Addressing social isolation, loneliness, and elevated suicide risk among vulnerable older adults through an 8-week caring contacts treatment:

A partially nested randomized controlled trial

NCT07204444

June 23, 2025

ADDRESSING SOCIAL ISOLATION, LONELINESS, AND ELEVATED SUICIDE RISK AMONG VULNERABLE OLDER ADULTS THROUGH AN 8 WEEK CARING CONTACTS TREATMENT:

A PARTIALLY NESTED RANDOMIZED CONTROLLED TRIAL

Protocol Number*: 1

National Clinical Trial (NCT) Identified Number: <Number, once assigned by CT.gov>

Principal Investigator*: Laura Shannonhouse

Sponsor: U.S. Department of Health and Human Services

Grant Title: Equipping the aging network to address social isolation, loneliness, and elevated suicide risk among vulnerable older adults during COVID-19 and beyond: A partially nested randomized controlled trial

Grant Number*: 90INNU0021-03-00

Funded by: Administration for Community Living; U.S. Department of Health and Human Services

Version Number: 1

Based on the NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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Based on the NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans

1. STATEMENT OF COMPLIANCE

This PN-RCT will be conducted in compliance with the International Council on Harmonisation Good Clinical Practice (ICH GCP) applicable United States (US) Code of Federal Regulations (CFR), and the U.S. Department of Health and Human Services' Terms and Conditions of Award. The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), and the Investigational new behavioral health treatment (BE WITH), if applicable, except where necessary to eliminate any immediate hazard(s) to the trial participants.

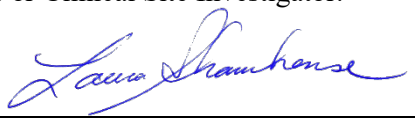
All personnel involved in the conducting of this study will have completed CITI training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) will be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

2. INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: _____

Name: Laura Shannonhouse
Title: Associate Professor
Affiliation: University of Florida
Address: 1221 SW 5th Ave Gainesville, FL 32601
Telephone: 352.359.0950
Email: lshannonhouse@coe.ufl.edu

Investigator Contact Information

[For multi-site studies, the protocol should be signed by the clinical site investigator who is responsible for the day to day study implementation at his/her specific clinical site.]

Signed: _____ Date: _____

Name:
Title:
Affiliation:

1 PROTOCOL SUMMARY

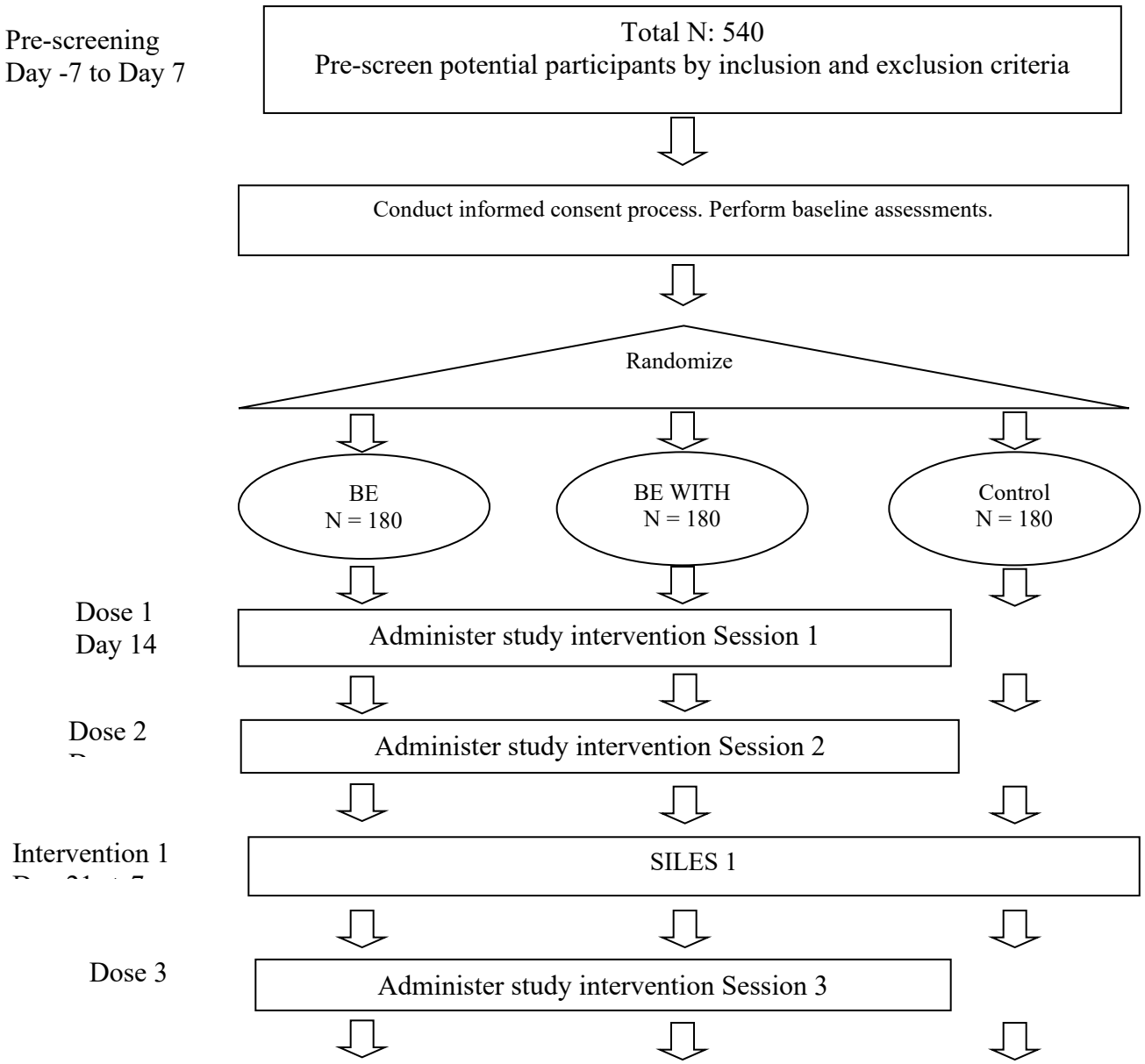
1.1 SYNOPSIS

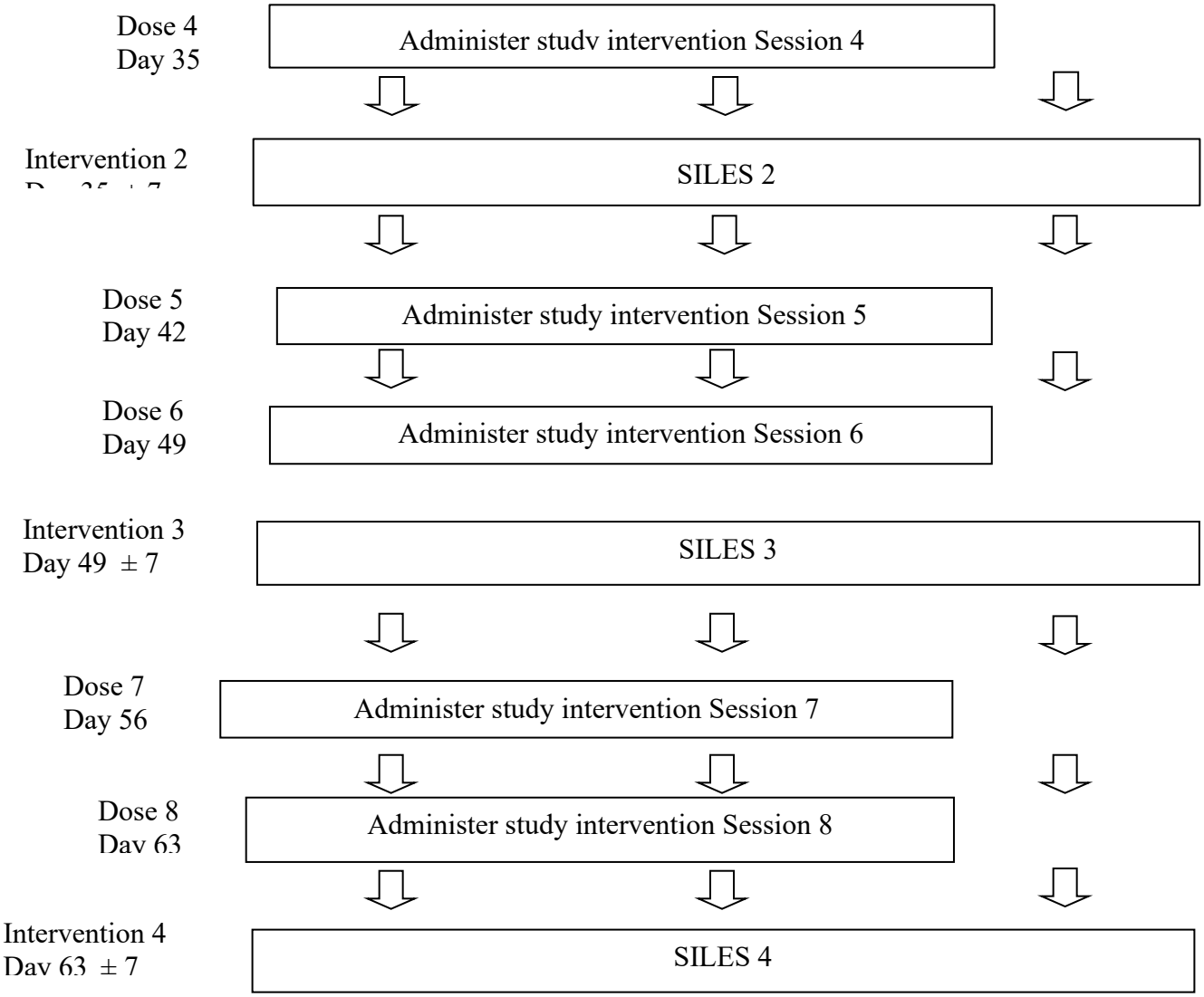
Title:	**ADDRESSING SOCIAL ISOLATION, LONELINESS, AND ELEVATED SUICIDE RISK AMONG VULNERABLE OLDER ADULTS THROUGH AN 8 WEEK CARING CONTACTS TREATMENT:** A PARTIALLY NESTED RANDOMIZED CONTROLLED TRIAL
Grant Number:	90INNU0021-03-00
Study Description:	This PN-RCT evaluates an 8-week caring contacts treatment that is delivered to older adults (urban racially diverse, suburban, and/or rural) in 20-30 minute warm calling "dosages", over 3 conditions. Conditions include 2 treatment (i.e. treatment provided by helpers trained in a standardized and manualized **B**elongingness and **E**mpathy training grounded in narrative reminiscence and the befriending literature (BE), and treatment provided by helpers trained in BE plus a standardized, manualized, and evidence-based suicide intervention training, the Aging Variant of LivingWorks ASIST (BE WITH), and 1 control (no treatment). Hypotheses include: (a) participants in the BE and BE WITH treatment conditions will experience significantly more improvement across measures than those in the control condition over the course of the 8-week treatment and (b) outcome improvements for those in treatment conditions will be more pronounced for those who begin the period at greater risk.
Objectives*:	**Primary Objective:** To develop BE WITH Innovation and equip the Aging Services Network (ASN) with proven skills to reduce social isolation, loneliness, and elevated suicidality and promote social support/well-being with older adults receiving nutrition services. **Secondary Objectives:** To validate and replicate BE WITH
Endpoints*:	**Primary Endpoint**: Reduction in social isolation, loneliness, and elevated suicidality and improved social support/well-being for older adult participants receiving nutrition services. **Secondary Endpoints:** Improved frequency of empathic and suicide intervention best practice behaviors by trained volunteers
Study Population:	Target *n* = 540 to adequately power the PN-RCT; men and women, aged 65 or older, receiving nutrition services, without instance of dementia or cognitive impairment, and in the state in the Southeastern US.
Description of Sites/Facilities Enrolling Participants:	There will be three Area Agencies on Aging, and 25 senior centers that will be involved in this clinical trial.

