide verbal permission for the telephone contact (see “in office script” for exact wording) and also verbally acknowledge that by providing their contact information they agree to be contacted by phone by study personnel. No name or other contact information is gathered until the patient is determined to meet initial inclusion criteria and to be willing to be called with additional information. These patients will then be provided with a brief brochure that explains the name of the study and relevant names of key study personnel who will be contacting them. Research staff will contact the interested individuals and conduct the remaining screening questions.
- Participants who do not screen as positive on the initial inclusion criteria questions on the screening form will be thanked for their interest. No name or contact information will be collected for these individuals.

- Strategy 5: Direct referral
  - Care managers and physicians at participating practices will have the option of telling subjects about the project by handing out the approved informational letter and suggesting patients call the study coordinator to learn more about the project.
  - The principal investigator has refined this recruitment method based on her experience with similar studies. Recruitment will involve identification of potential patients (of physicians who have agreed to participate) through coordination with the practice scheduler or the program i2b2; potential patients will be patients 60 or older without diagnoses of dementia, and scheduled within the next week to see his/her PCP. The scheduler will share dates, times, and locations for appointments that meet eligibility criteria; researchers will not have access to names of potentially eligible patients. Research staff will share with the physician the appointment times for which potentially eligible patients are being seen; the physician will thus be prompted to share information about the study with potentially eligible patients. The physician will emphasize to the patient that research staff are not aware of the patient’s name and if they decline to learn more about the study, their information will not be released to researchers. If the patient is interested in learning more about the study and gives permission, study staff will join the physician at the end of the visit to share information about the study and conduct the initial screening (if the patient is willing). Due to time constraints, the questionnaire does not contain all screening questions. Research staff will only join the visit if the physician indicates the patient has agreed to this. Those who screen positive to the screening questions (meet initial inclusion criteria), and who give verbal permission to have research staff call them with additional information about the study will then be invited to provide their name and contact information. They will be told that study personnel may contact them to provide additional information about the study and conduct additional screening questions to assess eligibility. Participants will provide verbal permission for the telephone contact and also verbally acknowledge that by providing their contact

information they agree to be contacted by phone by study personnel. Research staff will contact the interested individuals and conduct the remaining screening questions.

- Participants who do not screen as positive on the initial inclusion criteria questions on the screening form will be thanked for their interest. No name or contact information will be collected for these individuals.

- Strategy 6: Health Fairs

  - Study Staff members will attend local health fairs to provide information and recruit interested individuals. Interested individuals will approach study staff members at their table/booth. Brochures/bookmarks will be available for individuals to take with them. Study staff will ask if they would like to hear more about the study and if so, they will explain the study. If individuals are interested and time allows, study staff can ask the screening questions. If a subject is eligible, the staff member can set up a baseline appointment. If an individual does not have time for the full screening, study staff will give interested individuals a brief questionnaire with initial screening questions, with instructions that if the person is interested in completing the survey, he/she can complete the survey and return it to the staff member.

  - Those who screen positive to the screening questions (meet initial inclusion criteria), and who give verbal permission to have research staff call them with additional information about the study will then be invited to provide their name and contact information. They will be told that study personnel may contact them to provide additional information about the study and conduct the remaining screening questions to assess eligibility. Participants will provide verbal permission for the telephone contact (see “in office script” for exact wording) and also verbally acknowledge that by providing their contact information they agree to be contacted by phone by study personnel. No name or other contact information is gathered until the patient is determined to meet initial inclusion criteria and to be willing to be called with additional information. These people will then be provided with a brief brochure that explains the name of the study and relevant names of key study personnel who will be contacting them. Research staff will contact the interested individuals and conduct the remaining screening questions.

  - Participants who do not screen as positive on the initial inclusion criteria questions on the screening form will be thanked for their interest. No name or contact information will be collected for these individuals.

- Strategy 7: Informational Sessions

  - A study staff member will provide informational sessions at the medical center or community facilities, such as local senior centers/libraries/senior living communities/community organizations/etc that have agreed/invited us to speak about our research study. New individuals as well as previously screened/eligible individuals will be invited to attend. The study staff member will give a brief presentation about the study to interested individuals. If individuals are interested and time allows, study staff can ask the screening questions (for those not previously screened). If a subject is eligible, the staff member can set up a baseline appointment. If an individual does not have time for the full screening, study staff will give interested individuals a brief questionnaire with initial screening questions, with instructions that if the person is interested in completing the survey, he/she can complete the survey and return it to the staff member.

  - Those who screen positive to the screening questions (meet initial inclusion criteria), and who give verbal permission to have research staff call them with additional information about the study will then be invited to provide their name and contact information. They will be told that study personnel may contact them to provide additional information about the study and conduct the remaining screening questions to assess eligibility. Participants will provide verbal permission for the telephone contact (see “in office script” for exact wording) and also verbally acknowledge that by providing their contact information they agree to be contacted by phone by study personnel. No name or other contact information is gathered until the patient is determined to meet initial inclusion criteria and to be willing

to be called with additional information. These people will then be provided with a brief brochure that explains the name of the study and relevant names of key study personnel who will be contacting them. Research staff will contact the interested individuals and conduct the remaining screening questions.

- Participants who do not screen as positive on the initial inclusion criteria questions on the screening form will be thanked for their interest. No name or contact information will be collected for these individuals.

- Strategy 8: Facebook
  - We will use social media to recruit individuals from Facebook. A community Facebook page for "The Hope Lab" will be created to provide potential participants with information about the study and to facilitate communication. A screenshot of this page have been submitted along with sample unpublished advertisements/posts. Specifically, screenshots of unpublished Facebook advertisements have been submitted, and additional advertisements will be created and submitted as amendments. We will run 6 ads at a time to recruit participants. The ads will link participants to the Facebook page which will provide information about how to participate in research and provides a means to update potential participants about informational sessions and previous work the lab has done. We will also post information (date/time/location) regarding any information sessions we will be having. Potential participants will be able to send the research team inquiries about the study via email and phone, and the account will be monitored weekly. Subjects will be screened as per Phone screening below once they contact research staff and are interested. Facebook will only be used as a recruitment method. We have disabled posts by other people on the community page timeline, but they can contact the page privately. Comments on facebook ads will be monitored daily while they are running.
  - Stage 2: Phone Screening
  - Potential subjects will call and speak to research staff or leave a message with their name and phone number on the secure URMC voicemail system. When speaking with potential subjects, research staff will obtain verbal permission for screening (the script/verbal consent is uploaded in the application). During the verbal consent process, research staff will explain the main points of the study and ask the older adult if he or she might be interested in the study. If the older adult is interested in the study, research staff will obtain verbal consent and then conduct a brief eligibility phone screen (including the UCLA 3-item loneliness scale and 6-item screener), answer any questions he or she has about the study, and set up a time for the baseline interview (at a URMC office). If the older adult is not interested, research staff will thank him/her. Names and contact information will not be kept for those who are ineligible or not interested. Those who are ineligible or not interested will be informed that they may receive a study letter in the future (not sooner than a year) in case interests and eligibility may change.

