PROTOCOL TITLE:

Tailored Health Self-Management Interventions for Highly Distressed Caregivers: Family Members of Persons With Dementia

Identifiers: NCT04247347 Unique Protocol ID: 3R01NR01S817-04S1

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[USE THIS SOCIAL, BEHAVIORAL, AND EDUCATIONAL PROTOCOL TEMPLATE IF YOUR PROJECT INCLUDES SURVEY, INTERVIEWS, FOCUS GROUPS OR EDUCATIONAL RESEARCH ACTIVITIES WITH NO BIOMEDICAL/CLINICAL COMPONENTS]

INSTRUCTIONS:

• Use this template to prepare a document with the information from the following sections.

• Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, please mark as N/A. You may delete contents of sections, but will not be able to delete the headings of the sections.

• When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

• Consider using a different color font for your answers.

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UH FACULTY ADVISOR:

If the principal investigator's primary role at UH is resident, fellow or student, identify a faculty advisor.

N/A

OTHER DEPARTMENTS INVOLVED IN THIS STUDY (IF APPLICABLE):

VERSION NUMBER:

Include the version number of this protocol if assigned by an outside entity.

DATE:

8/7/2019
updated 11/20/19
updated 3/2/20 and 6/29/20
updated 8/19/20
updated 1/6/21 and 4/26/21
updated 6/30/21

Indicate the origin of this protocol (who conceived of and leads the development of the protocol regardless of funding):

☒ Investigator initiated *(Investigator(s) developed protocol, regardless of funding)*

☐ Industry *(Pharmaceutical, Device, etc.) (Industry developed protocol)*

☐ Federal *(NIH, DOD, etc.)*

☐ Cooperative Group *(SWOG, GOG, etc.)*

☐ Other - *Please specify:*

Funding

Objectives

*The **AIMS** of this supplement are:*

***1.** to examine the effectiveness of two health self-management interventions (resourcefulness training and biofeedback) in comparison with usual care (education) on the study outcomes specified in the parent study IRB-2016-1651 (health risks and physical and mental health from pre- to post-intervention) for caregivers of persons with dementia sampled in this supplement;*

***2.** to compare the responses to resourcefulness training, biofeedback, and education program of these caregivers with caregivers of persons with bipolar disorder (from parent study) on the three outcomes over time; and*

***3.** to explore similarities or differences between the two types of caregivers in terms of their need for intervention (determined by baseline cut scores on study measures) and preference for intervention (response at end of study). Family caregivers of persons with dementia will complete validated study measures at baseline and within one month following intervention.*

Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how it will add to existing knowledge. Include any relevant preliminary data.

Recent statistics show that nearly 35 million family members in the United States provide unpaid care to an adult with a disability or illness. Close to 72% of these 35 million family caregivers care for adults with psychological or behavioral conditions known to be highly distressing.

While family caregivers of persons with bipolar disorder, the focus of our parent study, exceed 10 million, the number of family caregivers of persons with Alzheimer's disease or related dementias is even greater. As the population >age 65 continues to age, the number of persons with Alzheimer's and other forms of dementia is expected to escalate. More than 15 million family members provide some form of care or assistance for the over 5 million American elders who have some form of dementia. Research shows that family caregivers provide more

than 18 billion hours of informal, unpaid care for elders with dementia, constituting an annual cost to the nation that surpasses $221 billion. In addition, the paid costs associated with health care, long-term care, and hospice for persons with Alzheimer's and other dementias are estimated to be $214 billion each year, making dementia one of the most costly chronic illnesses in our nation. Although Medicare or Medicaid may cover up to 70% of the expenses, family caregivers assume remaining costs by paying out-of-pocket, contributing to additional stress on them. Thus, the tremendous societal burden associated with Alzheimer's and other forms of dementia extends well beyond those who suffer from this devastating condition.

The trajectories of the two conditions differ: caregivers of persons with bipolar disorder experience the fluctuating moods, intensity, and unpredictability of bipolar disorder, caregivers of persons with Alzheimer's disease or related dementias (hereafter referred to as dementia) face a predominantly downward spiral of dementia symptoms and course of illness. Although both groups of caregivers are known to be highly distressed, to date, there are no published comparative studies of caregivers of persons with bipolar disorder and caregivers of persons with dementia. But there is no doubt that both types of caregivers are highly distressed and can benefit from tailored health self-management intervention. The findings from this study have the potential to generate new scientific knowledge about the effectiveness of novel, easy to use, independently performed interventions that can be self-tailored to promote caregiver health through education, biofeedback, or resourcefulness. Once established, these health self-management interventions can be tailored to match the needs and preferences of other comparably distressed family caregivers of persons with other chronic mental or physical conditions.

There are several scientific premises underlying the fundamental assumptions of the proposed study.

1. having a family member with any form of dementia is a devastating experience that takes its toll on other family members (i.e., spouses, adult children) who assume responsibility for the care and welfare of the care recipient.

2. The caregiving career follows a long-term trajectory that may last from 4 to 20 years and involves a predictable downward spiral of losses in the care recipient's mental and physical functioning accompanied by changes in the level of care needed.

3. Changes in level of care required to meet the needs of the care recipient over the course of dementia are reflected in a caregiving career comprised of the roles of primary caregiver (in the home) and care partner (with facility placement).

4. Family caregivers are prone to experience stress that can put their own health at risk and adversely affect their physical and mental health over time.

5. Interventions that strengthen a family caregiver's self-management skills will reduce their stress and ultimately sustain their physical and mental health over time.

Systematic reviews have shown that researchers have examined interventions for dementia caregivers who provide care in the home, including some that focused on reducing their stress or promoting/preserving health. NIH-funded researchers have engaged in multi-site projects, Resources for Enhancing Alzheimer's Caregiver Health (REACH), since 1995. They have tested educational support groups, behavioral care, skills training programs, family-based

interventions, environmental modifications, computer-based information, and communication services. All of the interventions were found to be superior to control conditions for female versus male caregivers and for caregivers with lower versus higher education. Positive outcomes include fewer depressive and anxious symptoms, greater satisfaction, and better sense of well-being. These studies, however, were limited to caregivers of persons with dementia in the home and did not include caregivers whose family member was living within a facility as proposed in this study. Thus, the interventions were not tested in those caregivers, who are believed to experience similar stress levels and deleterious effects on health. In addition, the interventions tested within the REACH projects did not include the implementation of biofeedback as a means for stress reduction or the teaching skills that constitute resourcefulness as proposed in this study.