Description of Study Intervention/Experimental Manipulation:	The 8-week warm calling treatment is delivered to older adults in 20-30 minutes, once a week by phone call, over three conditions: BE, BE WITH, and control. The BE condition involves receiving services from providers trained to foster belongingness and empathy. The BE WITH condition includes the BE training as well as the aging variant of LivingWorks ASIST (Applied Suicide Intervention Skills Training).
Study Duration*:	24 months
Participant Duration:	2 months

1.2 SCHEMA

Example #1 Flow Diagram *(e.g., randomized controlled trial)*




Dose 4
Day 35
Administer studv intervention Session 4
Intervention 2
SILES 2
Dose 5
Day 42
Administer study intervention Session 5
Dose 6
Day 49
Administer study intervention Session 6
Intervention 3
Day 49 ± 7
SILES 3
Dose 7
Day 56
Administer study intervention Session 7
Dose 8
Administer study intervention Session 8
Intervention 4
SILES 4

1.3 SCHEDULE OF ACTIVITIES

	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
MOUs with AAAs and senior centers	X									
Secure Lists of Potential Participants From Senior Centers	X									
Recruitment Phone Calls		X								
Baseline Survey		X								
Scoring of Baseline Survey		X								
Random Assignment to 3 Conditions		X								
Phone Calls Back to Participants with Corresponding Consent (BE, BE WITH, Control)		X								
Measurement Occasions				X		X		X		X
Call Dosages			X	X	X	X	X	X	X	X

3. 2 INTRODUCTION

1. 2.1 STUDY RATIONALE

Social isolation and loneliness are prevalent among older adults,[1] detrimental to their health and well-being,[1,2,3] and can lead to suicide.[4] While 24% of community-dwelling older adults in the United States are socially isolated, almost half of older adults report feeling lonely.[5,6] Loneliness and social isolation have deleterious effects on older adults' physical and mental health[7], including elevated risk of dementia,[8] hopelessness,[9] anxiety,[10] and increased morbidity.[11-12] When older adults feel like they do not belong (thwarted belongingness), and that they are a burden to others (perceived burdensomeness), desire for suicide increases.[13] An older adult dies by suicide every 65 minutes.[14] Yet these data only reflect officially reported suicides; many more are categorized incorrectly and/or go unreported (e.g., overdose, voluntary stopping of eating and drinking, withholding medical treatment[15]). Social isolation, loneliness, and elevated suicidality (SILES) were exacerbated by the COVID-19 pandemic.[16-19] In addition to elevated physical health risks,[20,21] older adults face deleterious psychological *and* social impacts from the disease.[22] Social support is one of the strongest predictors of positive psychological outcomes during disaster.[22,24]

2. 2.2 BACKGROUND

Applied Suicide Intervention Skills Training (ASIST), a standardized, manualized,

internationally recognized training developed by LivingWorks, has been adopted by the U.S. Armed Forces,[55] and the Centers for Disease Control.[15] Grounded in a public health framework, ASIST prepares *natural helpers* to facilitate life-assisting interventions at the moment needed.[36,56] ASIST is the only evidence-based *intervention* training that has been found to reduce suicidality in real time.[57-59] Emphasis is placed on the *"quality of the interaction between the natural helper and the person-at-risk,"*[15] with a focus on how that connection can reduce risk while connecting the person with resources. ASIST-trained helpers learn to address a variety of emotional disturbances,[60] and its intervention model (i.e., pathway for assisting life) can be generalized to work with additional challenges such as social isolation and loneliness. In some instances, ASIST has been found sufficient to keep the person-at-risk safe, with no further need for dedicated mental health services.[51] ASIST-saturated hospitals,[61] school systems,[62] and military contexts[55] have reported ***reduced suicides***, ***more brief interventions,*** and ***fewer referrals*** to other services. ASIST is appealing to the ASN, as it is ***not*** likely to increase the need for coordinating official mental health treatment as older adults are getting needs met in real time.

ASIST equips volunteers with intervention skills that keep them from feeling "immobilized" and unsure of how to help when they feel something is wrong with their older adult clients, which may prevent burnout. ASIST trained nutritional service (NS) volunteers are ready, willing, and able to ask directly about suicide, understand the stressors in client's life, work effectively with ambivalence about dying, identify reasons for living, and create a mutually agreed upon safe plan[46] (see Appendix C). In spite of its merits, ASIST was not developed with older adults in mind, and outcomes have not yet been rigorously evaluated in the ASN context. Similar to the augmented version of ASIST for the military, LivingWorks has agreed to work with us to adopt a new ***aging specific variant of ASIST*** (see letter of support). Modifications include video scenes of warning signs in older adults (i.e., voluntary stopping of eating and drinking), understanding thwarted belongingness and perceived burdensomeness in later life, and role plays relevant to working in the nutrition context. Trained NS volunteers will be able to identify and respond to the unique situations they may face during HDM, and now in other socially distanced communications with older adults.

Phone-based *Belonging through Empathy* (BE) Training will be a brief, online module to guide NS volunteers in how to foster a sense of belonging for older adults through empathic, engaged listening (see Appendix B). Concrete tips are provided for ensuring calls are conducted in a manner that fosters *relationships* -- putting natural helpers into the lives of older adults. People who are connected and feel understood are at less risk for suicide than those who are isolated. Belonging is a powerful reason for living among older adults,[63] and its absence is a proven risk factor for suicide.[12] Empathy consists of genuinely engaging, recalling details from previous conversations, and maintaining composure and care when painful material is identified.[28] Developments in biology and neuroscience routinely show that empathy is a core building block of human connection,[64-65] making it an essential skill for volunteers to develop and employ when speaking with older adults. By equipping NS volunteers to promote a sense of belonging through empathic techniques such as active listening, building trust, and communicating a sense of mattering, we aim to reduce social isolation, loneliness, and elevated suicidality for HDM recipients and former CM clients.

3. 2.3 RISK/BENEFIT ASSESSMENT

1. 2.3.1 KNOWN POTENTIAL RISKS

In the short term, there is the possibility that participation in this project may cause older adult participants to feel some worry or concern - for example, they may be asked about how they have been coping, and this may bring up feelings of anxiety. However, research has shown that talking about stressful life events provides opportunities to receive support and actually reduce stress. If participants experience any concerns,

the informed content specifies that study personnel are available to answer any questions they may have and to provide support. Another known risk is the possibility of the participants feeling a sense of loss once the study is over as they will have built relationships with their calling providers.

In the long term, there are no risks affiliated with participation in this study.

2. 2.3.2 KNOWN POTENTIAL BENEFITS

Immediate potential benefits: Social support has been proven across hundreds of behavioral health studies to be one of the strongest predictors of positive psychological outcomes following disaster. Research has also shown that connecting with others during crisis, disaster (i.e. pandemic) is helpful in the immediate. Across disasters talking about, expressing, and feeling one's feelings has been found to set persons apart from those that do not in terms of faring better as a result of experiencing crisis/disaster[39].

Long term potential benefits: Overall, we hope to gain information about the BE WITH innovation, and ideally submit BEWITH to be accepted on the National Council on Aging's (NCOA) evidence-based registry to enable warm calling programs to occur across the US. Currently, there is no program to make warm calls, or visits remotely on the NCOA registry, so the older adult participants in this study will be made aware (in the informed consent) of this larger purpose and that they are helping contribute to bringing these types of warm calling programs to older adults across the country.

3. 2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Older adults are the highest risk age cohort for suicide however the least likely to receive intervention. Creating an opportunity to receive an 8-week caring contacts intervention may be a standardized and measurable means of catching those at risk and responding to them in real time. While any risk to participants for participation is deemed extremely low, assessment questions might create some feelings of discomfort. Providing the assessment questions is a necessity for tracking mental health variables (including suicidality) as well as being able to measure the impact of the treatment across conditions.