  - Stage 3: In-person eligibility and baseline interview: A study coordinator (SC) will conduct the baseline interview. First, the SC will explain the study and obtain written, informed consent for the subject to participate. The process of obtaining informed consent also involves completing procedures to ensure the potential subject has the capacity to provide informed consent (see document "Determination of Capacity for Informed Consent). These procedures involve asking the potential subject a series of questions to ensure they understand the purpose of the study as well as risks and benefits, and the fact that participation is voluntary. These procedures are described in detail below in the section on "Informed Consent Procedures" (p. 13). It is at this point in the process that the person is considered to be an identified subject in the study (i.e., enrolled). Our exclusionary screens will be completed. Next, the SC will explain the need to interview the subject *alone* (to assure unbiased responses). The SC will then administer an additional set of baseline research measures that document standard demographic information; social and financial resources; physical health (providers, pain assessment, assistive devices), functioning (ADL/IADL ratings), well-being,

depression, anxiety, suicide risk, and social connectedness. If during the interview, research staff suspects elder abuse or severe neglect, or identifies unsafe living conditions (lack of heat in the winter months), the SC will provide the subject with information about care management services and the option of the SC making a referral for case management (if consent to release the subject's name and contact information to case management services is provided). The SC will then review next steps, including PI review for eligibility, the process of random assignment, and follow-up assessments (if eligible).

- Randomization: A simple randomization will be used in consultation with the study biostatistician. If eligibility can be confirmed by study coordinator at the baseline interview, the study coordinator will randomize the subject at that time. If there are any eligibility concerns, the study coordinator will notify the subject that randomization will happen at a later time. The PI will review baseline assessment data collected by SC's weekly to determine eligibility. The SC who conducted the baseline interview will call the subject to explain which condition (group) he/she was randomly assigned to. The SC will also describe next steps for initiating the intervention, answer any questions the subject has, and schedule the next follow-up interview.
- Intervention/Control: Those in the volunteer condition will meet with Lifespan to initiate the program. As per Lifespan requirements, a background check will be completed. If a subject fails the background check, Lifespan will notify the study team. Lifespan will not disclose the reason(s) why the subject did not pass the background check. They will only indicate that the subject did not pass. The study team will contact the subject and inform him/her that he/she cannot participate in the study. If a subject passes the background check, the RSVP volunteer coordinator will match the subject with a social volunteer activity. Those in the life review condition will be contacted by a study team member to give them information regarding this condition.
- Follow-up assessments: Subjects will be maintained in the study for 12 months. The initial intervention session (i.e., training) will begin within two weeks of randomization. Follow-up research assessments will be conducted for both conditions by email or mail at 3 and 9 months (or in-person if the subject does not have e-mail access and would prefer to complete them in-person) and in-person at 6 and 12 months. An assessment must be completed no later than two weeks after the target assessment date.

e) Assessment Measures & Administration Schedule:

The following tables specify the assessment measures we propose to use in the study:

Screening measures

Measure Name and Citation	*Construct Measured*	*Description & Psychometric Data*	*Estimated Administration Time*
Demographic characteristics	Not applicable	Age, gender.	1 minute
3-item UCLA Loneliness Short Form	Loneliness	A score of 6 or above has been shown to predict mortality. [18,29]	1 minute
6-Item Screener	Cognitive functioning	These 6 items ask questions measuring orientation and short-term memory.	1-2 minutes
National Institute on Alcohol Abuse and Alcoholism (NIAAA) single-item test	Alcohol misuse	This single item has greater than 90% sensitivity and specificity in the detection of alcohol use disorder.	1 minute Screening and 6 month visit
The CAGE Questionnaire[30]	Alcohol misuse	This 4 item questionnaire will be used as an exclusion screen. A	1 minute

		score of 2 or above is considered clinically significant.	Screening and 6 month visit
Self-Assessed Literacy Questions	Literacy	2 self-assessed questions regarding reading and writing abilities needed for the study	1 minute

Descriptive measures, and psychiatric/medical covariates

Measure Name and Citation	*Construct Measured*	*Description & Psychometric Data*	*Estimated Administration Time*
Demographic characteristics	Not applicable	Age, race/ethnicity, gender, sexual orientation, employment status (and history), income, education, living situation, marital status, PCP name, emergency contact, self-report endorsement of felony conviction.	3 – 5 minutes in-person interviews
Brief Grief Questionnaire[31]	Grief	This brief self-report measure assesses social functioning impairment associated with bereavement.	1 minute in-person interviews if applicable
Zarit Burden Inventory—Screening Version[32]	Caregiver burden	This brief measure assesses self-perceived degree of burden associated with providing caregiving.	1 minute in-person interviews if applicable
Medical conditions and medications	Physical health	This measure is checklist of self-reported medical conditions derived from the Minimum Data Set Version 2.0. Data on medications will be used to create the Composite Antidepressant Scale (CAD), a measure of antidepressant dosage. Questions about adherence to medicines will also be asked to determine if the prescribed dosage is being taken.	5 minutes in-person interviews
WHO Disability Assessment Schedule 2.0 WHODAS 2.0[33]	Functional impairment	Functional impairment will be measured by client self-reporting of six domains: cognition, mobility, self-care, social, life activities, and participation. In order to adequately characterize our sample, we will obtain the degree to which subjects experience functional impairment.	10 – 15 minutes baseline and final interview
Big Five Inventory-Short Form (15)[34]	Personality traits	This very brief self-report measure (15 items) assesses the “Big Five” personality traits. This measure is included because personality may moderate (or affect) outcomes.	3-5 minutes baseline only
PROMIS Depression and Anxiety Computerized Adaptive Tests[35]	Depression and anxiety symptom severity	These brief computerized adaptive tests has been found to be sensitive in detecting clinically significant depression and anxiety, as well as being sensitive to change.[36]	3-5 minutes all time points
Volunteering History Interview[37]	Subjects’ histories of volunteering for the	Developed by The International Labour Association.	5 – 15 minutes In-person interviews