Only one study examined biofeedback in caregivers of persons with dementia and it found that biofeedback was feasible and effective for stress management in family caregivers. The study was missing a control group and the sample was very small (N=32) and limited to in-home dementia caregivers whose care recipient attended a senior day care facility. However, systematic review of other intervention studies of dementia caregivers have described beneficial effects on caregiver health and of such skills as cognitive reframing, problem-solving, self-management, and help-seeking, all of which are included in resourcefulness training. Consistent with the personal (self-help) and social (help-seeking) skills taught during resourcefulness training, researchers have identified the need for interventions to assist dementia caregivers to seek out and mobilize social resources while enhancing personal coping effectiveness.

Resourcefulness Training (RT) has been found effective in reducing stress, depressive cognitions, and negative emotions, and improving mental and physical health in older adults and caregiver populations, including dementia caregivers. The PI's pilot research with dementia caregivers shows they have a substantial need for resourcefulness skills as indicated by both subjective and objective measures, and that the RT intervention was found to be acceptable and feasible for dementia caregivers, particularly when it was tailored to meet their needs and preferences. The RT protocol with dementia caregivers was found to have implementation fidelity. Effect sizes on measures of caregiving responses (i.e., stress, depressive cognitions, and negative emotions) were found to be moderate to large when the dementia caregivers were given a choice in how they performed and reinforced resourcefulness skills.

The findings from this study have the potential to generate new scientific knowledge about the effectiveness of novel, easy to use, independently performed interventions that can be self-tailored to promote caregiver health through education, biofeedback, or resourcefulness. Once established, these health self-management interventions can be tailored to match the needs and preferences of other comparably distressed family caregivers of persons with other chronic mental or physical conditions.

Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility. Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	*English Speaking*
2.	*At least 18 years old*

3.	*Have a living family member with Alzheimer's disease or another dementia*
4.	*Identify self as a primary caregiver*
5.	*In-home caregivers: must be currently providing a minimum of 4 hours per day of supervision/direct care for at least the last 6 months.* *Caregivers whose family member lives within a facility: must report visiting their care recipient at least once per week for at least the last 6 months.*
6.	*Be capable of performing informed consent and participating in study procedures.*

	Exclusion
1.	*Does not have family member with Alzheimer's disease or another dementia.*
2.	*Has not cared for a living family member for at least the last 6 months.*
3.	*Has knowledge of another family member in the same household enrolled in the study*
4.	*Currently pregnant*
5.	*Has a pacemaker*
6.	*Lives outside of the study area*

Number of Research Participants

Directions: Indicate the target number of research participants to be accrued locally, and, if this is a multi-site study, indicate the total number of research participants to be accrued across all sites.

Based on previous research by the PI and Co-Is, we conservatively estimate that ~20% of caregivers may not meet eligibility criteria. Thus, we will screen 125 participants to obtain the desired sample of size of 100.

Special/Vulnerable Populations

1. *Indicate specifically if you will include each of the following special populations by checking the appropriate box:*

☒ **Adults unable to consent**
☐ **Minors (infants, children, teenagers)**
☐ Wards of the state
☐ Foster Children
☐ **Pregnant Women**
☐ **Neonates**
☐ **Neonates of Uncertain Viability**
☒ **Employees of CWRU or UHHS**
☐ **Prisoners**
☒ **Illiterate Individuals**
☒ **Non-English Speaking**
☒ **University Students**

☐ **None**

2. If the research involves individuals that are included in a special/vulnerable population, describe the additional safeguards included to protect the rights and welfare of the individuals for each population indicated.

If family caregivers who do not speak/understand the English language come forward with interest in participating and if they meet all other study criteria, we will make accommodations for translating the study measures and intervention materials or for having and interpreter provide appropriate explanations. If an illiterate individual comes forward with interest in participating and if they meet all other study criteria, we will make accommodations to dictate the consent form and all study questions. If a caregiver is an employee or student of CWRU, the consent form identifies participation in this research study is voluntary and if they choose not to participate, it will not affect their current or future relations with the university. No caregivers unable to consent will be enrolled. Adults unable to consent are only subjects to the extent that there is any identifiable information about them collected through the caregiver. They will not be present for any interventions or interactions.

3. If excluding pregnant women, illiterate or non-English speaking individuals, provide a scientific rationale for the exclusion. Inconvenience or cost is not an acceptable rationale.

Pregnant women are excluded due to the measure of heart rate variability (HRV). The inclusion of pregnant women has the potential to alter the analyses that involve HRV measurement.

Recruitment Methods

Note: Attach all applicable recruitment materials to the last section of the Smart form under "Recruitment Materials."

1. Which of the following methods will be used to recruit research participants. – Select all that apply

☐ Email
☐ Phone call
☐ Letter
☒ Advertisement (e.g., poster, flyer, etc.)
☒ Social media
☐ Other. Please specify:

2. Describe when, where, and how potential research participants will be recruited.

The 100 family caregivers will be recruited from Cuyahoga County and 6 adjacent counties through social service advocacy agencies, community agencies, dementia care day programs and care facilities, and private physicians' offices who agree to provide us with access for posting / distributing information about the study. Agency personnel may assist us in identifying potential study participants who meet the following inclusion

criteria: caregivers will be at least 18 years old, report having a family member with dementia, and providing care or support for them for at least 6 months, but not necessarily in the same household (i.e. they may be living in a dementia care facility). However, we anticipate that most of the potential study participants will be those who see a posted advertisement or receive a flyer describing the study from one of agencies, centers, dementia care facilities, offices, etc., where we have permission to post / distribute information about the study. Contact information for the research office will be included on the flyers. Potential study participants will contact the research office for screening by a research team member to ensure he/she meets the eligibility criteria. If eligible, the team member will obtain their name, contact information (phone and/or email), address, and time / best method for the data collector to call to make an appointment to meet to discuss and enroll in the study, obtain their informed consent to participate, and conduct their first data collection interview.

In addition, agency personnel/health care professionals may nominate a caregiver for the study. We will use snowball recruitment by asking study participants to refer others like them to the study. We will also recruit via the internet using social media sites (e.g. Twitter, Facebook, Instagram, and other online sources).

3. Describe the source (e.g., from what department, EMR, etc.) of the research participants.

Potential study participants (who meet the study criteria) will be recruited through both public and private advocacy agencies, care facilities, support groups, community health centers, health fairs and other community events, print and e-newsletters (e.g. CASE Daily), listservs, local magazines and newspapers, ResearchMatch.com, Alzheimer's Association TrialMatch, and private physician offices in Cuyahoga and 6 adjacent counties in Northeastern Ohio.