The value of the information gained outweighs any risk of participation. Older adults at risk will receive 8 weeks of standardized and manualized warm calls, potentially with intervention if at risk of suicide, and the knowledge learned will enable us to get this treatment on NCOA's evidence-based registry. This will enable AAA's (Area Agencies on Aging) and senior centers throughout the country to use Title 3D dollars to put this program into their contexts to respond to older adults experiencing mental health distress and better respond to the problem of suicide in this population.

4. 3 OBJECTIVES AND ENDPOINTS

Objective	Metric/Variable	Hypothesis/role/endpoint	Analysis

Validate the **BE WITH** innovation	Reduce loneliness, and elevated suicidality, and increase the degree to which social needs are met	Over the 8-week treatment loneliness and suicide desire (as measured by the UCLA loneliness scale, Interpersonal Needs Questionnaire) will be significantly decreased, and the variable of social needs being met (as measured by the social provisions scale) will be increased for both treatment groups	Longitudinal growth modeling
Validate the **BE WITH** innovation	Three treatment conditions	Those older adult participants randomly assigned to the BE or BE WITH treatment condition will demonstrate significant improvements in mental health outcomes when compared with the control group	Longitudinal growth modeling
Validate the **BE WITH** innovation	Risk tier	Those older adults that start the 8-week treatment at medium or high risk will have statistically significant improvements when compared with those of low risk	Longitudinal growth modeling
Validate the **BE WITH** innovation	Provider effects	Determine if there is variance in outcomes as a result of the provider assigned. 60 providers were trained in either BE or BE WITH and carried caseloads of older adult clients enabling the nesting of effects to determine if there are individual or group level provider effects	Multilevel modeling
Validate the **BE WITH** innovation	Improved quality, frequency of empathic and suicide intervention best practice behaviors by trained NS providers	An augmented version of Gould's (2013) coding protocol was developed to quantitatively behaviorally code treatment call dosages.	independent quantitative behavioral coding, double coding, 2 protocols, inter-rater agreement, coefficient kappas

The main overarching objective of the clinical trial is to validate the 8-week BE WITH warm calling program, equipping the Aging Services Network (ASN) with proven skills to reduce social isolation, loneliness, and elevated suicidality, while also promoting social support/well-being. The goal of the validation objective is to garner the evidence needed to get the first such program on the National Council on Aging's Evidence Based Registry.

5. 4 STUDY DESIGN

1. 4.1 OVERALL DESIGN

This study is a partially nested randomized controlled trial research design (PN-RCT[74-77]) with a two-level structure of clients (level-1) nested within callers (level-2) for the two treatment conditions

which receive calls. Given that outcomes for older adults receiving calls from the same volunteer may be more similar than for those who receive calls from a different volunteer, the use of multilevel modeling can account for these data dependencies.

We will be investigating 1) how our *BE WITH* innovation reduces social isolation, loneliness, and elevated suicidality among HDM and former CM clients and improves their social support and well-being. Social isolation, loneliness, and elevated suicidality will be operationalized through a combination of validated psychometric measures taken before, during, and after the structured 8-week intervention. For older adults receiving calls, data from validated measures will be triangulated with behavioral observations of the older adults' emotional states based upon a structured analysis of recorded audio files.

We hypothesize that older adults in both treatment conditions will have *reduced: social isolation, loneliness, depression, anxiety, mental health distress, and suicide desire;* and they will have *increased*: *social connection, social support, and well-being* over time and in comparison to those in the control condition.

We will also investigate 2) how *BE WITH* improves the frequency of empathic and suicide intervention best practice behaviors by NS volunteers to older adult participants that have heightened social isolation, loneliness, and elevated suicidality. This will be demonstrated in both real-world settings and in situations where a *research confederate* presents a clinically heightened risk of social isolation, loneliness, and elevated suicidality. Evaluation of counseling or suicide intervention skills is challenging,[15] as observations of caregivers working with clients are required.

We hypothesize that those trained in both conditions will demonstrate *positive global counseling behaviors*; however, those trained in *BE WITH* will more often employ *suicide intervention practices* when needed.

Measured Outcome	**Sample**	**Data Collection / Tracking**
Reduction in loneliness, elevated suicidality, and improved social support/well-being for older adult clients Validated constructs (**see appendix D**): *Loneliness* (UCLA); *Social Support* (SPS); *Suicide -- Risk* (SBQ-R), *Suicide Desire* (INQ), *Suicide Capability* (FAD); *Depression* (PHQ); *Anxiety* (GAD); *Distress* (K6);	540 Clients, randomly assigned to 3 conditions. This includes the 2 tx conditions and a control that receive no calls Stratified random sampling by 3 levels of loneliness and suicidality (low, medium, and high risk tiers)	Data collection for older adult participants: · pre intervention (baseline) · measurement occasions every 2 weeks (total of 5 measurement occasions)

Improved frequency of empathic and suicide intervention best practice behaviors by NS volunteers Coded constructs: Adapted observation protocol[51] ·	60 Volunteers, randomly assigned to 2 conditions. · *BE* training only · *BE WITH* (*BE* training plus ASIST) Those trained in BE will be offered ASIST after the study.	Preceding the intervention study, all volunteers receive *BE* (phone-based social connection) training. *BE WITH* volunteers will be given the standardized and manualized ASIST training (if they have previously received ASIST, they will be provided with the ASIST refresher training).

Validated outcome measures are essential for effective evaluation of any mental health or suicide prevention programming. While the social isolation, loneliness, and elevated suicidality constructs we will study are listed in the following table, the specific psychological scales that measure them are listed and explained in Appendix D. The comprehensive battery of assessments has been field tested and well received by older adults (Appendix D). We have also completed cognitive interviews[70] (administered questions and sought feedback on the experience from older adults), and trained data collectors to use a conversational style in speaking with participants. Short forms of several of these measures will be completed weekly by the older adults and take 15 minutes to complete.

Analyses will investigate the effect of treatment conditions (*BE, BE WITH,* and control) on post-intervention outcomes (i.e. endpoints) while controlling for baseline responses (prior to intervention). Furthermore, analyses will explore differences between treatment conditions in longitudinal trends of client state as well as how volunteers utilize specific intervention skills over time. For this longitudinal data, a lower level of nesting will be included in the analysis: weekly call and state data (level 1) nested within older adults (level 2) nested within volunteers (level 3). However, the PN-RCT design would only have levels 1 and 2 for the control group.

2. 4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Due to increased social isolation and loneliness in older adults, experts have called for innovative approaches to address them, including "training nontraditional groups to provide psychological first aid, helping teach the lay public to check in with one another and provide support."[27] The aging services network (ASN) has made concerted efforts to reconfigure key programs to protect older adults and is prioritizing programs that can be delivered remotely. ADvancing States[25] has described how community-based organizations are launching programs intended to address social isolation and loneliness, with ***phone-based social connection*** identified as a promising strategy to engage volunteers and support at-risk older adults. In April 2020, the National Council On Aging (NCOA) surveyed community-based organizations about older adult clients' needs, and 62% described "staying socially connected while physically distancing" as a "high priority."[26] Meanwhile, the report indicated due to the pandemic, the need for home-delivered meals (HDMs) increased while that for other programs (e.g., chronic disease self-management, falls prevention, caregiver support) decreased.

In May 2020, we developed guidelines for the Administration for Community Living (ACL) regarding how nutrition services (NS) volunteers can foster and maintain meaningful connections with socially isolated older adults. That document, *Enhancing Socialization through Making Meaningful Volunteer Connections* (Appendix B), provides 15 recommendations for engagement in phone-based social connection. Although these programs are in early stages of

development within the ASN, there is evidentiary support that key skills such as active listening,[28] empathy,[29] and promoting a sense of belonging[30] may be vitally important. Unfortunately, no programs on the NCOA Evidence-Based Registry address social isolation, loneliness, and elevated suicidality. Our innovation seeks to remedy that.

3. 4.3 JUSTIFICATION FOR INTERVENTION

Many older adults who are at-risk for social isolation, loneliness, and elevated suicidality are also at risk for food insecurity or institutionalization. The Older Americans Act (OAA) Nutrition Program that includes congregate meal (CM) and HDM is *the largest and primary program* within home and community-based services (HCBS)[31], making it a strategic context to address other issues, such as social isolation, loneliness, and elevated suicidality, among at-risk older adults. Many homebound older adults have limited social contacts,[32] including 20% who have infrequent contact with friends or family.[33] NS volunteers often form an important part of older adults' social support networks.[34] In previous research, measures of loneliness and well-being improved for older adults after just two months of receiving HDM services.[35] Consistent with a public health approach to prevention[36], NS volunteers already function as ***natural helpers***, defined by suicide researchers as those "who already have close communication" with older adults either through their "ongoing job role" or by "virtue of personal qualities, such as warmth and empathy."[37-41] Volunteers from NS programs may be among very few individual(s) who interact on a *regular basis* with older adults receiving NS. This is particularly relevant to supporting older adults' mental health because depression rates are three times higher in older adults who require in-home care compared to community samples[42], and 13.4% of HDM clients reported suicidal thoughts to a volunteer[45]. NS volunteers are vital in helping these older adults remain safe and in the community.

Our team has previously established the ASN is a strategic context to address suicide risk, and NS volunteers are uniquely positioned to intervene due to their regular and ongoing interactions with older adults[43], due to their pre-established relationship with them.[44-45] Our previous work equipping NS volunteers with evidence-based skills to intervene with older adults experiencing suicidality is, to our knowledge, the first of its kind (ACL grant 90INNU0010-01-00). In our analysis we found NS volunteers were able to learn suicide intervention skills effectively (significant pre to posttest changes, high effect size) and utilize them to provide social support.[46] Furthermore, they exhibited increased comfort, competence, and confidence about responding to older adults at risk of suicide.[47] County leadership reported trained volunteers were "more aware", "more likely to pick up extra shifts", and "more invested" (see Cobb letter of support). NS volunteers demonstrated increased awareness of older adult mental health needs, and were better equipped to respond to suicide risk.[50] Although this training was only in one system for a limited time, more than 30 interventions were tracked, including some over the phone.[50] These findings provide a proof of concept for having NS volunteers address social isolation, loneliness, and elevated suicidality alongside their role in delivering meals, and that additional investigation of such trainings could well demonstrate the outcomes with older adults required for eligibility on the NCOA registry.