	prior year and past month		
Montreal Cognitive Assessment (MOCA)[38]	Global cognitive functioning	The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal. Nasreddine and colleagues report high sensitivity and specificity for MOCA scores in detecting MCI.[38] The MOCA has three alternate forms in English to prevent practice effects with repeat administration, as well as a form for blind individuals.	10 – 15 minutes at baseline and final interview (alternate form used at final interview)
Columbia Suicide Severity Rating Scale (CSSRS)[39]	History of suicidal ideation and behaviors	The CSSRS is an interview that assesses for worst-point lifetime and past month suicidal ideation and behavior. It has been shown to predict future suicidal behavior[39] and is the current gold standard for assessing suicide risk in clinical trials.	5 –15 minutes In-person interviews (time frame is “since last visit” for follow-up interviews)
Mood Improvement Protocol (MIP)	Self-perceived distress (before and after interview) and coping strategy (i.e., mood improvement activity)	The research interview may elicit negative reactions in individuals who are having difficulties in areas of their life related to questions in the assessment. Thus, this measure, adapted from procedures designed by Linehan and colleagues, is designed to enhance retention and improve subjects’ experience in the research assessments.	5 – 10 minutes In-person interviews
Qualitative Feedback	Subject’s experience in the research program	Open-ended questions to assess the subject’s experience throughout the research program	5-10 minutes 6 and 12 month interviews
Volunteer Satisfaction Survey and Volunteer Benefits Survey	Subject’s experiences in the volunteer program	Feedback to assess the subject’s satisfaction and benefits from volunteering	5 minutes Volunteer condition only 6 month and final interview
Life Review Satisfaction Survey	Subject’s experiences in the life review program	Feedback to assess the subject’s satisfaction with life review	2 minutes Life Review condition only 6 month and final interview
Credibility and Expectancy Questionnaire (CEQ)	Subject’s expected benefits	Questionnaire to assess subject’s expected benefits of the program	2 minutes Baseline and 12 month interview

Sexual Orientation Concealment Scale (SOCS)	Subject's concealment of sexual identity	Questions designed to assess lesbian, gay, and bisexual (LGB) individual's active concealment of their sexual minority status	2 minutes Baseline for those who answered as LGB on demographic form. 6 and 12 months – for those in volunteer group who had answered as LGB on demographic form at baseline.
Randomization Feedback	Subject's experience with randomization	Feedback from the subject on the randomization process and their satisfaction with the group to which they were randomized	5 minutes 12 month interview

Social connectedness measures

Measure Name and Citation	*Construct Measured*	*Description & Psychometric Data*	*Estimated Administration TIme*
Revised UCLA Loneliness Scale, version 3[27]	Global loneliness	Yields a continuous score, with greater scores indicating greater loneliness; it will be used to assess loneliness at all assessment time points. It has demonstrated excellent internal consistency, test re-test reliability, and construct validity (associations with social support and social network size),[27] including with older adult samples.[13,27] Importantly, it has been shown to be sensitive to change as a result of intervention.[40]	3 - 5 mins all time points
De Jong Gierveld Loneliness Scale[41]	Social and emotional loneliness	It had demonstrated excellent psychometric properties and construct validity.	3 - 5 mins all time points
Lubben Social Network Scale[42]	Social network size and frequency of contact.	This set of self-report questions has been shown to predict premature mortality.	3 – 5 mins; all time points
Interpersonal Needs Questionnaire (INQ) [43,44]	Thwarted belongingness (TB), perceived burdensomeness (PB).	Van Orden et al. [43] report high internal consistency coefficients for the thwarted belongingness (α=.85) and perceived burdensomeness subscales (α=.89). In support of construct validity, both subscales were found to positively correlate with suicidal ideation.	3 – 5 minutes all time points
Behavioral Activation Scale for Depression (BADS)—social subscale[45]	Social activation.	Kanter and colleagues present evidence of the scale's psychometric properties, including solid factor structure, internal consistency, and test-retest reliability.	2-4 minutes in-person interviews
Volunteer Functions Inventory[46]	Reasons individuals participate in volunteer activities	Konrath and colleagues demonstrated good psychometrics	3-5 minutes Volunteer condition only

		and a latent structure consistent with several subscales.	6 months and final interview
PROMIS Social Functioning Computerized Adaptive Tests[47]	Emotional support, informational support, instrumental support, satisfaction with social roles and activities, social isolation, companionship	These computerized adaptive tests measure several domains of social functioning.	5 – 7 minutes In-person interviews
Rosenberg Mattering to Others Scale[48]	Mattering to others (5 items)	This is the most commonly used measure of perceptions of mattering and has numerous reports of solid psychometrics	2 – 3 minutes In-person interviews

Quality of Life measures

Measure Name and Citation	*Construct Measured*	*Description & Psychometric Data*	*Estimated Administration TIme*
WHOQOL-BREF[28]	Health-related quality of life	This brief 36 item measure assesses several domains of health related functioning and quality of life. It has excellent psychometric properties and can be used cross culturally.	10 - 15 minutes baseline and final interview
PROMIS Quality of Life scales[49]	General life satisfaction, Meaning and Purpose, Positive Affect	These measure several domains of quality of life. The purpose in life items have been empirically linked to volunteering in older adults.[50]	4 - 6 mins in-person interviews
Reminiscence Functions Scale[51]	Measures reasons individuals engage in reminiscence, which is a key component of the life review intervention.	Robitaille et al. provide support for the 8 subscales and data that demonstrate adequate psychometric properties in a sample of older adults.	6 – 8 minutes Life review only 6 month and final interviews
Brief Measure of Generativity and Ego Integrity[52]	Generativity (perceptions of giving back, especially to younger generations) and ego integrity (looking back on one's life with meaning)	Vuksanovic and colleagues[52] provide data indicating that this shortened measure provides adequate construct coverage.	2 – 4 minutes In-person interviews
Attitudes to Ageing Questionnaire AAQ	Feelings on getting older	This set of self-report questions allow subjects to express their attitudes towards aging.	5 minutes In-person interviews

Total estimated time for entire baseline interview		90 – 153 minutes

f) Study Conditions:

Volunteering condition: HOPE volunteers are supported by Lifespan and the Senior Corps. The Senior Corps is one of Lifespan's many programs for seniors in the community. Its objective is to match seniors with volunteer opportunities that match their interests and capabilities. Subjects will begin training at Lifespan within two weeks of randomization. Aging Services agency-supported volunteer placement in a social volunteer activity is initiated for one year. The target expectation for volunteering is 4 times per month (about once per week). Lifespan collects monthly timesheets, which will include the number of hours and types of volunteer

activities done. The Senior Corps provides a small reimbursement for travel to volunteers as needed for travel related to volunteering. The other component of the intervention is on-going training ("booster sessions"), volunteer support groups, and educational activities offered by Lifespan. These gatherings for volunteers serve to promote retention in the program, assist volunteers with any problems/issues that have arisen, and promote social connectedness among volunteers. This is standard Lifespan policy.