4. Describe the methods that will be used to **identify** potential research participants.

When a person contacts the study to be screened, they will receive a screening ID in the Screening and Enrollment log. Contact information will then be collected including date of initial contact, name, telephone number(s), email address(es), and mailing address on all individuals screened will collected for our screening log; this information will be stored in a password-protected computer file (Box.com).

The project manager or other trained research staff will screen by phone to ensure that caregivers meet all eligibility criteria. We will also be collecting demographic information (gender, race, ethnicity, etc.). All individuals that are screened and asked questions to see if they meet eligibility criteria. At the end of the screening, they will be asked if they would like to consent to be contacted for future research opportunities (those that enroll in the study will also be asked if they consent for future research with the informed consent form). All screening question documentation will be kept in a screening form on REDCap along with screening ID.

After eligibility is verified during phone screening by team member, the consent form will be reviewed verbally, and questions about the study will be answered. The research team

member will then confirm and enter contact information in REDCap, as well as update the Box Screening and Enrollment Log; this includes the individual's full name, mailing address, phone number(s), email address, best time of day to call, and confirming if the study team can leave voice mail messages, text to schedule / confirm study visits and intervention check-ins, and/or send mail to their mailing address if we are having trouble contacting them by phone or email

5. Describe the feasibility of recruiting the required number of suitable research participants within the agreed recruitment period. For example, how many potential research participants do you have access to?

Based on previous research by the PI, we conservatively estimate that 20% caregivers may not meet eligibility criteria. Thus, we will screen 125 potential participants to obtain the desired sample size of 100.

Setting

Directions: Make sure to describe: 1) sites and locations where your research team will conduct the research; 2) where your research team will identify and recruit potential research participants; and 3) include the physical location where research procedures will be performed.

The project manager or other research team member will screen by phone to determine eligibility and schedule first data collection meeting. All data will be collected either in the community (e.g. participants home or other private venue of their choice, including mental health center/physician's office, private/ closed room in local library, etc.), on the campus of Case Western Reserve University (e.g. the School of Nursing).

Study participants (who meet the study criteria) will be recruited through both public and private advocacy agencies, care facilities, support groups, community health centers, health fairs and other community events, print and e-newsletters (e.g. CASE Daily), listservs, local magazines and newspapers, ResearchMatch.com, Alzheimer's Association TrialMatch, and private physician offices in Cuyahoga and 6 adjacent counties in Northeastern Ohio.

Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe where the consent process will take place:

After eligibility is verified during phone screening by a team member, the consent form will be reviewed verbally and questions about the study will be answered. Prior to initiating the first data collection, the consent form will be reviewed again and signed by both the study participant and data collector before beginning the data collection interview. The consent form will also ask if they consent to be contacted for future research opportunities (5/10/21).

COVID-19 remote modification: e-Consent, via REDCap Screening Project, will be emailed to potential participants for review e-signature and date after verbal review with team member. Once signed, data collector will be notified by email and will add their signature and date to the e-consent form. Current participants will re-consent electronically. Digital files of signed consent forms will be downloaded to a secure Box.com folder. Team members will have upload and view access, but will not be able to edit or delete files.

Updated COVID-19 Modifications June 2021: The study team will continue using virtual options when possible, but will also resume in-person study activities per the signed CWRU Safety Plan for In-Person Research Activities. An updated consent script will be emailed or read over the phone (for those with no email) informing already enrolled participants of updates to the Informed Consent Document and study procedures (6/30/21).

If a potential enrollee does not have email access at home, two consent forms will be mailed to them, along with a pre-stamped return envelope. They will be asked to sign, date, and return one copy, and to keep the second copy for their records. The corresponding data collector will sign and date the returned consent form. If an in-person data collection session is scheduled, the data collector may obtain signed informed consent at that time (6/30/21).

2. The time that will be devoted to the consent discussion:

There are no time constraints to the consent discussion. The consent discussion will take place during the screening phone call and again at the enrollment meeting, prior to data collection.

3. Any waiting period available between informing the prospective subject and obtaining the consent:

Yes. After verifying eligibility and reviewing the consent form during the screening phone call, there is a period of time between the phone call and the enrollment meeting. The length of time between the two varies depending on the meeting time selected by the research participant and team member.

COVID-19 remote modification: after phone screen and verbal review of consent form, e-consent will be emailed within 48 hours. Study will utilize REDCap's auto-email reminder to send up to 3 reminders over the course of two weeks. After that, a team member will follow-up by phone/text/email (potential participant's stated preference of communication) to see if they are still interested in joining the study. For consent forms mailed to the home, similarly timed follow-up will take place by phone (call/text) and/or email.

4. Steps that will be taken to ensure the research participants' understanding:

Study participants will have time to ask questions about the study and review the consent form before signing it.

5. Any process to ensure ongoing consent:

Within approximately one month of the first data collection session, the participants will be made aware of which of the three groups (education/ usual care, resourcefulness, and biofeedback) to which they have been randomly assigned. They will be reminded of remaining study procedures and research staff will answer any questions regarding study procedures or participant concerns as they arise.

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects:

The study participants will be informed that his or her participation in the research study is completely voluntary. If he or she chooses not to participate, it will not affect their current or future relations with the University or with physicians, mental health centers, or community venues from whom they may have obtained information about the study. Study participants will also be informed that there is no penalty of loss of benefits for not participating of for discontinuing participation in the study.

For Adult Participants
Indicate if you will be asking for a waiver or alteration of consent process or documentation (consent will not be obtained, written consent will not be documented)

☐ Yes ☒ No

If yes, indicate which part of the consent process you are requesting be waived or altered and the rationale for requesting the waiver or alteration:

☐ I will obtain consent, but not participant's signature

☐ I will obtain consent, but request a waiver for pre-screening purposes

☐ I will obtain consent, but request a waiver of some of the elements of consent (e.g. use of deception)

☐ I will not obtain consent, and I am requesting a full waiver of consent

1. Give the rationale for the request of a waiver or alteration of the consent process or documentation.

N/A

2. Explain how the research involves no more than minimal risk.

N/A

3. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants.

N/A

4. Explain why the research could not practicably be carried out without the waiver or alteration of consent.

N/A

5. Indicate if the subjects will be provided with additional information about the study after participation.
N/A
6. If you will obtain consent, but not document consent in writing (e.g. over the phone, verbally, electronic survey, etc.), please describe and provide a rationale.

☒ N/A
7. Describe how you will be documenting that a research participant has consented.

N/A

Additional Considerations for Consent Process with Adults
Non English Speakers *(Please select one)*

☐ I am **not** enrolling non-English speaking individuals in this research study. The following is justification for why non-English speaking individuals cannot be enrolled:

☐ I will be targeting non-English speaking adults
1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study.