4. 4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline assessment, 4 additional measurement occasions evaluating the treatment (8 weeks of treatment call dosages).

6. 5 STUDY POPULATION

1. 5.1 INCLUSION CRITERIA

In order to be eligible to be **a participant** in this study, an individual must meet all of the following criteria:

1. Provision of verbal informed consent
2. Classify as an Older Adult (65+)
3. Stated willingness and ability to comply with all study procedures
4. Receive nutrition services through the Aging Services Network (i.e. either HDM (home delivered meals services) or CM (congregate meals))
5. Be affiliated with one of the 25 senior centers we will contract with through a Memorandum of Understanding

In order to be eligible to be **a trained helper** in this study, an individual must meet all of the following criteria:

1. Provision of written informed consent
2. State willingness to comply with all study procedures
3. Be a staff or volunteer within the ASN (Aging Services Network), specifically within the 25 senior centers we are working with
4. Meet criteria for being a "natural helpers"[42] (i.e. be warm, empathic, and having ongoing interaction with participants through one's job role)
5. Be recommended by the senior center leadership as meeting these qualifications

2. 5.2 EXCLUSION CRITERIA

Exclusion criteria for **Participants**: An individual who meets any of the following criteria will be excluded from participation in this study:

1. Had a dementia diagnosis, or another form of cognitive impairment, and/or hearing impairment that would preclude phone conversation.
2. Participation in another warm calling behavioral treatment or intervention study simultaneously occurring in this state

The reasons given to exclude participants with dementia/cognitive impairment diagnoses from large-scale clinical research are partially related to the concern of a potential risk of abuse and exploitation. Further, those with cognitive impairment are not able to give informed consent, and there are measurement challenges with behavioral health data.

Exclusion criteria for **trained natural helpers**: An individual who meets any of the following criteria will be excluded from participation in this study:

1. Does not have ongoing interactions with potential old adult participants (i.e. is a part of an optimized nutrition service provider in which they do not serve the same older adults consistently over time
2. Participation in another warm calling behavioral treatment or intervention study simultaneously occurring in this state

3. 5.3 LIFESTYLE CONSIDERATIONS

N/A

4. 5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently randomized and assigned to one of the 3 treatment conditions. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria (i.e. cognitive impairment) will be removed from the study.

If participants drop out between being consented, randomized, and assigned, they will have the opportunity to be rescreened and join a subsequent wave of treatment.

5. 5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

To adequately power the PN-RCT we need 540 participants. We plan to recruit and screen three times that number, and enroll a minimum of 200 more, to account for potential attrition issues.

Recruitment strategies include the following:

1. Flyers to be provided to older adults receiving HDM through their home delivered meal provider along with their meal
2. Announcements of the study opportunity to be received by older adults through their case managers
3. After 1 and 2, graduate research students will make personalized calls to the older adults to go over the recruitment script and study procedures.

Sample information to be provided to older adults:

You are invited to take part in a research study. It is up to you to decide if you would like to take part in the study. The purpose of the study is to investigate the BE WITH innovation. You are invited to participate because you are a recipient of HDM services in X county. A total of 540 older adult clients receiving HDM will be included in the study. If you choose to participate, you will take a survey that will determine your eligibility, and you will be compensated for your time to take this survey. Your role in the study will take place over an 8-week period. Depending on your randomly assigned group, this time may be spent talking on the phone, and/or answering a short survey. The risks of being in this study include potentially having more worry or anxiety. This study is designed to benefit you, as the BE WITH program is designed to give more interpersonal connections to older persons. Overall, we hope to gain information about how nutrition services can provide more support to older adult clients.

The purpose of the study is to investigate the BE WITH training for nutrition service volunteers and understand how it impacts the wellbeing of nutrition service clients. You are invited to take part in this research study because you are, or have recently been, a nutrition service client. A total of 60 volunteers will be invited to take part in this study along with up to 540 older adults.

If you decide to take part, you will talk to a student at GSU by phone who will ask you some questions in a survey. You will receive $20 for taking this survey. Based on that survey, if you meet criteria for the program, we will contact you, and you will be assigned to either a study group or a control group. If you are assigned to the study group, you will be called by a volunteer once per week for 8 weeks, and using an audio feature on teleconferencing software, both you and the volunteer will be recorded. However, all identifying information will be removed from the recordings. During this project, you may receive a call from a number you do not recognize. This will be the software we are using to connect you with volunteers, and to keep both of your identities safe. Once the call is recorded, no one will be able to connect your name or number to the recording. All involvement with this project will be done remotely, therefore you can participate from your home. All participants who enroll in the program are asked to spend 15-20 minutes completing a survey every other week over the phone.

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

There is the possibility that participation in this project may cause you to feel some worry or concern - for example, the volunteer may ask you about how you're coping as they talk with you, and this may bring up feelings of anxiety. However, research has shown that by talking about things that are on our mind we feel better. If you experience any concern, we are available to answer any questions you may have and to provide support. No injury is expected from this study, but if you believe you have been harmed, contact the research team as soon as possible. Georgia State University and the research team have not set aside funds to compensate for any injury. Overall, we expect the risk of participation will be low/minimum.

Participation in this study may benefit you personally. Research has shown that connecting with others during crisis, disaster, and pandemic is helpful. Overall, we hope to gain information about the BE WITH innovation, and ideally submit BE WITH to be accepted on the National Council on Aging's (NCOA) evidence-based registry to enable warm calling programs to occur across the US. Currently, there is no program to make warm calls, or visits remotely on the NCOA registry, so you are helping us make that happen.

The alternative to taking part in this study is to not take part in the study.

If you choose to participate, and do not meet eligibility criteria, you will be provided $20 dollars for taking the baseline survey and your involvement will be complete at that time. If you do meet criteria to be enrolled in the BE WITH program, based on your assigned group, you will be required to take part in weekly phone calls and/or complete a survey every other week. If you are eligible and choose to participate, you will be mailed $20 cash at the start of the 8 weeks, and $80 in cash after you complete the eight-week program. This means that you are entitled to $100 total if you complete the eight-week program.

Your participation is voluntary. You do not have to be involved in this project. If you decide to be in the study and then change your mind, you have the right to drop out at any time. You may stop participating at any time. If you stop participating, this will not cause you to lose any compensation you have already received, but you will not receive any future payments.

We will keep your records private to the extent allowed by law. The following people will have access to any information that you provide:

- *Dr. Shannonhouse*
- *GSU Institutional Review Board*
- *GSU Office for Human Research Protection (OHRP)*
- *The Administration for Community Living (part of the Federal Department of Health and Human Services)*

We will use a code generated from a combination of your initials and county to de-identify you on project records to protect your confidentiality. The information gathered from the calls will be stored on a password-protected and firewall-protected computer. The key that holds your code will be stored separately from the data to protect your privacy. The audio recordings and any transcripts will be destroyed within 2 years along with the code key information. Since any information that is sent over the internet may not be secure, we are only using data encrypted protocols and are not logging IP addresses. Also, only one supervising staff member at the Southern Georgia Regional Commission will know that you have elected to participate. That person will not have any access to your phone recordings or surveys and will not even know which group you have been assigned to.

Contact Dr. Laura Shannonhouse at 352.359.0950 or lshannonhouse@coe.ufl.edu

- *If you have questions about the study or your part in it*
- *If you have questions, concerns, or complaints about the study*

We will give you a copy of this consent form to keep.

7. 6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

1. 6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

1. 6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

The BE WITH program is grounded in (1) the Befriending and Narrative Reminiscence literature which are best practices in working with older adults, and (2) the Interpersonal Psychological Theory of Suicide (ITPS)[33,34]. BE WITH includes an 8-week warm calling treatment that is delivered to older adults (racially and economically diverse, urban, suburban, and/or rural). At the start of the program, older adults are asked to reminisce about their life, and provide the treatment provider some information that can be built upon in subsequent call dosages (see graphic below).

Each week an older adult participant will receive a 20-30 minute "call dosage" from treatment providers that are trained in 1 of 2 protocols:

(a) BE condition which involves receiving call dosages from providers trained to foster **b**elongingness and **e**mpathy (2 hours), grounded in the befriending literature[35,36], and narrative reminiscence[37]. Aging Network Providers trained in BE provide a “small dose of sincere connection”, through **narrative reminiscence**, and the **“befriending”** strategies.

While the majority of the warm calling of BE WITH centers on this basic connections intervention, there will also be individuals who need more than connection, but rather targeted intervention as approximately 20% of older adults receiving home and community-based services are at risk of suicide[38].

(b) BE WITH condition includes receiving call dosages from providers trained in BE + the aging variant of LivingWorks ASIST (Applied Suicide Intervention Skills Training)[40]. Those older adults assigned to this treatment condition will have both the connections intervention, as well as suicide interventions in the chance that one is needed.

(c) control group includes no treatment, or call dosages. Every two weeks graduate research students administer the measureset, just as they did for the 2 treatment conditions.

The same time intervals of outcome measures are administered across all 3 conditions.