Control Condition: The active control group was chosen to control for (and minimize confounding by) potential non-specific effects of participating in a study intervention; expectancies about benefit; and starting a new cognitively engaging activity. Subjects randomly assigned to the active control group will complete a self-guided life review exercise over 12 months.[53,54] This standardized and evidence based intervention is commonly used to reduce depression and promote well-being in later life; further, it was recently tested (and validated) as a self-guided intervention to improve well-being by Lamers and colleagues[54]; life review was also used as a control condition for a NIA-funded randomized trial of problem solving therapy for older patients with macular degeneration (R01AG032032, Sörensen, PI)[53] that was recently completed in the UR Department of Psychiatry. Dr. Sörensen will be available to advise the HOPE team regarding implementation of this condition. To minimize the social nature of providing the intervention (i.e., minimizing confounding our conditions), the life review will be largely self-guided, including replacing the counselor (and one-on-one sessions) with email support and a self-help book, per the protocol of Lamers and colleagues.[54] Subjects will complete two sections of the life review (with the self-help book) each month and send 'assignments' twice per month to an email 'counselor' who will respond with supportive comments within three days (per Lamers et al., protocol). The minority of subjects who do not have access to email will be provided the opportunity to participate via regular mail. The Lamers and colleagues' intervention was found to enhance psychological well-being. Studies examining individual life-review, including Sörenson's, indicate that life review reliably reduces depressive symptoms, but does *not* reduce loneliness (though group life review may increase social integration).[55] Further, life review is associated with high compliance rates, comparable to—or exceeding—compliance rates for other evidence based interventions for older adults.[53,56] These data indicate that life review will represent a *face valid* intervention for subjects, thus increasing expectancies of positive benefit and promoting compliance and retention. Our active control condition will provide benefit to subjects without reducing loneliness, thus addressing one of the largest confounds for behavioral interventions, especially interventions of an extended duration—expectancy effects[57,58]—while also promoting high compliance rates.

g) Analytic Procedures:

Power analysis is conducted to test treatment effects by the intent-to-treat (ITT) analysis for the primary hypothesis. We assume a conservative 20% attrition rate and a 0.3 within-subject correlation. A sample size of N = 300 (or N = 150 per treatment group) will allow us to detect a small effect size of 0.2 for loneliness, with 80% power based on a two-sided type I alpha = 0.05. The assumed within-subject correlation of 0.3 reflects the relatively long time lag between consecutive assessments. The proposed sample size also has 80% power to detect 32% mediation effects for loneliness, a continuous outcome. If full mediation is not achieved for any of the mediators considered, 32% mediation effects are sufficiently large to be of clinical importance for the outcomes of interest.

Descriptive statistics will be computed to summarize distributions of each outcome, with means and standard deviations for continuous outcomes and percent for categorical outcomes. Two-sample t tests (or the Mann-Whitney-Wilcoxon rank sum test) and Chi-squares will be used to examine balance of treatment randomization for continuous (if distributions are highlight skewed) and categorical variables. The primary hypotheses are concerned about the effectiveness of volunteering on reducing loneliness vs. control. Examination of mechanisms (mediation, Aim 2) as well as dose-response relationships (Aim 3) and moderators (Aim 3) of the intervention will also be examined. Aim 1 (and Aim 3 H4 on moderation) will be tested using longitudinal regression models, while the mediation hypothesis (Aim 2) will be examined by structural equation models, and dose-response relationships (Aim 3) by structural mean models.

The two most popular longitudinal models are the generalized linear mixed-effect models (GLMM) and the weighted generalized estimating equations (WGEE). Weighting is based on inverse probability of drop-out, extending standard GEE from valid inference only under missing completely at random to missing at random, similar to GLMMs. For inference about treatment effects, both models can be applied. However, parametric

GLMM requires distribution assumptions, making inference sensitive to departures from assumed distributional models.[59-61] The semi-parametric WGEE requires no such assumption, thereby providing valid inference for a broader class of data distributions. We will use both models; if discrepancy arises between the two, we will report the results based on WGEE. Both models address missing data under the missing at random (MAR) mechanism.[62-64] Biased estimates may still arise if missingness follows the non-ignorable non-response (NINR) mechanism. Although quite rare, and we do not anticipate such a missing data mechanism in this study, we will examine this issue by performing sensitivity analyses under some non-ignorable missing data models.[59,65] Structural equation models (SEM) will be applied to test the mediation hypothesis involving the putative mediators of usefulness and social support.[66] Again, the popular maximum likelihood (ML), generalized least squares (GLS), and weighted least square (WLS) estimates are all biased under MAR, if parametric assumptions are not met by data in the study.[67,68] We will also use recent distribution-free methods for more robust inference.[67] If results differ significantly between the maximum and distribution-free methods, only estimates from the latter will be reported. Common indices for assessing goodness-of-fit include likelihood ratio, Akaike (AIC) and Bayesian criteria. For SEM, popular goodness-of-fit measures include chi-square test, the comparative fit index (CFI), the index of Tucker and Lewis (TLI), and Root Mean Square Error of Approximation (RMSEA).[66,69,70]

The ITT analysis for Aim 1 provides intervention effects averaged over all subjects randomized to the intervention conditions. When intervention compliance (volunteering hours/satisfaction for subjects in the volunteering condition) demonstrates a dose-response relationship, as we hypothesize in Aim 3, complier average causal effects (CACE) are appropriate; thus we will use them to test Hypothesis 3. CACE is a compliment to ITT analyses and provides an answer to a different question than is answered by ITT analyses (i.e., the result of complying vs. being offered an intervention).[71] CACE provides valid causal inference because it maintains randomization and includes all subjects in the analysis, as with ITT.[72] CACE provides different intervention effects for individuals depending on their levels of compliance, which can be quite informative, especially when there is large variability in intervention compliance and strong dose-response relationships. The ITT and CACE estimates from a similar intervention study by Gruenewald, et al.[73] show that not only were the CACE effect sizes much larger than their ITT counterparts (small ITT vs. large CACE effect size), but the temporal trend also reversed; while the ITT effect sizes decreased, the CACE effect sizes increased from 4 months to 12 months post intervention, indicating substantial heterogeneity in intervention compliance and strong dose-response relationships. Since volunteering time is only required for the volunteering condition, standard statistical models cannot be used to perform CACE analysis. The CACE approach enables an estimate of the treatment effect at each level of "compliance" (i.e., amount of hours volunteered), without the need for a measure of compliance in the control group. In this way, we will be able to tell how well volunteering reduces loneliness at different "doses" of volunteering. The two most popular methods for addressing intervention compliance are the parametric principal stratification (PS) and the semi-parametric structural mean model (SMM).[74-76] Unlike the PS, the SMM not only allows for continuous dose variables, but also requires no parametric model for data distribution such as normality, thereby yielding robust inference for a broader class of data distributions. We will use the latest SMM based on the structural functional response models (SFRM) for our CACE analysis, which not only allow for continuous, but also multiple dose variables. [74-76] We are particularly interested in potential non-linear dose-response relationships so that we may determine optimal dose intervention whereby increased exposure (i.e., number of hours volunteered) becomes less worthwhile (in terms of reducing loneliness).

