Title: Dementia Caregiver Career Study

NCT04603482

Date: February 1, 2023

[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.*

PROTOCOL TITLE:
Self-Management Intervention: Considering Needs & Preferences of Dementia Caregivers

(aka "Caregiver Career Study")

PRINCIPAL INVESTIGATOR

Jaclene Zauszniewski
Nursing Science
216-368-3612
jaz@case.edu

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:

V1 12/19/19
V2 Updated 1.3.20
V3 Updated 10.7.2020, 11.23.20
V4 Updated 2.18.21, 5.14.21
V5 Updated 8.29.22
V6 Updated 2.1.23

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

Our **primary aim** is to examine the effects of a health self-management intervention (Biofeedback or Resourcefulness Training) delivered by need or preference in family carers of persons with dementia on caregiving responses **(1a)** and health outcomes **(1b)** over time. We hypothesize that family carers who receive either Biofeedback Training (BF) or Resourcefulness Training (RT) based on need or preference will have better health outcomes than carers in the attention control condition, regardless of caregiving phase.

The **second aim** is to determine whether differences exist among caregivers, care partners, and caretakers in carer responses **(2a)** and health outcomes **(2b)** over time. All carers will complete measures of caregiving responses and health outcomes at baseline (T1), 6 months (T2), and 12 months (T3). The four-week interventions will occur between T1 and T2 data points. Carers may use the intervention as often as they wish (i.e., self-tailoring); dosing and fidelity will be measured. Repeated measures bivariate and multivariate analyses will address the study aims while controlling for dementia symptom severity and caregiving demands.

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.

Dementia is the most under recognized health crisis of the 21st century, with over 46 million people worldwide living with dementia, a number that is expected to reach 131.5 million by 2050.4 In the United States, family members provide care for over 5.4 million elders with some form of dementia. Regardless of cause, dementia has a slow, progressive, fairly predictable downward course, with losses in mental and physical functioning that generate negative **carer responses** (i.e., perceived stress, depressive cognitions, negative emotions) and may seriously compromise the family carer's health risks and physical and mental health (i.e., **health outcomes**). Research shows that within six months of a transition to a new caregiving phase (i.e., from caregiver, to care partner, to caretaker), the health of family carers shows evidence of substantial decline. Although researchers have identified factors occurring throughout the caregiving career that may adversely affect the carer's health, interventions to promote health self-management by reducing negative caregiving responses have not been tested in carers who have recently transitioned into the role of caregiver, care partner, or caretaker. Consistent with

the Precision Medicine Initiative, which presents an innovative model that accounts for individual differences and empowers health care recipients (i.e., family carers) to participate actively in health care decisions, sustainable self-management interventions should be designed and tailored to match the carer's needs and preferences and then tested with randomized, controlled trials.

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

1) Having an elderly 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 their care and welfare;
2) The caregiving career follows a long-term trajectory that may last from 4-20 years and involves a predictable downward spiral of losses in the elder's mental and physical functioning, accompanied by changes in the level of care needed by the elder;
3) Changes in level of care required to meet the needs of the elder over the course of dementia are reflected in a caregiving career comprised of the roles of primary caregiver (in the home), care partner (with facility placement), caretaker (following death of the loved one);
4) Family carers, regardless of phase in the caregiving career, are prone to experience stress and depressive thoughts and feelings that can adversely affect their physical and mental health over time; and
5) Existing interventions that strengthen family carer's self-management skills, including Heart Rate Biofeedback (**BF**) and Resourcefulness Training (**RT**),© will reduce their stress, minimize their depressive feelings, and ultimately sustain their physical and mental health at any phase of the caregiving career.

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 carers 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 carers 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.

Systematic reviews have shown that researchers have examined interventions for dementia carers who are primary caregivers, 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, and 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 women versus men and for caregivers with lower versus higher education. Positive outcomes include

fewer depressive and anxious symptoms, greater satisfaction, and a better sense of well-being. These studies, however, were limited to one phase of the caregiving career, primary caregiving; interventions were not tested in care partners or caretakers, 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 of such skills as cognitive reframing, problem-solving, self-management, and help-seeking, all of which are incorporated within 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

Seminal research suggests that the primary carer role for elders with dementia typically falls on the shoulders of the closest and most accessible family member (spouses, adult children), with the caregiving career being punctuated by significant events that prompt a transition in the caregiving career, which has been conceptualized in three phases. Few studies have examined the experiences of family carers in the three phases of the caregiving career. Those that have showed that the carer's sense of control declined with in-home caregiving, stabilized during institutional placement, and improved after bereavement, and that carers in all three phases had different, unmet needs for assistance and informational support that contributed to similar stress levels. These studies support further investigation of dementia caregiving as a career with distinct phases designed to capture the carer's responses to a recent transition into a new phase of the caregiving career. Research shows that within six months of a transition to a new caregiving phase (i.e., from caregiver, to care partner, to caretaker), the health of family carers shows evidence of substantial decline. To date, no studies of the three phases of the dementia caregiving career that examined the responses to recent transitions into a new phase of the career have been conducted. This study will be the first to do so.