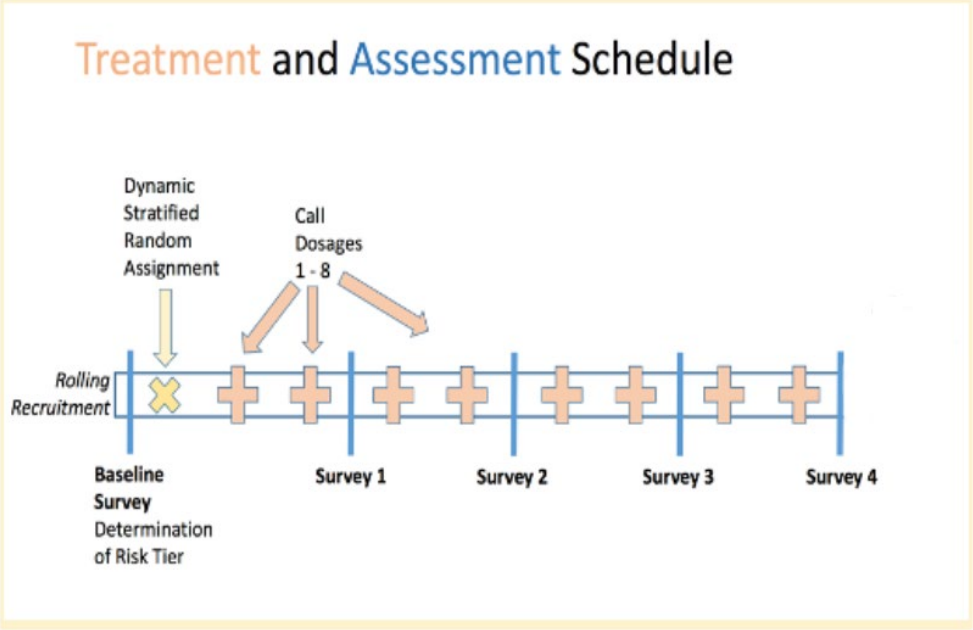
2. 6.1.2 ADMINISTRATION AND/OR DOSING

Sixty trained providers (30 in each treatment condition) will provide the treatment to an assigned caseload of older adults via the phone. We are working with software developers (i.e. Friendlybuzz) who built a system to automatically record the audio files of the treatment dosages. Research team members will populate the caseloads of the older adult clients into Friendlybuzz for the treatment providers which enables the older adults contact information to remain protected (a requirement of our community partners). After caseloads are populated, treatment providers will call into the Friendlybuzz system; treatment providers push "1" for their first older adult, "2" for their second, and so on through their caseloads of 5-7 older adults each.

Treatment providers will not have any interaction with the older adults outside of providing the treatment. Every two weeks, after two call dosages (20-30 minutes each), data will be independently collected from the participants from trained graduate students at Georgia State University. This will go on for an additional 3 measurement occasions, for a total of 4 measurement occasions + the baseline (see graphic below).

Complete participation includes eight full call dosages between the average of 20-30 minutes each. Please see the graphic below for the complete treatment and assessment schedule.

8.



1. 6.2 FIDELITY

1. 6.2.1 INTERVENTIONIST TRAINING AND TRACKING

The five core components to the BE training include:

1. **reciprocity**: the feeling that both parties are benefiting
2. **intimacy**: willingness to share deeply (superficial sharing at first helps build the relationship, but deeper sharing is what leads to positive outcomes)
3. **reliability** & **respect** (calling at the time you say you are going to call creates consistency and reliability, and that the older adult matters
4. **proximity**: feeling more connected to people within your community
5. **autonomy**: feeling both parties are willingly participating with each connection

Analogous to CPR (lay providers equipped to help someone that is drowning), anyone can learn "suicide first aid", or LivingWorks ASIST. Persons trained in ASIST connect directly with the older adult at risk through a six-step model called the *Pathway for Assisting Life (PAL).* The PAL model matches *six needs* of the older adult-at-risk with *six tasks* of the caregiver.

Persons-at-risk (and helpers) often perceive only two options: (a) to die by suicide, or (b) to live. Choosing to live or die can be a tough choice when an individual is struggling with suicidality. The ASIST training introduces a third option, which is to *stay safe for now*. Through engaging the PAL model those trained help the patient-at-risk identify ambivalence about dying, confusion, and even reasons for living. This is a little miracle that saves lives, as it removes the dichotomy of life/death, and ASIST training equips lay providers to do this. Caregivers are not taking away the choice to suicide, and the person's autonomy. Rather, ***through*** the intervention, caregivers return autonomy to persons-at-risk by helping them identify *their own reason(s) to live*, and link that to a safety plan that puts suicide on hold for the moment, which may turn into staying safe in the long term. The 6 steps of the PAL include:

1. Notice and explore invitations (i.e. voluntary stopping of eating and drinking, withholding medical treatment, withdraw, talking directly about suicide, etc.)
2. Asking directly about suicide
3. Not only listen, but sincerely hear the story about suicide
4. Work effectively with ambivalence about dying, which involves listening closely for confusion, ambivalence, hesitancy to die by suicide as the person is sharing their story, and offering a 3rd option (to stay safe for right now) which is an easier choice to make, and more aligned with the reality that there is some hopelessness that things will never change, and offering this 3rd option creates space for the opportunity for some things to change
5. Developing mutually and agreed upon safety plans
6. Confirming actions (or asking the older adult to repeat the safety plan back to us that we have developed together to assess their degree of commitment to it)

Success of the training will be evaluated through pre, post and follow up training level outcome measures. Further interventionists will be objectively rated by trainers and supervisors.

The degree to which those trained adhere to the intervention will be managed with the use of the Friendlybuzz system. This enables the research team to track the fidelity and delivery of the intervention in real time. This system automatically records and transcribes each treatment dosage, while organizing the treatment dosages within each participant, nested within each treatment provider, along with the dates and duration of each of the treatment dosages.

There will not be any changes to any groups or clusters (i.e. treatment providers' caseloads of older adult participants) unless there is a challenge with a treatment provider. If there is such a challenge,

we will first support the treatment provider through the weekly supervision groups. If the challenge persists or in the very rare case that we have a treatment provider that can no longer provide the treatment, any older adult participants that are assigned to the treatment provider will be re-baselined, and re-randomized to a new treatment provider. Again, we imagine this to be very rare.

2. 6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

We will use weighted stratified random assignment[41]. After participants are baselined, we will score their data and assign them a risk tier (low, medium, high). Subsequently, we will randomize them to one of 3 conditions: BE condition, BE + ASIST condition, or control. Since the trial is being conducted in cohorts (waves), and to ensure the least amount of time between being baselined and starting the treatment, participants will be randomized one by one after they are baselined. The weighted component enables there to be equal representation of both risk tier and number of participants across all 3 treatment conditions within the confines of the ongoing nature of the trial.

At the time of baseline, participants are assigned 2 codes: one that is fully numeric, and another that is alphanumeric. The PI and graduate student(s) will have access to the unblinded data (i.e. both the older adults' names, codes, and baseline data) as the PI is supervising the process and a few graduate students will be helping with scoring, and the weighted stratified random assignment. The methodologist will only have access to the participants' codes and raw data. They will remain blind to ensure the most objective analysis of the data.

If a participant remains at elevated risk for suicide at the conclusion of the treatment, we will unblind them and report to their assigned case manager.

We will also use separate documents with participant codes only to track the following: treatment condition, rebaselines, any survey/measurement issues, risk tiers, etc. to ensure an additional level of rigor in protecting against any bias. Further, in all tracking files that the PI's research lab utilizes, only participant IDs will be utilized (i.e. tracking which participants are up for the next measurement occasion, etc.).

The only potential inadvertent unblinding that we could foresee would be with respect to the use of the Friendlybuzz system. The treatment providers do need to know the first names of the older adult participants, therefore ONLY their first names will be available. The data team, however, is completely distinct from the treatment team, and will not have access to the Friendlybuzz system.

3. 6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Participants' adherence to the study procedures will be tracked in two ways: (1) through the Friendlybuzz system (tracking adherence to the treatment), and (2) through lab tracking documents (adherence to the measurement, data collection). The Friendlybuzz system will allow us to track in real time the call dosages as they are coming in, the duration of those, timing, etc. The lab tracking documents will enable us to know which participants need the next measurement occasion for data collection. These two

processes remain separate and distinct, to ensure that the treatment is distinct from the measurement of the treatment.

Treatment providers are required to complete training a priori, and utilize the documents and tools (i.e. guidelines for making sincere connections, reminiscence table whereby there are questions provided in each area of the older adults life for the treatment provider to track and follow up on in subsequent sessions, etc.) provided to them to deliver 8 high quality treatment dosages to their caseload of older adult participants that are 20-30 minutes in duration each. They are required to track that, as well as attend weekly supervision and check in with a supervisor who is tracking their treatment delivery through the Friendlybuzz system.

Participants are required to complete a "participation plan" which will be mailed to them after they are baselined, meet eligibility criteria and are randomized. Those randomized to one of the two treatment conditions are required to participate in 8 call dosages and 4 additional measurement occasions. Those randomized to the control group are required to participate in 4 additional measurement occasions and provided with the option to receive 8 call dosages 2 months later (delayed waitlist control).

4. 6.5 CONCOMITANT THERAPY

N/A

1. 6.5.1 RESCUE THERAPY

N/A

9. 7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

1. 7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

Since this study involves older adults there may be death which would result in the participants' inability to continue the study.

2. 7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants may withdraw voluntarily from the study at any time, and/or the PI may discontinue a participant from the study if the participant has cognitive impairment and has somehow not been excluded previously. The rationale includes (a) limited/incorrect data being collected from any participant with cognitive impairment, and (b) may be potentially distressing to participants with cognitive impairment. The only reason this is included here is in the very slight chance that a participant with cognitive

impairment gets through the screening processes we have in place, PIs have the obligation to remove them from the study.

We will have ongoing contacts with older adult participants throughout the 8-week study. We anticipate low attrition due to weekly doses being provided by the ASN providers we train and supervise to provide the treatment as well as every other week data collection by trained graduate students. During supervision meetings with both those trained providing the treatment, as well as those collecting the data, any challenges will be discussed and addressed. Data collectors have an "on call" schedule in which at all times there are 2 members of the PI's lab that will be tracking data and data needs. In addition, daily tracking will occur by the grant coordinator who will post any missing data through de-identified participant ID codes in a shared GroupMe with the trained data collectors to ensure that those "on call" can collect that data in real time.