Aim 1 compares subjects randomized to either the volunteering or control on loneliness (continuous variable). **H1a:** There will be a condition effect on loneliness at all time points indicating differing levels of loneliness in the direction: control > volunteering. Longitudinal models will be employed with loneliness as the response, and condition, time and their interaction as the predictors, controlling for age, gender. If a significant difference exists (a significant time by condition interaction), appropriate linear contrasts will confirm the hypothesized directional effects. For **H1b**, the same analytic strategy will be used, but with quality of life (continuous) as the response variable. Aim 2 involves mediation analysis: is to examine perceived usefulness and social support as mediators of the intervention effect on loneliness. **H2a**: Increases in social engagement at 6 months is hypothesized to mediate the effect of intervention condition on decreased loneliness at 12 months. The SEM-based mediation models will be applied, with social engagement as the mediator, intervention condition as the predictor and loneliness as the outcome, controlling for age, gender. If the null of full mediation is rejected, we will estimate direct, indirect and total effects to assess the strength of mediation. The same analytic strategy

will be used for perceived usefulness and social support (**H2bc**). Aim 3 involves when volunteering will provide maximal benefit. **H3:** Greater hours (compliance) and satisfaction will be associated with better outcomes. We will apply the SFRM-based SMM to analyze dose-response relationships. We will first model dose using non-parametric methods and then characterize the patterns using parametric methods. This allows us to capture detailed dose and response relationships and provide more interpretable findings. **H4:** The longitudinal model for H1a will be used with functional status as a moderator variable.

h) Data and Safety Monitoring Plan:

(i) ***Overview:*** 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 the 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 *modified DSMB* that, while constituted by individuals connected to the study, will systematize monitoring safety issues throughout its duration.

(ii) ***DSMB Membership*****:** Dr. Jeffrey Lyness will chair the DSMB. Dr. Lyness is Professor of Psychiatry at URMC and an expert in research and clinical care of older adults. Other members will include Kimberly Van Orden, Ph.D., Yeates Conwell, M.D., and Deborah King, PhD. Dr. Van Orden is the principal investigator of the project and Dr. Conwell is a Co-Investigator and geriatric psychiatrist. Deborah King is the outside member of the DSMB and is a clinical geropsychologist.

(iii) ***DSMB Responsibilities and Actions*****:** The DSMB will maintain an overview of the quality of the accumulating data and provide guidance to the PI on interim analyses and stopping rules. The DSMB will also serve as liaison among study investigators and the University of Rochester Medical Center Research Subjects Review Board (RSRB) and the NIH. It will review and approve, disapprove, or suggest modifications to the study protocol and/or consent documents to assure both scientific integrity and that studies adhere to human subject protection policies. It will monitor, provide feedback, and report on scientific and ethical issues related to study implementation for the protection of human subjects and advise on ethical issues related to adverse events. The DSMB will monitor adverse event reports for purposes of determining whether their nature, frequency and severity are consistent with expectations. It will report to the RSRB and NIH any unanticipated problems involving risks to subjects (per 45CFR46). If considered related to the study, unanticipated adverse events involving risks to subjects or to others must be reported by the P.I. and/or DSMB to the RSRB. The RSRB will promptly inform NIH. Along with the RSRB and NIH staff, the DSMB can recommend remedies or other appropriate actions such as introducing new monitoring protocols, altering inclusion or exclusion criteria, or recommending changes in the informed consent documents.
As well, the DSMB will be charged with ensuring that the study protocol maintains subjects' confidentiality in a manner that is appropriately balanced with issues of clinical care and safety, where relevant, and will monitor data management activities. The DSMB will review requests for interim analyses and approve, disapprove, require additional information, or defer decisions.

The DSMB will be kept apprised of all severe adverse events on an ongoing basis and will serve as the final arbiters of whether individual subjects should be removed from the protocol. The DSMB will be called upon whenever possible to render judgments in the advent of a severe adverse event. We acknowledge that there may be rare instances where some emergent situation occurs that was unanticipated regarding the welfare of the subject. In these situations, the University of Rochester Medical Center's RSRB or the DSMB may be contacted to help resolve the situation.

(iv) ***Meeting Schedule*****:** At a minimum, the DSMB will convene on an annual basis. DSMB conferences will be assembled in-person, and conducted in accordance with federal and state health privacy

legislation and relevant standards. The Chair and the P.I. will determine meeting logistics based upon urgency and the availability of DSMB members.

(v) **Adverse Events (AEs) and Serious Adverse Events (SAEs).**

We will abide by the rules governing reporting of adverse events as defined in NIH Policy on Data and Safety Monitoring in Clinical Trials (September 2002, revised 2007). Any event will be reported to the RSRB if it is "serious," "unexpected," and "related."

Reportable Events: Definition of terms

- "Serious" means any event that causes a prolonged or permanent harm that is psychological, social, legal or financial. Examples most pertinent to this study include a subject's death from any cause; a suicide attempt or hospitalization due to depression.
- "Unexpected" means that the event was unforeseen and has not been previously encountered, known, or recognized and was not identified in nature, severity, or degree of incidence in the protocol, supporting documentation, the informed consent document, or the RSRB application.
- "Related to the study" means that there is some aspect of the study (e.g., a research procedure, existence of a laptop database, etc.) that is directly related to the event. An example pertinent to this study is breach of confidentiality by which private information about the subject was made known to other community members. Events for which the relationship to the study cannot be clearly determined based on review of all available data will be classified as "possibly related to the study" and reported according to the same guidelines as for related events.
- "Event" is an incident, experience, or outcome that occurs to a subject participating in an RSRB-approved research study.

The following rules describe the procedures for adverse events that will guide us:

- AEs are reported to the sponsor, regardless of whether they are considered study related. They may include hospitalization or death.
- The date and time of onset and outcome, course, intensity, action taken, and causality to study treatment will be assessed.
- The Principal Investigator has the final decision regarding what is to be reported on the adverse event form, and has the option to reclassify an AE as a serious adverse event (SAE). In general, a serious adverse event (SAE) is an event where a relationship to the research study cannot be ruled out and the event is life threatening/results in death OR disabling/incapacitating OR requires or prolongs hospitalization OR involves an overdose OR was otherwise unanticipated, related to the study procedures or could lead to one of the other serious event conditions.
- In case of an SAE: The date and time of onset and outcome, course, intensity, action taken, and relationship to study treatment will be assessed. SAEs will be reported to the CDC, DSMB, and the RSRB within 24 hours. A written report will be forwarded to NIH, DSMB and the RSRB within 5 working days of the investigator's discovery of the event.

i) Data Storage & Confidentiality:

Electronic data will be collected in a password protected, secure web-based application called REDCap (Research Electronic Data Capture). This web-based data entry system replaces the current process of collecting data on paper copies and entering the data afterwards via a system residing on a local computer. The electronic data capture system provides a secure, HIPAA-compliant web-based application that is flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data and has real time validation rules (with automated data type and range checks) at the time of entry.