2. List the language(s) other than English that will be targeted:

☒ I am **not** targeting non-English speaking individuals. If a non-English speaking individual is eligible for the study, we will use the following procedures to enroll:
1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study.

> *If family caregivers who do not speak/understand the English language come forward with interest in participating and if they meet all other study criteria, we will make accommodations for translating the study measures and intervention materials or for having an interpreter provide appropriate explanations.*

2. List the language(s) other than English that will be targeted:

Adults Unable to Consent
☐ I am **not** enrolling adults unable to consent in this research study – *please leave the rest of this section blank.*

☐ There is an anticipated direct benefit to the subject. Explain:
☒ There is NOT an anticipated direct benefit to the subject. Explain:
No caregivers unable to consent will be enrolled. Adults unable to consent are only subjects to the extent that there is any identifiable information about them collected through the caregiver. They will not be present for any interventions or interactions.

1. Describe the process to determine whether an individual is capable of consent.

Inclusion exclusion requires that the caregivers be caregivers of those with dementia and in addition a waiver of assent is requested.
2. List the individuals from whom permission will be obtained in order of priority (e.g. durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child).

Waiver is requested
3. For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in the research.

☒ N/A
4. Describe the process for assent of the research participants. Indicate:
1. Which subjects that are unable to consent will be required to give assent? If not all, explain why.

Waiver is requested for all patients with dementia because they will not be present and it would be impractical to obtain it and the waiver will not impose on their rights or welfare. Patients with dementia will be living in a variety of places, and may not be able to be practically reached by phone or in person for giving assent solely for the purposes of collecting data about them (perceptions and observations by the caregiver) that may potentially identify them indirectly. The burden of attempting to gain an assent would be more harmful to these patients than any potential benefit. In addition, it would make the research project impractical and the benefits of the research justify the waiver of assent. There are suitable data security and other means of preserving confidentiality in place.

2. Describe whether assent of the research participants will be documented and the process to document assent.

N/A a waiver is requested. No interaction or intervention with those who are unable to consent.

☐ The subject will be informed about the research to the extent compatible with the subject's understanding.
☐ Subjects will be closely monitored.
☐ The subject will be withdrawn if they appear unduly distressed.

Research Participants Who Are Not Yet Adults (infants, children, teenagers)
☒ I am not enrolling participants who are not yet adults in this research study. – *please leave the rest of this section blank*
1. Will parental permission be obtained from:

☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child
☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child
☐ Requesting a waiver of parental permission

If you are getting parental/guardian permission:
1. Indicate how you will be documenting the permission:

☐ Signed consent form
☐ Requesting a waiver of documentation of parental permission

2. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's participation in research.

If a waiver of parental permission is being requested:
1. Describe how the study is designed for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects, if applicable.

2. Describe how the research could not practicably be carried out without the waiver of parental permission.

a. Indicate if the subjects will be provided with additional information about the study after participation.

3. Will assent be obtained from:

☐ all of the children
☐ some of the children
☐ none of the children

If assent will be obtained from some children, indicate which children will be required to assent.

When assent of children is obtained, describe how it will be documented.

4. For children who are pregnant, describe how assent and permission are obtained.

☐ N/A

Sharing of Results with Research Participants

Results will be shared with research participants:
☒ Yes ☐ No
If yes, describe how the results will be shared.
Study participants will receive a one-page summary of the aggregated results by mail or email based on contact preference.
Results will be shared with others:
☒ Yes ☐ No

If yes, describe with whom and how the results will be shared.

Aggregated results of the study will be shared with others through manuscripts and presentations.

Study Design/Procedures

Directions: 1) Describe the overall study design. 2) Provide a description of all study-related research procedures being performed, including the length of time involved. 3) Include procedures being performed to monitor research participants for safety or minimize risks. 4) Describe the source records including medical or educational records, which will be used to collect data about subjects.

The proposed 1-year randomized controlled trial will compare the effectiveness of two tailored health self-management interventions (resourcefulness training and biofeedback) with usual care in family caregivers of persons with dementia.

Before the T1 interview, the data collector will obtain the caregiver's written informed consent to participate. All research staff (including the project manager, data collectors, and interventionists) will be required to complete the "human subjects" training and obtain certification prior to entering the field for data collection or intervention. The consent form will explain the expectations of caregivers as research participants, risks they may encounter, benefits they may accrue, measures to be taken to maintain confidentiality, and voluntary nature of their participation. Potential study participants will be told they are being asked to participate in a study to examine method for helping family caregivers to self-manage their health. They will be told that they will be randomly assigned (using a computerized system) to one of the three treatment conditions. They will be told the study involves 2 face-to-face interviews with a trained data collector during which objective, validated questionnaires and HRV measures will be completed, as well as an intervention ("stress management method") between the first and second data collection interviews. The caregivers will be told that their confidentiality will be protected and that their names will not be revealed; results of the study will be reported in aggregate. They will be told that they are free to withdraw from the study at any point in time and that they do not need to supply responses to all questions posed on the study questionnaires. They will be told about the possible risk of feeling distressed while answering questionnaires or completing their daily logs, or using the biofeedback device (if applicable) and about measures that will be taken to minimize / manage the distress, including discontinuing participation and referral to mental health professionals if needed. They will be told that if a research team member, during a data collection or intervention meeting or call, suspects or witnesses any signs of elder abuse, neglect, or exploitation, a report will be filed with the county department of job and family services in compliance with Ohio law. They will be told about the potential benefit of stress reduction. Finally, they will be told that they will receive an incentive of $20 at T1 and $25 at T2. In addition, they will receive $20 for completing the face-to-face intervention session and $5 for each week of completion of the progress log (up to 4 weeks or $20). Participants will receive up to $85 for completing all study activities.

Following informed consent, research staff will collect detailed contact information and schedule the first data collection session. The data collection for caregivers sampled involves two structured face-to-face sessions with data collectors. Data will be collected at baseline (T1) and within one month after the 4-week intervention (T2). Measures include dementia symptoms, caregiver reactions, caregiving involvement, dementia knowledge, resourcefulness, heart rate

variability, health risks, and health outcomes, comprising the 156-item questionnaire. Demographic information will also be collected (e.g. occupation, annual income, education, and questions about the care recipient such as age, number of years diagnosed with dementia, specific diagnoses, and questions related to the participant's caring of their family member with dementia). Research assistants will encourage caregivers to respond to items displayed on an iPad/ tablet as they wish, ensuring there are no right or wrong responses. At the first data collection session, the study participant will receive a resource list for Dementia Care support and services in Cuyahoga and surrounding counties.