Any participant that chose to withdraw will be supported for their choice. We anticipate that older adults may have health issues, hospitalizations, and/or various other serious adverse events in their lives and we will ensure the tracking of these for attrition reasons. The data to be collected at the time of study discontinuation will include the following:

- The reason(s) for discontinuing the participant from the intervention (for attrition tracking)
- If the participant is due to complete assessments and whether or not those assessments will be administered at the time of discontinuation

For any participants that discontinues due to a health issue, hospitalization or otherwise and wishes to continue treatment, we will offer to re-baseline them and re-enroll them in a subsequent wave of treatment to ensure that the challenge that existed in their life does not keep them from being able to participate.

3. 7.3 LOST TO FOLLOW-UP

The following actions must be taken if a participant fails to answer the phone with attempts to administer treatment and collect data:

- We will attempt to contact the participant, reschedule the missed survey or call with the trained helper within the next 72 hours and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls or reach out to the designated senior center case manager). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

As far as any missing data that may result, we are utilizing the Intent to Treat (ITT) approach therefore all data from any participants lost to follow-up will be included, and data not collected left blank in the longitudinal multilevel modeling analysis.

10. 8 STUDY ASSESSMENTS AND PROCEDURES

1. 8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

Research Measures for BE WITH

Socialization

1. University of California, Los Angeles Loneliness Scale (UCLA) measures loneliness

https://fetzer.org/sites/default/files/images/stories/pdf/selfmeasures/Self_Measures_for_Loneliness_and_Interpersonal_Problems_UCLA_LONELINESS.pdf

2. Social Provisions Scale (SPS-5) measures social needs (table 2).

https://www.canada.ca/en/public-health/services/reports-publications/health-promotion-chronic-disease-prevention-canada-research-policy-practice/vol-39-no-12-2019/original-quantitative-research-social-provisions-scale.html

Health and Wellbeing

3. Generalized Anxiety Disorder (GAD-7) measures anxiety.

https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf

4. Patient Health Questionnaire (PHQ-9) measures depression.

https://med.stanford.edu/fastlab/research/imapp/msrs/_jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9%20id%20date%2008.03.pdf

5. Short Form Health Survey (SF-12) measures quality of life.

https://www.hoagorthopedicinstitute.com/documents/content/SF12form.pdf

6. Interpersonal Needs Questionnaire (INQ-15) measures suicide desire. The team will be using the thwarted belongingness scale only due to results from previous study.

https://psy.fsu.edu/~joinerlab/measures/INQ-15.pdf

7. Session rating scale measures the quality of the therapeutic alliance between a counselor and a client. This scale was adapted from a clinical context to assess the alliance between the older adult client and the volunteer/provider.

https://www.uvm.edu/~cpincus/Session%20Rating%20Scale.pdf

Measure	Acronym	What it measures	When to measure	Reliability/ Validity	Number of items	Sponsor (ACL) Category

University of California, Los Angeles Loneliness Scale	UCLA	Loneliness	All time points	Cronbach's alpha: 0.72 Discriminant validity and convergent validity demonstrated	3 items	Category 2: Socialization
Generalized Anxiety Disorder	GAD-7	Anxiety	All time points	Cronbach's alpha: 0.92 Good criterion, construct, factorial and procedural validity demonstrated	7 items	Category 3: Health and Well-being
Patient Health Questionnaire	PHQ-9	Depression	All time points	Cronbach's alpha: 0.89 Good concurrent validity when compared with SRQ-20 (71%, $p < 0.001$) and construct validity demonstrated	10 items	Category 3: Health and Well-being
Social Provisions Scale	SPS-5	Social Needs Being Met	All time points	Cronbach's alpha: 0.88 Criterion-related and structural validity demonstrated	5 items	Category 2: Socialization
Short Form Health Survey	SF-12	Quality of Life	All time points	Reliability: test-retest correlation of 0.76 for 12-item Mental Component Summary (MCS)	12 items	Category 3: Health and Well-being

				Relative validity estimates for 12-item MCS ranged from 0.60 to 1.07 (median = 0.97) in relation to 36-item short-form scale		
Interpersonal Needs Questionnaire	INQ-15	Suicide Desire-thwarted belongingness scale only	All time points	Reliability: Thwarted Belongingness - Cronbach's alpha: ~ 0.85 Good construct validity (thwarted belongingness correlated significantly with loneliness and low social support) and criterion-related validity (thwarted belongingness uniquely predicts current suicidal ideation: odds ratio = 1.59, $p < .01$)	15 items (8 TB)	Category 3: Health and Well-being

***Please review the table below for a summary of the main mental health measures utilized in this PN-RCT.*

Participant screening includes administration of the UCLA, INQ, and SPS, scoring them, and assigning a risk tier. Participants that are middle or high risk will be enrolled in the trial, whereas those that are low risk do not meet eligibility and will be called back to clarify/answer any questions they may have. Measures will be scored the same day, risk tiers and randomization assigned the same day, whereas the call backs to participants may take up to 72 hours.

Trained graduate student data collectors will be administering all assessments via the phone verbally to older adults. Each received training and administered the measure set, was provided with feedback, and made adjustments to ensure that the measures were administered with fidelity across the trial. Further,

there were notations in Qualtrics to indicate reverse coded items, etc., in which wording may be particularly confusing to older adults to remind data collectors to slow down, repeat, and/or rephrase to ensure that the older adult understood each and every item.

2. 8.2 SAFETY ASSESSMENTS

If a participant meets risk criteria for suicide desire at baseline, they are provided in real time, from data collectors, local and national resources (i.e. 1-800-SUICIDE, 988, local crisis center, G-CAL, etc.). If they remain at heightened risk over time, the PI and research team will communicate that to the senior center case manager assigned to their case.

3. 8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

1. 8.3.1 DEFINITION OF ADVERSE EVENTS

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

2. 8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

Refer to your institutional review board for the latest guidance and definition of Serious Adverse Events (SAE). In some cases, it may be appropriate to create a list of expected events that do not need to be reported to the IRB.

3. 8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

1. 8.3.3.1 SEVERITY OF EVENT

All adverse events will be assessed by the Principal Investigator, Dr. Laura Shannonhouse, and if necessary one of the two Co-PIs, Drs. Matthew Fullen or Dr. Erika LeBlanc. For any adverse events (AEs) not included in the protocol, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities (i.e. daily life stressor, etc.).
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning (i.e. illness, new diagnosis, etc).
- **Severe** – Events interrupt a participant's usual daily activity, potentially life-threatening or incapacitating (i.e. medical hospitalization, death, etc.)

2. 8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed by an appropriately-trained clinician/researcher. The degree of certainty about causality will be graded using the categories below.

- **Related** – The adverse event is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the adverse event, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the adverse event.
- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

3. 8.3.3.3 EXPECTEDNESS

A clinician/researcher with appropriate expertise in the treatment will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

4. 8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during the treatment, and/or data collection.

All AEs, not otherwise precluded per the protocol, will be captured on our lab tracking file. Information to be collected includes event description, time of onset, severity, relationship to study procedures, and whether or not the AE will impact the participant's ability to participate. All AEs occurring while on study will be documented appropriately regardless of relationship.

All AEs will attempt to be followed up with resolution, to the degree possible. However, in some cases, resolution may not be possible (i.e. hospitalization, death).

Data collectors will record any AEs that present during data collection, and treatment providers will record any AEs that present during treatment.

5. 8.3.5 ADVERSE EVENT REPORTING

There are no responsibilities of investigators for reporting of AEs outside of the study team and the clinical database with the exception of sustained suicide risk, which as previously noted will be reported to the case managers assigned to those particular older adult participants. This is noted in our MOUs with the 22 participating counties.

6. 8.3.6 SERIOUS ADVERSE EVENT REPORTING

In consultation with the PI, a trained member of the study team will be responsible for conducting an evaluation of a serious adverse event and shall report the results with the sponsor, and if relevant the participating AAAs (Area Agencies on Aging).

7. 8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8. 8.3.8 EVENTS OF SPECIAL INTEREST

N/A

9. 8.3.9 REPORTING OF PREGNANCY

N/A

4. 8.4 UNANTICIPATED PROBLEMS

1. 8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

2. 8.4.2 UNANTICIPATED PROBLEMS REPORTING

The Principal Investigator will report any unanticipated problems (UPs) to the Institutional Review Board (IRB) and to the sponsor.

Any UP report will include the following information:

- Grant #/IRB #
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the PI's Office of Research and Compliance (IRB) within 7 days of when they arise
- If there are any deviations from the protocol, a protocol deviation form will be submitted to the Office of Research and Compliance within 7 days of the deviation
- Upon reconciliation of the deviation, the PI will provide written documentation through federal monitoring reports of any AEs and/or protocol deviations

3. 8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

11. 9 STATISTICAL CONSIDERATIONS

1. 9.1 STATISTICAL HYPOTHESES

Primary Endpoint(s):
We hypothesize that older adults in both calling conditions will have reduced: social isolation, loneliness, depression, anxiety, mental health distress, and suicide desire; and they will have increased: social connection, social support, and well-being over time and in comparison to those in the control condition.

Secondary Endpoint(s):
We hypothesize that volunteers in both treatment conditions will demonstrate positive global counseling behaviors: demographics, The Empathy scale; however, those trained in BE WITH will more often employ suicide intervention practices when needed: SIRI-2.