REDCap servers are housed in a local data center at the University of Rochester and all web-based information transmission is encrypted. REDCap was developed in a manner consistent with HIPAA security requirements and is recommended to University of Rochester researchers by the URMC

Research Privacy Officer and Office for Human Subject Protection. A laptop or iPads will be used to collect the encrypted data on REDCap.

No protected health information will be stored on portable media, including laptop computers or removable hard drives. The data (including names and all identifiable information) will be encrypted using SSL. Only authorized study personnel and regulatory personnel (e.g. auditors) will be allowed access to data. All access to the database will be controlled by passwords with varying levels of security and access. The iPads or laptop will be used by the coordinator and subject.

Users will be assigned access to the application by personnel in the Department of Biostatistics and/or study personnel. REDCap also tracks who enters the data. No data are stored on the iPad or laptop devices.

In addition, all applications, projects, and user accounts are stored on mirrored disks. If one disk should fail, the remaining disk of the mirror is used, and no data loss or downtime is experienced. Weekly, a backup is removed from the site and stored in a secure location. Only specific users are allowed access to projects; the system administrator specifies these users. Watcher programs are used to keep a close eye on disk utilization, rogue, user and daemon processes, as well as rogue system alterations. These programs help to tune the system for maximum performance and help maintain the reliability of the system. Security monitoring programs are used to alert us to possible security holes, which may be exploited by would-be crackers. The University of Rochester Medical Center also maintains a firewall in front of their Enterprise network, providing an additional level of security.

In order to protect the confidentiality of subject information, we will take a number of precautions. These include training of research interviewers in confidentiality procedures; entry and storage of data using coded identification labels; maintenance of project computers (both PRN and clinical research hardware) in secure locations with restricted access by enforced password protection.

IV. RISK BENEFIT ASSESSMENT

1. Risk Category

Minimal risk.

2. Potential Risks

a. For the assessments/questionnaires, the risks are as follows: discovery of depression or suicide ideation, 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 in previous research with older adults; no sustained negative effects from assessments are expected, but negative outcomes cannot be ruled out.

b. The interventions, volunteering and life review, carry the risk of causing emotional distress or fatigue. Our volunteers may experience stressors as a result of volunteering.. Our intervention includes support for volunteers through these experiences. Subjects assigned to life review may write and think about memories of negative experiences; they will receive support for such experiences. No sustained negative effects are expected, but negative outcomes from behavioral interventions cannot be ruled out. The volunteer coordinator and care manager are experienced in working with older adults and in assisting volunteers through situations involving loss. The life review supervisor is also experienced in working with older adults and assisting participants through the experiences of recalling stressful memories.

c. Regarding alternative interventions, subjects will not be prohibited from seeking out supportive social services, or volunteering their services to others (for ethical reasons), but subjects will be asked to refrain from initiating *new* long-term volunteering experiences during their time in the study. If a subject in the volunteering group does engage these services, he/she will be followed for the full 12 months, with documentation of the nature and extent of that engagement, and evaluation of its impact on the outcomes of interest.

3. Protection Against Risks

a. 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. Risks associated with subject burden or distress 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 and a half 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, internet-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 Drs. Van Orden and Conwell's past research involving older adult populations. 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. Internet surveys will be housed in REDCAP and subjects will directly enter their responses into REDCAP.

b. 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.

c. We propose to manage potential distress elicited by the research assessment with implementation of a "Mood Improvement Protocol" (MIP). The MIP is designed to enhance retention and improve subjects' experience in the research assessments. We propose to include procedures to help such subjects manage distress that may arise during the research assessments. Specifically, the MIP involves the research assessor (study staff) collaboratively creating a coping plan for managing distress with the subject prior to completing the interview. Such coping strategies include: engaging in chit chat with study staff, sharing a cup of tea, etc. The protocol also involves having the subject rate his/her level of distress at the start of the interview and after the interview. This will allow study staff to better manage the risk of distress by providing a gauge of subjects' change in level of distress at the conclusion of the interview. If a subject remains highly distressed after the interview (highly unlikely), study staff will engage in a coping activity with the subject and/or call Dr. Van Orden. We have successfully used this procedure in prior studies.

d. 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 Dr. Conwell, who will maintain cell phones for this purpose. If neither is available, or if otherwise necessary, intervention will be provided by a clinician with Psychiatric Emergency Department.

4. **Informed Consent Procedures:** A CRC will obtain verbal consent from subjects before beginning the phone screening. At the conclusion of the phone screening, the CRC will explain that written informed consent will be obtained at the next assessment at an office at the University of Rochester Medical Center. The CRC will obtain written consent from subjects before the baseline in-person assessment only after subjects have received both verbal and written explanations of the study and indicated their full understanding. They will be informed that the study is designed to examine the effects of volunteering or life review on health and well-being of older adults in the community. They will be informed of their rights as research subjects, including the right to refuse to participate in the study, and to withdraw their consent at any time, as well as potential risks and benefits of participation, including financial compensation, and rights to privacy and confidentiality. Specifically, individuals will be told 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 still receive full reimbursement for that assessment; and they may withdraw from the research study at any time without negative consequences to their treatment in the Strong Memorial Hospital healthcare system. Moreover, participants will be informed that they will be asked to participate in assessments whether or not they complete treatment, that they will be financially compensated for participation in assessments whether or not they complete treatment that they have the right to refuse to participate in any study assessment session. Subjects will be compensated for the assessment sessions for their time and effort ($50 for the baseline interview, $10 for the REDCAP internet-based/mail survey follow-ups at 3 and 9 months and $35 for 6 and 12 month follow-up in person interviews). Data storage and safety will also be described to them. Informed consent will also include information about costs of volunteering/life review (i.e., no cost). The process of random assignment will be described to subjects as “the flip of a coin.”