Within two weeks of the first data collection session, caregivers will be randomly assigned using a computer program to one of the three interventions (usual care/ education, resourcefulness, or biofeedback). Caregivers will receive the training and perform one health self-management intervention between the T1 and T2 data collections. The education, resourcefulness training, or biofeedback training will be introduced during a single face-to-face session in the caregiver's home/other private venue via a voice-over PowerPoint presentation presented on a tablet. All 90 caregivers who receive an intervention or usual care will keep a written log for the 4-week intervention period between the first (T1) and second (T2) data collection interviews. The caregivers will receive a pamphlet on their intervention (based on the PowerPoint presentation), a tracking log, and will received telephone, email or text follow-up (preference of the study participant) for the next 28 days while performing the intervention independently and at their convenience. Interventionists will be carefully trained by Drs. Zauszniewski and Juratovac during a 2-day session that will include intervention delivery, cultural diversity training, and methods for providing psychological support/referral (e.g., "first call for help") in case caregivers experience psychological or physical distress during the training session or 28-day intervention period. Interventionists will be blinded to fidelity measures and different interventionists will provide education, resourcefulness training, and biofeedback; they will keep field notes and have weekly supervision by Dr. Juratovac.

The first data collection session involves the additional measures of Financial Stress & Resourcefulness, and the second data collection adds an Intervention Evaluation Questionnaire that will ask participants for feedback regarding the intervention they received. Participants randomized to the Resourcefulness Training will be asked to complete the RT Skills Scale as part of the Intervention Evaluation Questionnaire.

COVID-19 remote modification – Beginning in July 2020, participants will provide e-consent via REDCap vs. written consent in person. If a person does not have email or would prefer to sign a paper consent form, two copies of the consent form will be mailed to their home, with instructions to sign and date both, and return one copy to the study office with the addressed and stamped envelope that is also provided (see page 9). Current participants will re-consent electronically. Enrolled study participants will have the option to download a copy of the consent form for their records, or it can be mailed / emailed to them (participant preference).

Updated COVID-19 Modifications June 2021: If an in-person data collection session is scheduled, the data collector may obtain signed informed consent at that time (6/30/21).

The two face-to-face interviews will instead consist of two remote data collection session. We will use phone (Google voice), Zoom (computer video), and/or email to complete the data

collection. For phone or video data collection, an email will be sent, if possible and requested, to participants with the answer response choices for each survey (this can also be sent by mail). If we are using phone for data collection, the Research Assistant (RA) will ask the participant each question and record the responses in our REDCap Surveys project. If collecting data using Zoom video, the RA will share the screen of the REDCap Surveys project, and record the answers for the participant as they review each survey question. If neither of those two options are available for the participant (e.g., limited phone minutes, inability to use Zoom), and/or email is preferred, the study may email the REDCap surveys to study participants for them to complete on their own at an agreed upon date / time (similar to in-person appointment); in this instance, the RA can be available to answer questions or clarify information as needed, by phone or email. It may be that none of these options will work for a study participant, in which case we will consider that data "missed" if we cannot wait to collect the data in person at a later date (when we resume normal study activities). The precise method(s) will depend on the ability and resources of the study participant. We will contact active participants with Zoom/ phone instructions, by phone/text and/or email, as needed, and we will record the methods used for each data collection done remotely.

Heart-rate variability (HRV) data will be collected with the Byteflies or a similar HRV device. Once a data collection (T1 or T2) is complete, a team member will make an arrangement to collect HRV data at their home or another agreed-upon location at a set day and time.

- *Remote HRV data collection: The participant will receive instructions of how to use the HRV device for a 20-30 minute data collection of HRV; this instruction sheet will also include safety information. The team member will be available to provide support during this time by phone or video call. The data collection may happen at the time of drop-off or sometime that day. There will be a pre-determined time set for pick-up of the device. If need be, this process may be repeated in order to obtain reliable data, and if this data is unable to be collected due to scheduling, it will be considered missing data for that time point.*
- *In-Person HRV data collection: Following approved safety plan guidelines (June 2021), a research team member will meet with the study participant to collect the HRV data in person. The data collection will take 10-20 minutes; the entire meeting should be completed within 30 minutes. Like remote data collection, this process may be repeated in order to obtain reliable data (not confirmed until data is analyzed by another team member). Currently enrolled participants will consent to this updated procedure.*

Delivery of the intervention will also be conducted remotely. After randomization, an intervention team member will schedule a 45-minute video call to present the intervention. This meeting will include a power point presentation, a review of the online tracking log, and instructions for the 28-day intervention period. An electronic copy of the corresponding

the study participant.
Gift cards will replace in-person cash compensation throughout the study period.

Study Timeline (optional)

ClinicalTrials.gov Information

Directions: If this study has been registered on ClinicalTrials.gov, provide the ClinicalTrials.gov identifier and the investigator/sponsor responsible for registering. If this study has not been registered on ClinicalTrials.gov, provide the rationale as to why and if/when it will be. If it does not meet the requirement for being registered on ClinicalTrials.gov, please state that.

NCT04247347 Jaclene A. Zauszniewski

List of Data to be Collected

• *Indicate what identifiers you will collect*

☒ Name
☒ Address *(e.g., Zip code, other geographical designation, etc.)*
☐ Dates related to an individual *(e.g., Date of admission, birth, surgery, etc.)*
☒ Telephone number
☐ Fax number
☒ Email address
☐ Social security number
☐ Medical record number
☐ Health plan beneficiary number
☐ Account number
☐ Certificate/license number
☐ Any vehicle or other device serial
☐ Device identifiers or serial numbers
☐ Web URL
☐ Internet protocol (IP) address
☐ Finger or voice prints *(includes audio recordings)*
☐ Photographic images *(includes video recordings)*
☒ Other: Any characteristic that would uniquely identify the individual

If other, please explain:

Heart rate variability requires non-invasive electrocardiography

1. List all other data to be collected for the research study. Attach all data collection tools on the Local Site Documents page of the SpartaIRB smart form (Other Attachments).

• Questionnaires to measure dementia symptoms, caregiver reactions, caregiving involvement, dementia knowledge, resourcefulness, health risks, health outcomes, and financial stress and resourcefulness. (Listed under site related documents as 'instruments & measures.pdf')
• Intervention evaluation questionnaire
(Listed under site related documents as 'DCS intervention eval questionnaire.pdf')
• Intervention tracking logs
(Listed under site related documents as 'resourcefulness sample tracking log page.pdf', 'biofeedback sample tracking log page.pdf', 'dementia education sample tracking log page.pdf')
• COVID-19 questionnaire at T1 and T2

Data Analysis Plan

Directions: Describe the data analysis plan, including any statistical procedures. If applicable, provide a power analysis, and study/safety endpoints.