2. 9.2 SAMPLE SIZE DETERMINATION

To determine appropriate sample sizes, we used formulas developed for PN-RCTs with continuous outcomes[76] and binary outcomes[77] as well as results from a closely related study[52] that tested the effect of the ASIST intervention with similar outcome measures. To detect an effect size of .40 with a continuous outcome, utilizing a Type I error rate of .05, power of .80, ICC of .20, and R^2 of .50 (for baseline covariate), we need 270 older adults with 30 volunteers each calling 6 older adults. For a binary outcome under the same assumptions,[78,79] we would require 414-522 older adults with 46-58 volunteers for most estimates of the probability of an outcome in the treatment and control groups. Recruiting 540 older

adults (180 in each condition) and 60 volunteers (30 for each treatment condition) provides an adequate sample to evaluate major effects of interest in all proposed analyses.[80]

3. 9.3 POPULATIONS FOR ANALYSES

The population for analysis includes all randomized participants who met inclusion criteria. We are using the Intention-to-Treat (ITT) Approach, meaning that even those participants that had an AE or dropped out of the treatment will still be included.

4. 9.4 STATISTICAL ANALYSES

1. 9.4.1 GENERAL APPROACH

For descriptive statistics, categorical and continuous data will be presented percentages, means with standard deviations, and ranges. For qualitative research, procedural and interpretive rigor will be monitored and maintained with the use of particular CQR methodology such as Consensual Qualitative Research[43,44] paired with odds ratio analysis to ensure that there are no demographic or treatment confounders. For inferential tests, we will use p-value at .01 and confidence intervals for statistical significance, along with effect sizes, etc. Covariates and confounders are pre-specified in the sections below. Checks of assumptions (e.g., normality) underlying statistical procedures will be performed and any corrective procedures needed and recommended by our biostatistician will be applied.

2. 9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

This validation study is a partially nested randomized controlled trial design (PN-RCT[74-77]) with a two-level structure of clients (level-1) nested within callers (level-2) for the two treatment conditions which receive calls. Given that outcomes for older adults receiving calls from the same volunteer may be more similar than for those who receive calls from a different volunteer, the use of multilevel modeling can account for these data dependencies. Analyses will investigate the effect of treatment conditions (BE, BE WITH, and control) on post-intervention outcomes while controlling for baseline responses (prior to intervention). Furthermore, analyses will explore differences between treatment conditions in longitudinal trends of client state as well as how volunteers utilize specific intervention skills over time. For this longitudinal data, a lower level of nesting will be included in the analysis: weekly call and state data (level 1) nested within older adults (level 2) nested within volunteers (level 3). However, the PN-RCT design would only have levels 1 and 2 for the control group.

3. 9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Analysis of the secondary endpoint(s) are not dependent on findings of the primary endpoint. The SIRI-2, an objective measure of suicide intervention skills, is calculated by comparing the trained helpers (paraprofessionals') ratings of how helpful or harmful a suicide intervention response was to a suicidal scenario to expert, criterion ratings. The top score one can make on the SIRI-2 is a 13, with 60 being fairly common in crisis center volunteers and most lay providers scoring in the 90s. Higher scores mean lower skills on SIRI-2, and the PI on this team developed new scoring and subscales[45] which also gets at

the degree to which a trained helper may underestimate the harmfulness of a response or overestimate the helpfulness of responses, enabling a second more nuanced scoring process. The Empathy scale is a Likert type self-report measure that is continuous. Repeated Measures ANOVA will be used to assess the degree to which trained helpers' suicide intervention skills and empathy are impacted as a result of the training (pre/post training measures) as well as at the end of the treatment (third and final measurement occasion). Demographics, prior training, prior experience and role will be evaluated as potential confounders. Results of RMANOVA will be presented with standard errors or effect size. Multiple imputation will be used to address any missing data.

4. 9.4.4 SAFETY ANALYSES

N/A

5. 9.4.5 BASELINE DESCRIPTIVE STATISTICS

For primary endpoints, tests of baseline equivalence will be run to ensure fair comparison across treatment groups, ensure outcomes can be attributable to the treatment, for enhancing validity, and for informing decisions about pooling data.

6. 9.4.6 PLANNED INTERIM ANALYSES

Since the clinical trial is structured to occur in cohorts, the longitudinal multilevel modeling (growth modeling) analysis will be run after each cohort is completed. Despite early cohorts being underpowered, we find significant value in understanding if the data are trending in the expected directions, and/or if there are any issues that need to be addressed. The methodologist running the analysis will remain unblinded throughout the analysis process. There are no temporary suspension or safety findings that would prompt temporary suspension of the treatment. The frequency of monitoring the end points is daily as older adult participants are on a rolling recruitment and finishing their treatment at different points in time. There is no effect of the interim analysis on the final analysis as it is the same analysis. Type I error results when running many different types of tests, however we are running the main analysis with an underpowered sample so that we are learning and understanding as we go. The final analysis will be the same code just with all the participants across all 4 cohorts.

7. 9.4.7 SUB-GROUP ANALYSES

Sub-group analyses on the primary endpoints will be assessed in two ways: (a) multi-level modeling by treatment severity group (same primary analysis, conducted independently for low, medium, and high risk patients), and (b) cluster analysis to explore any potential differential treatment effects across predefined patient subgroups (e.g., age, sex, race, etc.). Interaction terms between any subgroup variables (i.e. age, sex, baseline severity) and treatment condition will be included to assess whether the trajectory of outcomes over time varied by subgroup. This approach will enable the examination of both between- and within-patient variability while accounting for repeated measures and clustering.

Since the secondary endpoints are serving as a fidelity check (i.e. trained helpers increased skills, retained skills, etc.) and were are only planning for approximately 60 trained helpers, which would be under powered, any differences in sub-groups, we imagine will be challenging to detect. Despite this,

RMANOVA assesses mean differences across multiple time points, accounting for the within-subject correlation inherent in repeated measurements. Sub-group analysis will include testing interaction effects between time and categorical subgroup variables (e.g., age, sex, race) to determine if outcome trajectories differ across these groups.

8. 9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

While individual participant data will be tracked by measure and time point, results will be presented in group form.

9. 9.4.9 EXPLORATORY ANALYSES

In addition to the main clinical trial analysis, and sub-group analyses this team will run a series of additional analyses to learn the most from this trial. These include a series of moderation analyses, both cross-sectionally and longitudinally, as there is literature to support rurality as a moderator, as well as the therapeutic alliance. We also plan to run an analysis on the long-term effects of the treatment. We will analyze qualitative data using Consensual Qualitative Research methodology, as well as Content Analysis to look both across participants, and deeply at each treatment dosage of a random sample of participants. Finally, we will be evaluating the treatment dosages by applying a quantitative coding protocol and running additional multilevel modeling, and triangulation between the measurement data described above and these coded audio files of treatment dosages.

12. 10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

1. 10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

1. 10.1.1 INFORMED CONSENT PROCESS

1. 10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Informed Consent for Older Adult Clients
Title: A partially nested randomized controlled trial of the BE WITH innovation
Principal Investigator: Dr. Laura Shannonhouse
Sponsor: Administration for Community Living

I. **Introduction and Key Information**: The purpose of the study is to investigate the BE WITH innovation. You are invited to participate because you are an older adult receiving now, or who recently received, home and community-based services from a Meals on Wheels organization or County Senior

Center with whom we collaborate. A total of up to 1100 older adults will be recruited for this project. If you choose to participate, you will take a survey that will determine your eligibility, and you will be compensated for your time to take this survey. If you meet eligibility for the program, your role in the study will require up to 40 minutes each week (for 8 weeks). Depending on your randomly assigned group, this time may be spent talking on the phone, and/or answering a short survey. The risks of being in this study include potentially experiencing some minimal worry or anxiety when you are talking about any stressors you may be experiencing, however research has shown that talking about it helps in the long run. This study is designed to benefit you, as the BE WITH program is designed to give more interpersonal connections to older persons. Overall, we hope to learn from you about how nutrition services can provide more support to older adult clients.

II. **Purpose:** The purpose of the study is to investigate the BE WITH training for nutrition service volunteers and understand how it impacts the wellbeing of nutrition service clients. You are invited to take part in this research study because you are, or have recently been, a nutrition service client. A total of 60 volunteers will be invited to take part in this study along with up to 1100 older adults.

III. **Procedures:** If you decide to take part, you will talk to a student by phone who will ask you some questions in a survey. You will receive $20 for taking this survey. Based on that survey, if you meet criteria for the program, we will contact you, and you will be assigned to either a study group or a control group. If you are assigned to the study group, you will be called by a volunteer once per week for 8 weeks, and using an audio feature on teleconferencing software, both you and the volunteer will be recorded. However, all identifying information will be removed from the recordings. During this project, you may receive a call from a number you do not recognize. This will be the software we are using to connect you with volunteers, and to keep both of your identities safe. Once the call is recorded, no one will be able to connect your name or number to the recording. All involvement with this project will be done remotely, therefore you can participate from your home. All participants who enroll in the program are asked to spend 15-20 minutes completing a survey every other week over the phone.

IV. **Future Research:** Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

IV. **Risks:** There is the possibility that participation in this project may cause you to feel some worry or concern - for example, the volunteer may ask you about how you're coping with a current life stressor you are experiencing as they talk with you, and this may bring up feelings of anxiety. However, research has shown that by talking about things that are on our mind we feel better. If you experience any concern, we are available to answer any questions you may have and to provide support. No injury is expected from this study, but if you believe you have been harmed, contact the research team as soon as possible. The research team and their affiliates have not set aside funds to compensate for any injury. Overall, we expect the risk of participation will be low/minimum.

IV. **Benefits:** Participation in this study may benefit you personally. Research has shown that connecting with others during crisis, disaster, and pandemic is helpful. Overall, we hope to gain information about the BE WITH innovation, and ideally submit BE WITH to be accepted on the National Council on Aging's (NCOA) evidence-based registry to enable warm calling programs to occur across the US. Currently, there is no program to make warm calls, or visits remotely on the NCOA registry, so you are helping us make that happen.