    - 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. 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.
    - 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 subject leaves. The PI will also be in contact with Dr. Conwell regarding potential imminent dangerousness, which may involve the use of emergency services and law enforcement authorities.
    - When obtaining informed consent, a “Determination of Capacity for Informed Consent” protocol developed will be utilized. The consent form will be read aloud to subjects, who will be encouraged to ask questions throughout the process. At the conclusion of the consent process and prior to requesting that they sign the form, all clients are asked the following questions:
        - Could you please tell me what this study is about?
        - What are the potential risks to you of participating in this study?
        - What are the benefits for participating in this study?
        - Do you understand that your participation in this study is voluntary and that you may stop at any time or not answer any questions that you feel uncomfortable answering?
        - Do you have any questions about the interview or the treatment?
        - If in answering these questions the subject is unable to demonstrate an understanding or appreciation of the issues, the investigator and subject further review the consent form and repeat the pertinent questions. Subjects who achieve a demonstrated understanding of the study are determined to have capacity to provide informed consent. For those who do not, they are thanked for their time, informed that they are not eligible for the study, and provided reimbursement for the assessment. Subjects’ answers are characterized on a checklist that is kept with the research record as documentation of the consent process.

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 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, Lifespan or University clinicians, 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. This training session will be developed, in tandem, by training staff in the Department of Psychiatry and by the HIPAA compliance officer for Lifespan.

7. Potential Benefits to the Subjects

Half of the study subjects will receive a volunteering intervention aimed to reduce loneliness – an intervention that targets a significant risk factor for reduced well-being, morbidity and mortality. The other half of subjects will receive an evidence based life review intervention that has demonstrated benefits for well-being. 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. 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.

8. Importance of the Knowledge to be Gained

There is a pressing public health need to find interventions that reduce loneliness in later life. *Reducing loneliness would significantly improve the lives of older adults by improving well-being and promoting health and longevity.* There is infrastructure nationwide that provides volunteering opportunities and support for older adults—the Senior Corps—indicating that volunteering is an accessible intervention for older adults. If shown effective at reducing loneliness, dissemination efforts would involve connecting primary care patients and aging services clients who are lonely with this type of intervention, which we have shown to be feasible in our companion study of older adult peer companionship, The Senior Connection (TSC).

9. Alternatives to Participation

Regarding alternative interventions, subjects will not be prohibited from seeking out supportive social services, or volunteering their services to others (for ethical reasons), but subjects will be asked to refrain from initiating *new* long-term volunteering experiences during their time in the study. If a subject in the volunteering group does engage these services, he/she will be followed for the full 12 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

In line with NIH requirements, we plan to register the trial.

VII. SUBJECT IDENTIFICATION, RECRUITMENT AND CONSENT/ASSENT

1. Method of Subject Identification And Recruitment

Recruitment strategies involve:

1) initial contact:
    a. informational letter sent to home
    b. flyers and advertisements
    c. HARP database study (RSRB 67245) referrals
    d. In-person recruitment in PCP offices
    e. Direct referral via providing an informational letter from physicians and care managers
    f. Informational Sessions
2) informational phone call;
3) in-person interview for written informed consent and assessment.

As described in the Procedures section, recruitment via informational letter will involve completing a data request (via secure software, and only involving patients within the covered entity), and cleaning the data on a secure, password-protected device. A designee from the practice will then be given an opportunity to review the list and exclude individuals as needed. After the list of patients has been "cleared," staff from the research team, the Center for Research Support or The University Copy Center will prepare and send informational letters to each individual. The letters will briefly explain the study, as well as inform potential subjects that their participation is entirely voluntary, and that their decision regarding participation in this study will in no way affect their medical care. Additionally, the letter will invite those who may be interested to call research staff.

The phone call will involve providing potential subjects with additional details about the study. For those who are willing to continue, the research coordinator will schedule an in-person assessment within five business days. During the assessment, the study coordinator will again explain the study and obtain written consent for the subject to participate. Baseline assessments will be completed. Finally research staff will remind the subject of the randomization process and the assessment follow-up schedule and answer any remaining questions. If eligibility can be confirmed by study coordinator at the baseline

interview, the study coordinator will randomize the subject at that time. If there are any eligibility concerns, the study coordinator will notify the subject that randomization will happen at a later time. After the interview, study staff will review the assessment with the PI. Once determined to be suitable for randomization, stuff staff will randomize the subject and call him/her to notify the subject of the group to which he/she has been assigned.

2. Process of Consent

The CRC will obtain written consent from subjects before the baseline in-person assessment only after subjects have received both verbal and written explanations of the study and indicated their full understanding. They will be informed that the study is designed to examine the social supports of older adults in the community, and whether people receive benefit from participating in social types of volunteering. They will be informed of their rights as research subjects, including the right to refuse to participate in the study, and to withdraw their consent at any time, as well as potential risks and benefits of participation, including financial compensation, and rights to privacy and confidentiality. Data storage and safety will also be described to them. Finally, the process of randomization to one of two conditions will be described; subjects will be told that if they choose to participate they will randomly assigned to one of two conditions: volunteering or life review.

3. Subject Comprehension and Capacity to Consent

A Capacity for Informed Consent protocol will be implemented for all potential participants (see attached document: "Determination of Capacity for Informed Consent"). The capacity assessment will consist of a series of open ended questions administered to the subject that follow explanation of the study. It will address the subject's knowledge and understanding of the study's objectives, the voluntary nature of participation, ability to withdraw at any time, consequences of withdrawing, possible risks and benefits of participation. For subjects who have difficulty in one or more of these areas, further review of the relevant elements of the study will be provided in order to improve their knowledge and understanding to a level that enables them to make a meaningful choice about participation. A form (i.e., "Determination of Capacity for Informed Consent") will be completed for each subject documenting the results of the decision-making capacity determination, a copy of which is maintained with the consent form.

4. Debriefing Procedures

At the final 12 month interview, research staff will give those assigned to life review information about volunteering. If they are interested, a Lifespan brochure that lists all Lifespan programs and contact information will be given to the subject.

5. Consent Forms

See attached.

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

There are no costs to the subject. Parking at URMC will be paid for by the study. For those who take the bus, a bus pass will be provided.

8. Payment for Participation

Participants will be paid $50 for the baseline interview, $10 for each internet-based/mailed/in-person survey follow-ups (3 and 9 months), and $35 for in-person interviews at 6 and 12-months. Each participant, therefore, may be reimbursed a maximum of $140 for their time and effort.

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Protocol Addendum 2/9/22

HELPING OLDER PEOPLE ENGAGE (HOPE):
A Randomized Trial of Volunteering to Reduce Loneliness in Later Life
Study Protocol for R01AG054457

Due to Covid-19 restrictions, all study visits are remote. These changes will remain in effect until URMC/NIH guidance changes regarding research and our high risk population (people over the age of 60). We have reassessed safety procedures and obtained DSMP guidance and will allow volunteer activities that RSVP has approved for volunteering. These agencies will have a documented safety plan and will be reviewed by members of our DSMP Committee. Any subject wishing to participate in at home volunteer activities may still continue to do so. Any additional changes will be reviewed by our DSMP committee and discussed with program officer before we will revert to our original protocol and resume all in-person activities.