*The **primary study aim (Aim #1)** is to examine differences across our three groups of family caregivers of persons with dementia on caregiver health outcomes from pre- to post-intervention. The underlying analyses for **A1** are built around the repeated measures analysis of variance (RMANOVA). The primary analysis will be a three group × two time waves RMANOVA. These analyses will compare the three groups: 1) usual care (education), 2) resourcefulness, and 3) biofeedback across two time waves of health risks and physical and mental health outcomes. When using RMANOVA, one not only assesses mean differences across time, but also group differences and the interaction of time × group, which will allows us to test the trend of the means over time across the three groups. The RMANOVA, not only is used to determine if there are mean differences across the two time periods, it also uses orthogonal polynomial contrasts to determine linear trends of the means across time. Orthogonal polynomials are weights assigned to each time period that models a linear trend. RMANOVA will determine if these trends in the means are significant. A linear trend is indicated if there is a steady increase or decline in scores from the first time wave to the second time wave.*

*The second aim (**Aim #2**) identifies the responses to usual care (education), resourcefulness training, and biofeedback separately on the three health outcomes between the caregivers of persons with dementia sampled within the proposed administrative supplement with the caregivers of persons with bipolar disorder sampled in the parent study. This aim involves three separate analyses to compare the two groups of caregivers within each of the three treatment groups (education, resourcefulness training, and biofeedback) for each of the three health outcomes. For each intervention/treatment program, a two group by two time point RMANOVA will be used to determine differences within and between groups and the interaction of time × group. For example, one RMANOVA will examine differences between caregivers of persons with dementia and caregivers of person with bipolar disorders on health risks over two time points.*

*The third study aim (**Aim #3**), to explore differences between the two groups of caregivers in terms of their need for intervention (determined by baseline cut scores on study measures) and*

preference for intervention (response at end of study), as these outcomes are categorical (i.e., education group, resourcefulness training group, or biofeedback group), we will use chi square analyses to determine the extent to which caregivers of persons with dementia differ from caregivers of persons with bipolar disorder separately for their need group and for their preference group in health self-management interventions.

Confidentiality of Data

1. To maintain the confidentiality of the data:

☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data..

☐ Other (please explain)

Provide a plan to destroy identifiers including how and when.

2. How are you storing your electronic data?

☐ UH Redcap
☒ CWRU Redcap
☐ Secure Research Environment (SRE)
☒ CWRU Box
☐ OnCore
☐ UH Secure Network Drive
☒ CWRU Secure Network Drive
☐ Other - List storage method and provide justification:

3. Storage location of the paper research data and documents, if applicable:

☒ Paper research data and documents will be stored in a double-locked secure environment in the following location:
France Payne Bolton School of Nursing study office

4. Will data be shared?

☐ Yes

1. List the exact data elements that will be shared:
2. Describe how data will be sent:

☒ No
☐ N/A
(Please note: if sharing data, please contact the UH Grants and Contracts Specialist or CWRU Tech Transfer Office to ensure the proper contracts/agreements are in place.)

HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?

☐ Yes ☒ No

If yes, indicate how HIPAA authorization will be obtained (check all that apply):

☐ HIPAA authorization is in the consent form

☐ Requesting a full or partial waiver of HIPAA for prescreening
☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*
☐ Requesting a full or partial waiver of HIPAA
☐ I will complete the Request for Waiver of HIPAA Authorization form. *See SpartaIRB Library*

Devices

☒ This is **not** device study. The protocol is considered non-therapeutic (non-therapeutic is defined as research not intended to diagnose, prevent, cure, mitigate, treat, etc. a disease or condition) by the FDA. – *You may delete the rest of this section.*

OR

☐ This is a device study. The protocol is considered therapeutic (research intended to diagnose, prevent, cure, mitigate, treat a disease or condition) by the FDA.

1. Is there an IDE (Investigational Device Exemption) for the proposed study?

☐ Yes, provide an official letter of support or proof of approval which identifies the IDE holder and IDE number.
☐ No

2. Is the device (and its use) a non-significant risk device for the proposed study design?

☐ Yes
☐ No
☒ N/A

3. If the research involves device(s), describe your plans to use, store, handle, administer and track those device(s) to ensure that they will be used only on research participants and be used only by authorized investigators.

Risks to Research Participants

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.

No physical, psychological, social, legal, or economic risks other than associated with daily living, are expected for the caregiver who participates in this study. Thus, the risks for emotional/physical distress should be minimal. Several measures will be taken to minimize the potential risk for distress while completing study questionnaires, HRV measurement, or during the interventions that involve tracking logging about the use of education,

resourcefulness skills or breathing techniques, or use of the biofeedback device. If a caregiver becomes upset during a data collection interview or intervention meeting or phone call/email/text, the team member will offer to end it immediately, provide emotional support and/or make a referral to a mental health professional as needed. It is possible that discussion of stresses related to having a family member with dementia may stimulate emotional responses in the caregiver during the 4 week interventions. All weekly phone call/email/text field notes will be stored in REDCap. In addition, there will be ongoing supervision by the intervention supervisor (Juratovic), who is an experienced, doctorally-prepared nurse. The data collectors and interventionists will report adverse effects to Dr. Juratovic and PI Zauszniewski as soon as discovered.

In regard to the use of the HRV measuring instrument, there have been no reported safety risk with the use of this instruments. It has passed electromagnetic interference and compatibility tests. Thus, there is no danger of electric shock from use of the device. We let the individual know that the device is for research purposes only and not meant to be diagnostic, the data obtained from the device will record heart rhythm but will not give information about treatments needed for heart health. If the individual would like more information about heart health or risk, they will be encouraged to talk to their doctor.

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable.

☒ N/A

3. If applicable, describe the risks to others who are not research participants.

☒ N/A

4. Describe the availability of medical or psychological resources that research participants might need.

☒ N/A

Provisions to Protect the Privacy Interests of Research Participants

Directions: Describe the steps that will be taken to protect research participants' privacy interests. (consider issues such as physical space, proximity to other, and participant preferences)

After eligibility is verified during phone screening by a team member, we will confirm with all study participants whether or not we can leave a voicemail message on their phone(s), and whether or not we can send mail to their home (in the event we cannot reach them by phone, and/or if they are randomized to the control group). We will also ask if there are any disclosure concerns and make note if applicable in REDCap contact form.