Although the conceptualization of the dementia caregiving career dates as far back as 1992, little research has been done to explicate the caregiving trajectory and transitions that occur during the progressive course of dementia. The preponderance of research on dementia

caregiving has focused on in-home **caregivers**, and has shown that despite interventions aimed at reducing negative outcomes, 59% of family carers continue to report emotional stress and 43% believe that caregiving significantly depleted their physical health. Research has also shown that family caregivers continue to be involved in various forms of care following institutional placement, a time when the family carer becomes a **care partner**. Care partners of institutionalized elders with dementia experience similar effects on their stress level and health as in-home caregivers, as their involvement in the care of their family member continues. However, while the source of their stress is now associated with different factors (communication challenges with staff, role conflict), their stress levels remain unchanged.

As the final stages of dementia culminate in the death of the loved one, family carers become **caretakers**. This caregiving career phase is typically overlooked, though caretakers may continue to experience stress and depressive thoughts and feelings that compromise their physical and mental health. As caretakers mourn their loss, they must engage in caring for their deceased loved ones in a new way (i.e., their belongings, property, estate). Thus, even as active caregiving ceases, effects of stress on health remain, losses and transitions continue, and caretakers must simultaneously rebuild their identity and sustain their health while experiencing bereavement. To date, research has not highlighted the importance of including the caretaking role as part of the caregiving career. However, one study that followed dementia caregivers for one year after their care recipients died found that almost half of the caregivers had clinically significant depression.

Based on the foregoing review, this study will: 1) include a sample of dementia carers that include caregivers (in-home), care partners (with a facility), and caretakers (bereaved) who have recently (within six months) transitioned into a new phase of their caregiving career; 2) examine the effects of two self- management interventions delivered to carers based on their need (cut score) or preference in comparison with an attention control condition; 3) explore differences in carers at the three phases of the caregiving career on caregiver responses to their recent transition and health outcomes over time; and 4) control for the effects of number of months in carer role, dementia symptom severity, and caregiving demands. As such, this will be the first study to investigate self-management interventions across all three phases of the caregiving career of dementia carers.

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. At least 18 years old
2. Have a living family member, or a recently deceased family member diagnosed with Alzheimer's disease or another dementia
3. Identify self as a primary caregiver
4. In-home C**aregivers**: must be currently providing a minimum of 4 hours per day of supervision/direct care, and have entered that role within the past ~~six~~ twelve months;

Care partners whose family member moved into a nursing or assisted living

facility within the past ~~six~~ twelve months, and must report visiting their care recipient at least once per week (or have similar involvement with COVID-19 restrictions).

Caretakers (i.e. bereaved) whose family member is deceased within the past ~~six~~ twelve months, and are persons with direct oversight of the deceased person's belongings, estate, finances, etc., and/or while their family member was alive, did they consider yourself a primary caregiver (whether care recipient was at home or in a facility).

5. 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 with dementia within the last ~~six~~ twelve months, or the family member has been deceased for more than ~~six~~ twelve 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 carers may not meet eligibility criteria. Thus, we will screen ~~~375 participants~~ 600 individuals to obtain the desired sample of size of ~~300~~ 350.

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 ~~300~~ 350 family caregivers will be recruited from Cuyahoga County, ~~and~~ 6 adjacent counties (Lorain, Medina, Summit, Portage, Geauga and Lake), as well as Erie, Huron, Ashland, Wayne, Stark, Mahoning, Trumbull, and Ashtabula counties.

The potential research participants will be recruited through a variety of community-based strategies:

- We will post flyers and distribute postcards in the community to recruit potential study participants, as well as recruit through social service advocacy agencies, and other community agencies.
- We will contact dementia care day programs and care facilities, and private physicians' offices who agree (with a signed Letter of Cooperation) 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 inclusion criteria. We may also recruit through these agencies with digital or printed ads in newsletters.
- We will collaborate with community agencies (e.g. senior centers) to conduct short presentations to interested audiences. Time permitting, we will utilize the NIH Recruiting Older Adults into Research (ROAR) open-source short form PowerPoint presentation (https://www.nia.nih.gov/health/recruiting-older-adults-research-roar-toolkit) in addition to presenting information about our study (e.g. distributing flyers).
- Health fairs and other community events.
- We will recruit via the internet using social media sites (e.g. Twitter, Facebook, Instagram, and other online sources). We will also utilize paid digital and print advertising in local newspapers and other appropriate media outlets, including the use of advertorials and/or posted ads.
- Digital recruitment may include a link to a secure REDCap form so that people may leave their contact information for us to follow-up with. The form will include a brief description of the study.
- Most 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, postcards, and other advertisements. 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 research team member will confirm their name, contact information (phone and/or email), address, and time / best method for the research team to contact them, and proceed with the consent process and scheduling the first data collection session.
- Finally, we will use snowball recruitment by asking study participants to refer others like them to the study.