Study visits – Baseline, 6 months and 12 months will be conducted via phone or zoom and online. 3 and 9 month surveys will remain remote either online or by phone. If a subject is unable or unwilling to use zoom, the visits will be done by phone with self-administered studies sent by e-mail.

Consent – Consent will be done at the baseline visit over the phone or through zoom. At the screening call, the study coordinator will 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 been documented. The email will not include PHI.

To verify the subject’s identity - the study team will add security questions to answer at the time of accessing the survey/eConsent. These questions will be pre-established security questions such as “What is your favorite color?” or “What is the name of the street you grew up on?” that are included on the signature page of the eConsent. The responses will be agreed upon by both the study team and the subject during the screening call. The answers will be saved in the subject record for verification later.

The consent process will be the same as in-person. The consent form will be read aloud to subjects, who will be encouraged to ask questions throughout the process. 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 will sign electronically as well. Consents will be stored within REDCap, and a copy will be e-mailed to the subject.

Intervention – Volunteering will remain through RSVP and may include both in the community and at home volunteer activities. Placements in the community are reviewed by RSVP and will have a documented safety plan.

Measures: The only measure that will need some adjustment will be the MOCA. If a subject cannot use zoom, a few of the visual questions would not be able to be performed. MOCA

without the visual elements is considered the Blind version of the test and can be used with a modified cutoff score given that the maximum total score for the Blind version is 22 and the full version maximum total score is 30.

We are adding one additional measure that will be completed at every visit (baseline, 3 month, 6 month, 9 month, 12 month). Because our study is looking at social connectedness, which is affected by the pandemic, we are adding a new measure on the pandemic's effect that was just published (Cawton et. Al., 2020).

We are adding an additional measure (Older Adult Social-Evaluative Scale) that will be completed at Baseline and 12 months to assess factors that may affect non-compliance with intervention.

Inclusion/Exclusion criteria: Subjects must have access to a device and internet to complete remote study visits. Those who do not have access to a device/internet will be excluded at this time. For subjects who cannot use zoom and will do the MOCA without the visual elements, we will use a cutoff score of 15. A score of less than 15 will be used as exclusion for the telephone administered MoCA. This cutoff score is equivalent to our cutoff score for the full MOCA based on validation studies comparing the MoCA delivered in person with visual elements to the MoCA delivered via telephone without the visual elements (Zietemann et al., 2017).

Number of Subjects: The study will recruit and enroll up to 400 subjects into the study. The target number of randomized subjects is n=150 in each group. Due to greater than 10% of those enrolled being not eligible or not willing to be randomized, we must enroll up to 400 subjects to try to reach our target number of randomized subjects.

Recruitment procedures:

Strategy 2: We are including in this strategy a media press release and essay submission to newspaper to reach more potential subjects.

Strategy 9: We are adding a new strategy to use direct mailing. Sending informational postcards through the 'Every Door Direct Mail® (EDDM®)' program, which is a program created by the United States Postal Service®. The program enables advertisers to reach every address within targeted carrier routes, at reduced rates, without the need for additional mailing services or specific lists. We propose to use Staples Direct Mail because it is a service that combines printing and mailing for the EDDM process. The study team, therefore, will not have access to any names or addresses. This recruitment method allows demographic targeting, including by age. Without seeing individual household information, we are able to identify which mail carrier routes contain the highest density of adults age 65 and older. However, postcards are sent to every address/mailbox within your selected carrier routes. A carrier route is a group of addresses used by the USPS® to deliver mail in a specific area. ZIP Codes™ may contain anywhere from several to more than a dozen carrier routes depending on the rural or urban nature of the region. We can upload the informational postcard approved with this amendment to the Staples Direct Mail website, select which carrier routes we should like to use, and the rest is managed by Staples Direct Mail. We do not have access to the names/addresses of those sent mail. We propose to use a

Staples Direct Mail template; a graphic designer at Staples then uploads our approved text information into the template. Potential subjects can contact our study team and be screened using the contact information on the direct mailing.

Strategy 10: We are adding a new strategy to use recruitment e-mails sent to patients of Trillium Health who are age 60 and older. We have received approval from the Research Steering Committee at Trillium Health. An e-mail from Trillium Health with a short description of our study along with a link to our study website will be sent to any patient who is age 60 or older. The Research Steering Committee has approved the e-mail for this purpose. Our study staff will not have access to any Trillium patient information. Trillium staff will create and send the e-mails.

In addition to e-mails, recruitment letters from Trillium Health will be sent to patients of Trillium Health who are age 60 and older. We have received approval from the Research Steering Committee at Trillium Health. Letters will be generated and sent by staff at Trillium Health, and study staff will not have any access to any Trillium patient information. These letters, prepared by staff at Trillium Health, will introduce the study including a brochure. The letter will indicate it is sent by Trillium Health, and invite those who may be interested to call research staff. These letters will state that participation in the study is entirely voluntary, and that participation or non-participation will not influence one's medical care. Letters will only be sent to patients once.

In addition to the e-mails and letters, Trillium Health will also list our study on their research opportunities webpage. https://www.trilliumhealth.org/patient-and-community-services/research-opportunities A brief description of the study will be listed along with our contact phone number and e-mail address. An approved study recruitment flyer/brochure will also be included on the website.

We propose recruiting from Trillium Health to increase diversity and boost recruitment numbers. This is in support of an administrative supplement we previously received to increase recruitment of SGM (sexual and gender minority) older adults (supplement information submitted in modification #5: 4/12/19). E-mails will not be targeting any specific population and will be sent to all patients over age 60, however the Trillium population is an enriched sample regarding SGM because of who selects care at Trillium.

Strategy 11: We are adding recruitment strategies via our geriatric medicine practices at UR Medicine. The UR Medicine Geriatrics Group will place our informational brochures in waiting rooms and patient exam rooms. UR Medicine Home Care (URMHC) will share brochures with patients who receive their services. In addition we may contact potentially eligible URMHC clients who have indicated that they are interested in participating in research when they complete the consent process via URMHC. In 2021, URMHC developed and implemented a process for existing URMHC patients to indicate willingness to be contacted about participation in research studies. These procedures are part of a clinical workflow conducted by clinicians; responses are contained in a clinical database. Using this process, URMHC patients, while receiving HHC visits, will be asked if they agree to be contacted by URMC researchers for future research participation, knowing that each study will be introduced and consent will be sought individually. If the patient agrees to be contacted by URMC research about future

research opportunities, he/she will choose “yes”, sign, and indicate their preferred contact method (i.e., phone, email, or mail). This information has been incorporated electronically, along with the signature, in the URMHC electronic health records. Upon IRB approval, URMHC will provide a list of URMHC patients who have consented for future research contacts at the time for their initial HHC visits, along with their contact information. Study staff will contact those patients and explain the study per the verbal script. If interested, the screening questions will be completed by phone.

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