Privacy language is included in the informed consent form. Participants have the option of withdrawing from the study at any time and can request that no further information be shared about them from that point on. Participant names will not be shared in any report of the finding or with other study participants. Data collection interviews and intervention sessions will be conducted in a private setting (i.e. participant's home or other venue).

Confidentiality will be assured during all phases of the project by the following procedures. Screening and Study ID numbers will be used for all caregivers. A list of screening and study ID numbers with identifying names, phone numbers, and addresses will be kept locked in password-protected files in Box.com and REDCap. The survey data will be kept in a separate file from the data collected during the study and will only be accessible to the PI and research staff that need access to assure accurate follow-up in this longitudinal study. This identifiable information will be destroyed after all data have been collected.

Confidentiality issues will be addressed during training of research staff that will do the data collection and the interventionists. All data collected throughout the study, including signed consent forms, quantitative data using the REDCap system, HRV parameters, tracking logs, emails, and field notes maintained by research assistants and interventionists will be stored in locked files and password protected computer databases only accessible to the PI, Co-Is, project manager, and research staff. These data will not include any identifiable information that may have been obtained during recruitment and screening. These measures have been used successfully to protect the rights of human subjects in our previous studies. In addition, we will implement the following specific strategies to protect data obtained from the tracking logs or emails used by the caregivers:

1) Structured tracking log specific to intervention/ stress management method – caregivers will be provided with a structured tracking log for their use during the four week intervention between the first (T1) and second (T2) data collection interviews. If they receive a paper copy of the tracking log, versus completing an online log, they will be instructed to store the tracking log a private place (known only to them) in their home during the four weeks. They will be directed to not use real names of friends, relatives, etc. within the tracking log entries; they may use alternative names if they wish. Interventionists will review the tracking logs immediately upon retrieval (after the 28 day period) and if names are found, they will be blackened out and not appear within the transcribed text data files. The tracking logs will be stored in a locked cabinet in the research office and the text files will be stored in a password protected computer database. Both the tracking log and text files will be kept for a period not to exceed 3 years.

2) Email - Individuals may use email to get more information about the study, and/or to contact staff once enrolled in the study. Email contacts and outcomes will be recorded generally on our contact forms, which use Study ID number and not names. If an email needs to be printed or otherwise saved, it will be securely downloaded to a PDF file, with names and other contact information redacted, and delete the original email message. The PDF file will be stored in the password protected computer file for a period not to exceed 3 years.

COVID-19 remote modification:

Tracking logs will be sent electronically, but the option will remain to send a paper copy to the study participant, to be collected after the 28-day intervention.

Prior to a scheduled phone or video call with a participant, we will encourage them to find a quiet / private place to talk. At the beginning of each phone or video call, the team member will confirm that it's a good time to meet virtually, and ask who is in the room with them / confirm that they are able to talk with the study team member.

Potential Benefit to Research Participants

☐ There is potential benefit to research participants.

Describe the potential benefits that individual research participants may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits.

☒ There is **no** direct benefit to research participants.

If no direct benefit, state the potential benefit to society or others. *Do not list compensation.*

Withdrawal of Research Participants

Directions: Describe the anticipated circumstances under which research participants will be withdrawn from the research without their consent. Also include the procedures that will be followed when a research participant withdraws or are withdrawn from the research, including partial withdrawal from procedures with continued data collection.

☐ N/A

Participants have the option of withdrawing from the study at any time and can request that no further information be shared about them from that point on. If a study participant withdraws consent to participate in the study, a research team member will notify the project manager to complete end of study documentation.

The project manager will review cases regularly with research staff to determine which study participants should be withdrawn from the study. Research participants will be withdrawn from the research without their consent if they are non-responsive to phone calls, emails, texts, or letters and considered lost to follow up.

Data that were collected prior to a study participant's withdrawal will be de-identified and still be used in the data analysis for the study. After withdrawal, no further data will be collected for that participant.

Alternatives to Participation

Directions: List other options to participation. If subjects will be compensated with extra course credit, the course instructor offering extra course credit must provide alternatives to earn extra course credit. The alternative assignment must require equal or less time and effort for the same amount of earned extra credit that you can earn through participation in research. If there are other available clinical treatments, what would be included if a subject continued on standard of care therapy. If there is a viable alternative you must list it in the consent.

☒ The alternative is for research subjects not to participate.

Costs to Research Participants

☒ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *You may delete the rest of the section.*

1. Describe what costs research participants will be responsible for as a result of their participation in the research, including but not limited to: clinical services required by the protocol deemed billable to insurance, transportation to study visits, parking, costs of drugs, cost of therapy, lost broken or stolen devices, etc.

2. Explain who will be responsible for payment of provided services in the event of insurance denials.

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source.

Research Participant Compensation

☐ There is no compensation for research participants – *please leave rest of this section blank*

☒ There is compensation for research participants.

Describe the schedule, payment method, and payment total of any incentives or compensation that research participants will receive for participation in the research (e.g., gift cards or cash with amount, t-shirts, devices, bags, swag, etc.)

Incentives will be increased over time: $20 at T1 and $25 at T2. Caregivers will also receive $20 for the face-to-face intervention session and $5 for each week (up to 4 weeks/ $20) of completion of the progress log. Thus, each subject may receive up to $85.

COVID-19 remote modification: Gift cards equal to the cash amount will be sent to study participants after completion of the identified study activities.

☒ There will be reimbursement for research participants.

Describe the schedule, payment method, and payment total of any reimbursement that research participants will receive for participation in the research (e.g., gift cards or cash with amount, etc.)

If someone takes a bus or drives to CWRU or other community location to meet a research team member for T1, T2, or an intervention meeting, we will reimburse that individual a 2-trip bus pass or parking voucher as appropriate.

Compensation for Research Related Injury

Describe who will pay for the costs of medical treatment and/or compensation in the event of a research related injury:

☐ Funding agency is providing some/all payment for injury

☐ Funding agency is providing no payment for injury

☒ N/A

Provisions to Monitor the Data to Ensure the Safety of Research Participants

1. Describe how often the data will be monitored for completeness, accuracy and adherence to the protocol.

2. Indicate if there will be a Data and Safety Monitoring Board or Committee:

☐ There will **not** be a formal Data and Safety Monitoring Board/Committee.

☒ There will be a formal Data and Safety Monitoring Board/Committee.
Provide information about the DSMB/C including the contact information of the committee member(s) (as applicable); whether it is independent from the study sponsor; how often it meets; the type of data that will be used; written reports, etc.