VII. **Alternatives**: The alternative to taking part in this study is to not take part in the study.

VIII. **Compensation:** If you choose to participate, and do not meet eligibility criteria, you will be provided $20 dollars for taking the baseline survey and your involvement will be complete at that time. If

you do meet criteria to be enrolled in the BE WITH program, based on your assigned group, you will be required to take part in weekly phone calls and/or complete a survey every other week. If you are eligible and choose to participate, you will be mailed $20 cash at the start of the 8 weeks, and $80 in cash after you complete the eight-week program. This means that you are entitled to $100 total if you complete the eight-week program.

IX. **Voluntary Participation and Withdrawal:** Your participation is voluntary. You do not have to be involved in this project. If you decide to be in the study and then change your mind, you have the right to drop out at any time. You may stop participating at any time. If you stop participating, this will not cause you to lose any compensation you have already received, but you will not receive any future payments.

X. **Confidentiality:** We will keep your records private to the extent allowed by law. The following people will have access to any information that you provide:

- Dr. Shannonhouse and Kirsty Houston
- Institutional Review Board
- The Administration for Community Living (part of the Federal Department of Health and Human Services)

We will use two different codes to ensure we de-identify you from your data. The first is a numeric code that is assigned to you, and the second is a code generated from a combination of your initials and county both de-identify you on project records to protect your confidentiality. The information gathered from the calls will be stored on a password-protected and firewall-protected computer. The key that holds your code will be stored separately from the data to protect your privacy. The audio recordings and any transcripts will be destroyed within 5 years of completing the study, along with the code key information. Since any information that is sent over the internet may not be secure, we are only using data encrypted protocols and are not logging IP addresses. Also, only the case managers at the participating agency will know that you have elected to participate. That person will **not** have any access to any of your data and will not even know which group you have been assigned to.

XI. **Contact Persons:** Contact Dr. Laura Shannonhouse at 352.359.0950 or lshannonhouse@coe.ufl.edu

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study

The IRB reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, problems, information, input, or questions about your rights as a research participant.

XII. Consent: We will give you a copy of this consent form to keep.

2. 10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent will be administered over the phone to potential older adult participants. If they consent, older adult participants will be provided the baseline measure set, and informed that they will be subsequently contacted after they are assigned a treatment condition. After scoring their measures, and weighted stratified random assignment, participants will be mailed a participation plan. A member of the research team will also go over the details regarding their participation with them over the phone during the call back.

2. 10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants, investigator, funding agency, and regulatory authorities. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol
- Determination that the primary endpoint has been met
- Determination of futility
- The funding that has been secured is cut early and abruptly

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, or other relevant regulatory or oversight bodies.

3. 10.1.3 CONFIDENTIALITY AND PRIVACY

All records will be kept private to the extent allowed by law. The following people will have access to identifiable information:

- Dr. Shannonhouse and Kirsty Houston
- Institutional Review Board
- The Administration for Community Living (part of the Federal Department of Health and Human Services)

We will use two different codes to ensure we de-identify you from your data. The first is a numeric code that is assigned to you, and the second is a code generated from a combination of your initials and county both de-identify you on project records to protect your confidentiality. The information gathered from the calls will be stored on a password-protected and firewall-protected computer. The key that holds your code will be stored separately from the data to protect your privacy. The audio recordings and any transcripts will be destroyed within 5 years of completing the study, along with the code key information. Since any information that is sent over the internet may not be secure, we are only using data encrypted protocols and are not logging IP addresses. Also, only the case managers at the participating agency will know that you have elected to participate. That person will **not** have any access to any of your data and will not even know which group you have been assigned to.

4. 10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

After the study is completed, the de-identified, archived data will be stored, and made available for use by other researchers including those outside of the study if deemed appropriate. Data will not be transmitted to any other entity unless the PI moves universities.

5. 10.1.5 KEY ROLES AND STUDY GOVERNANCE

Principal Investigator	Medical Monitor or Independent Safety Monitor
Dr. Shannonhouse, Ph.D., Associate Professor	Dr. Barrio Minton, Ph.D., Professor
University of Florida	University of Tennessee
1602 Norman Hall, Gainesville FL 32611	444 Claxton Education Building, 1122 Volunteer Blvd
352.359.0950	865-974-8382
lshannonhouse@coe.ufl.edu	cbarrio@utk.edu

6. 10.1.6 SAFETY OVERSIGHT

Safety oversight will be accomplished through a quality assessment by an outside external evaluator, Dr. Casey Barrio Minton, a full professor with program evaluation expertise, millions of dollars in external funding, and leadership roles in this content area. She is independent from the study, free of conflicts of interest, and will conduct evaluations prior to the start of the trial, monitoring checks during it, and then a formalized evaluation after the trial is complete with all levels of participation (i.e. research team members, leadership, trained helpers providing the treatment, participants, etc.).

7. 10.1.7 CLINICAL MONITORING

Clinical coordinators will lead weekly accountability groups with trained helpers. These individuals will monitor the administration of the treatment, timing, call dose duration, and provided regular and routine feedback to the trained helpers providing the treatment.

8. 10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The PI and methodologist (Drs. Kirpich and Shannonhouse) will perform internal quality management of survey data (baseline and 5 measurement occasions) as well as the audio file and transcript data. Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance with the research protocol (and data collection training), accuracy, and completeness of data. Feedback will be provided to data collectors to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on source documents (see **Section 10.1.9, Data Handling and Record Keeping**). To ensure accuracy, study staff will compare a representative sample of source data against the database, targeting key data points in that review.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to de-identified source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and/or inspection by local and regulatory authorities.

9. 10.1.9 DATA HANDLING AND RECORD KEEPING

1. 10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the clinical trial data collection staff under the supervision of Principal Investigator, Methodologist, and Co-Investigators. While all will be responsible for accuracy, completeness, and timeliness of the data reported, the PI and Methodologist are taking lead on tracking and cleaning of all data in real time, and will give feedback as needed to data collectors to ensure accuracy, completeness, and timeliness. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data.

Data collectors will regularly and routinely log meta-data on the data collection in a share file that is de-identified. This enables them to communicate with one another which participants have had data collection for which measurement occasions.

Clinical meta-data (i.e. treatment dose date, time, duration, etc.) as well as outcome data (i.e. audio files of treatment dosages and transcripts) will be automatically collected via the Friendlybuzz system. Friendlybuzz and Qualtrics (two data storage systems) both include password protection and internal quality checks.

2. 10.1.9.2 STUDY RECORDS RETENTION

Study documents will be retained for a minimum of 5 years after the last approval of a marketing application or published journal article. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10. 10.1.10 PROTOCOL DEVIATIONS

It will be the responsibility of any grant key personnel (i.e. investigators, methodologist, data collectors, treatment providers, etc.) to use continuous vigilance to identify and report deviations within 24 hours of

identification of the protocol deviation to the Principal Investigator/Project Director. Any and all deviations will be reported to the Office of Research and Compliance at the PI's primary institution, as well as the federal sponsor. Finally, if any such deviations occur, they will be discussed as a team to ensure learning and prevention of any future deviations.

11. 10.1.11 PUBLICATION AND DATA SHARING POLICY

To determine authorship on manuscripts that emerge from this grant, this team will utilize the APA Authorship Determination Scorecard. The structured tool is designed to identify activities, allocate credit, and determine an order of authorship in research projects. Based on the significance and workload of each activity, points are allocated to the items. Contributors to each article are then evaluated based on their involvement with each scholarly activity, and individually assigned a proportional number of points relevant to their contributions. The sum of points for each contributor then determines their overall contribution score. Authorship is structured in an order of highest scoring contributions to the lowest.

This study will be conducted in accordance with the following publication and data sharing policies and regulations: National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of federally funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from federal funds to the digital archive PubMed Central upon acceptance for publication.

Dissemination will be informed by the Yale Center for Clinical Investigation best practices, including (a) leveraging existing resources, relationships, and networks fully, (b) delivering scholarly data-driven manuscripts, (c) delivering data-driven formal presentations (i.e., conference talks) to inform practice, service delivery, program development, and policy making, (d) translating findings to communicate properly with community members through non-academic outlets (i.e., op-eds; press releases), (e) providing research summaries of relevant key findings for Area Agencies on Aging, (f) providing an expanded research summary (policy research) document to key ASN stakeholders, and (g) using the project work plan to guide efforts.

12. 10.1.12 CONFLICT OF INTEREST POLICY

Any conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to disclose those conflicts a priori, and have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

2. 10.2 ADDITIONAL CONSIDERATIONS

There are no additional considerations not currently covered in this protocol template, such as particular institutional or IRB-related requirements.

3. 10.3 ABBREVIATIONS AND SPECIAL TERMS

ACL	Administration for Community Living
ARC AAA	Atlanta Regional Commission Area Agency on Aging
ASIST	LivingWorks Applied Suicide Intervention Skills Training
ASN	Aging Services Network
BE	Belonging & Empathy Trained Volunteers
BE WITH	Belonging & Empathy With Intentional Targeted Helping
Co-PIs	Co-Principal Investigators Dr. Fullen & LeBlanc
CP	Community Partners (GA DAS, NC DAAS, ARC AAA)
DC	Data Coders / Collectors
EE	External Evaluator Dr. Barrio Minton
GA DAS	Georgia Department of Aging Services
IPTS	Interpersonal Theory of Suicide
IRB	Institutional Review Board
IS	Implementation Support
M	Methodologist Dr. Kirpich
MHS	Mental Health Coordinators
MSS	Methodology Support Student
NC DAAS	North Carolina Division of Aging and Adult Services
NCOA	National Council on Aging
NS	Nutrition Services
PD	Project Director & Co-PI Dr. Shannonhouse
PN-RCT	Partially Nested Randomized Controlled Trial
QR	Qualitative Researcher Dr. Whisenhunt
SAE	Serious Adverse Event
SILES	Social Isolation, Loneliness, and Elevated Suicidality
US	United States
VS	NS Staff & Volunteers

4. 10.4 PROTOCOL AMENDMENT HISTORY

We will log any changes of IRB-approved versions of the protocol, and contextualize with a description of the change and rationale.

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