A Safety Monitoring Committee (SMC) has been formed as the monitoring entity for this grant. The SMC is independent from the study sponsor and consists of:

- *Dr. Ronald Hickman , SMC chair, who serves as the Associate Dean for Research and is Associate Professor, Frances Payne Bolton School of Nursing, CWRU*
  Rlh4@case.edu
- *Dr. Sara Douglas, Assistant Dean for Research, and Professor, Frances Payne Bolton School of Nursing, CWRU*
  Sld4@case.edu
- *Dr. Joseph Calabrese, Professor of Psychiatry from the CWRU School of Medicine,*
  Joseph.calabrese@UHhospitals.org
- *Study team members will include Dr. Jaclene A. Zauszniewski, PI, and Dr. Christopher J. Burant, statistician cxb43@case.edu*

1. Monitoring Study Safety

a) Monitoring schedule - Twice per year throughout the project, the SMC will review data on the study regarding study safety. For example, the SMC will review any occurrences of caregiver emotional distress that required intervention by data collector or interventionist as well as those requiring referral and follow-up and instances where caregivers withdrew from the study.

b) Audits for compliance with IRB requirements – Random internal audits of 10% of the files will be done twice annually to insure the approved IRB protocol is being followed. The SMC will review recruitment procedures, compliance with meeting the inclusion/exclusion criteria, consistency with random assignment process to the treatment conditions, provision of interventions within timeframe defined within the protocol, and scheduling of data collection sessions as outlined within the protocol.

c) Conformance with informed consent requirements – Random internal audits will be conducted twice per year to verify that informed consent requirements are being met. For example, the SMC will review 10% of the consent forms for signatures and dates, make sure all consent forms are accounted for and stored in locked files and that the correct form is being used. Data collectors will be asked to describe the consent process quarterly to re-assess their knowledge of this process quarterly and review / retraining will be done as needed.

d) Verification of source documents – This study does not involve printed or written documents; data will be collected through electronic data capture using REDcap software and then downloaded directly into SPSSPC files. Heart rate variability data will be downloaded from the assessment device and transcribed into the SPSSPC files. These sources will not include any data that would be personally identifiable.

The SMC will review 1) all causes of mortality (e.g., caregiver death); 2) issues with participation (e.g., numbers and reasons for withdrawing from the study or refusing interventions, etc.) as well as recruitment refusal (percent and reasons) and subject attrition (percent and reasons); 3) missing data (including whether there are systematic patterns or whether data are missing at random); and 4) errors in data entry (which are expected to be minimal given the use of software for data collection with direct download into SPSS). In addition, differential attrition from the intervention groups (including the control and usual care groups, and the groups assigned to intervention based on need or personal preferences) will be monitored.

If concerns or problems are identified by the SMC, they will be reported to the IRB and NINR/NIH via email by Dr. Zauszniewski and Dr. Hickman, respectively, within 3 business days after they are identified. If there are recommendations made by the SMC, the action plan for response or notice of any actions taken by the IRB regarding the research and any responses to those actions will be provided to NINR Officials within 2 weeks.

e) Investigator compliance – Compliance of the investigators and all research team members who will have access to the data will be monitored annually. All research team members will be CREC certified; the CWRU intranet hosts a website where verification of compliance with continuing education for all investigators and team members can be evaluated.

2.) Reviewing and Reporting Adverse Events/unanticipated problems

1. Event identification

At the onset and for the duration of the study, all research staff and investigators will have instructional review of the nature and types of unanticipated and adverse events as described by the CWRU IRB. Potential risks for this study may include caregiver distress and breach of confidentiality (as described above). Caregiver distress may be identified by the data collector (during data collection) or the interventionist (during the interventions or phone follow-up). Breach of confidentiality may be identified by any research team member.

2. Reviewing and reporting

As they occur, all unanticipated events and adverse events will immediately be reported to Dr. Zauszniewski (PI) who will report them to the IRB according the CWRU IRB protocol reporting procedures for both serious and non-serious adverse events and unanticipated problem reporting. These will be summarized in the semi-annual reports to the SMC. Annual progress reports to the CWRU IRB and NINR/NIH will include a summary of the SMC's activities and findings as well as any adverse events regarding human subjects. Program Officials at NINR will be informed in a timely manner (3 business days) of unanticipated problems (e.g., a data breach) or unexpected serious adverse events that may be related to the study protocol or IRB-approved revisions to the study protocol that indicate a change in risk for participants. All adverse events and protocol deviations will be reviewed with the staff involved within 3 business days. Factors leading up to the event or deviation will be discussed and strategies for

preventing recurrence will be developed and implemented immediately.

Community-Based Participatory Research

☒ This is **not** a community-based participatory research project – please leave the rest of this section blank

☐ This is a community-based participatory research project

Describe the involvement of the community in the design and conduct of the research.
Note: Community based research is research that is conducted as an equal partnership between academic investigators and members of a community. In Community Based Participatory Research (CBPR) projects, the community participates fully in all aspects of the research process.

MULTI-SITE RESEARCH (when UH or CWRU is the IRB of Record)

Does this project have multiple sites?

☐ **Yes**

☒ **No** – please leave the rest of this section blank

Non-Local Site Information for Multi-Site Studies

*If this is a multi-site study where you are the **lead investigator,** list the following information for each relying site:*

1. Name of site:
2. PI of relying site:
3. Name of IRB contact:
4. Phone number of IRB contact:
5. Email address of IRB contact:

Non-Local Recruitment Methods for Multi-Site Studies

*If this is a multi-site study and research participants will be recruited by methods **not under the control of the local site** (e.g. call centers, national advertisements) describe those methods. Local recruitment methods are described above.*

1. Describe when, where, and how potential research participants will be recruited.

2. Describe the methods that will be used to identify potential research participants.

3. Describe the materials that will be used to recruit research participants.

Multi-Site Research Communication Plan (when you are the lead investigator)

*If this is a multi-site study where you are the **lead investigator**, describe the processes to ensure communication among sites including:*

☐ *All sites will have the most current version of the protocol, consent document, and HIPAA authorization*

☐ *All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site's IRB of record)*

☐ *All modifications have been communicated to sites, and approved (including approval of the site's IRB of record) before the modification is implemented*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies*

☐ *All local site investigators conduct the study in accordance with applicable federal regulations and local laws*

☐ *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy*

*If this is a multi-site study where you are the **lead investigator,** describe the method for communicating to engaged participant sites the following:*

1. *Problems:*
2. *Interim results:*
3. *The closure of the study:*

Additional Information

If you have any additional information regarding your study not covered in the template, please include it here.

References

Please reference the Investigator Manual for local institutional requirements.