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

Potential study participants will be recruited through flyer postings, health fairs and other community events, print and e-newsletters (e.g. CASE Daily), community bulletin boards (both physical and virtual, e.g. Case Campus Groups), listservs, local magazines and newspapers, volunteer recruitment sites such as ResearchMatch.com and Alzheimer's Association TrialMatch, both public and private advocacy agencies, care facilities, support groups, community health centers, and private physician offices in Cuyahoga and ~~6 adjacent~~ other approved counties in Northeastern Ohio.

To enhance recruitment of bereaved caretakers, we will also work with a large mortuary firm in Cleveland, known for its efforts to provide post-funeral support to bereaved families, as well as other mortuaries that serve the study area. We will also work with funeral homes, regional hospice agencies, bereavement support groups, and online obituary and memorial sites (e.g. Cleveland.com, legacy.com). Letters of Cooperation will be obtained from these agencies.

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 & 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 REDCap and 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.). ~~They will also be asked if they would like to be contacted regarding future research opportunities that may be of interest to them.~~ All screening question documentation will be kept in a screening form on REDCap along with screening ID.

If the screenee is eligible:
After eligibility is verified during phone screening by team member, the consent will be reviewed verbally, questions about the study will be answered. They will be asked if they verbally consent to the study, with the understanding that the Consent Form will be reviewed and signed prior to the first timepoint (T1) data collection. If they agree to participate, the research team member will then confirm and update any contact information into CWRU Box Screening and Enrollment Log and REDCap form; 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. The study enrollment/first data collection appointment will be made at this time.

If the screenee is <u>not</u> eligible/ declines verbal consent:

If the individual does not meet the study criteria, they are asked if they would like to have their contact information kept on file in the event that the screening criteria are modified (e.g. study radius) and would like to be contacted to re-assess eligibility. If they say yes, the staff member will proceed to collect contact information in CWRU BOX and REDCap form (confirm full name, mailing address, phone number(s), email address).

Screening data (questions asked to determine eligibility) is kept in the REDCap form in which it was entered in for tracking and reporting purposes.

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% 45%~~ 58% of caregivers may not meet eligibility criteria. Thus, we will screen ~~~375 ~550~~ 600 individuals ~~potential participants~~ to obtain the desired sample size of ~~300~~ 350.

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).

COVID-19 Modifications: Consent, data collection, and intervention delivery has been modified to include virtual options: email, video chat (Zoom), phone, or some combination of the three, to meet study participants' needs). This information is included throughout the protocol.

Updated COVID-19 Modifications May 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.

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

To enhance recruitment of bereaved caretakers, we will also work with a large mortuary firm in Cleveland, known for its efforts to provide post-funeral support to bereaved families, as well as other mortuaries that serve the study area. We will also work with regional hospice agencies, bereavement support groups, and online obituary and memorial sites (e.g. Cleveland.com, legacy.com). Letters of Cooperation will be obtained from these agencies.

Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

- 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.

  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, a blank copy of the consent form is emailed to the participant via the REDCap e-consent framework, and a copy of the signed consent form is auto-saved in the REDCap File Repository. This File Repository saves, with each file, the date and time of consent, the version of the consent form signed, and an IP address. Digital files of signed consent forms (ONLY) will be backed up and 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.

  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.

- 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.

- 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 business hours. Study will utilized REDCap's auto-email reminder to send 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.

- 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.

- 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 study arms (Self-management need, self-management preference, or attention control) 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.

- 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

- Give the rationale for the request of a waiver or alteration of the consent process or documentation.
  N/A
- Explain how the research involves no more than minimal risk.
  N/A
- Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants.
  N/A
- Explain why the research could not practicably be carried out without the waiver or alteration of consent.
  N/A

- Indicate if the subjects will be provided with additional information about the study after participation.
  N/A
- 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

- 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

- 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.

- 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.

SCREENING: Prior to the first data collection session, the individual is screened over the phone. If the screenee is eligible, the consent form will be reviewed verbally, questions about the study will be answered. They will be asked if they verbally consent to the study, with the understanding that the Consent Form will be reviewed and signed electronically by an e-consent form, or if requested, a consent form will be mailed to the home for signature, date and return (envelope provided), and prior to the T1 data collection. If they verbally agree to participate, the

research team member will then confirm and enter contact information into CWRU Box and a REDCap form; 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. The study enrollment/first data collection appointment will be made at this time.

CONSENT: At the first meeting, before the T1 interview begins, the data collector will confirm receipt of signed consent form (digital or paper). 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 study arms (Self-management need, self-management preference, or attention control). They will be told the study involves 3 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 a gift card valued at $20 at Time Point 1 (T1), $25 at T2, and $30 at T3. In addition, they will receive $20 for completing the face-to-face or virtual intervention session and $5 for each week of completion of the progress log (up to 4 weeks or $20). Participants will receive up to $115 for completing all study activities.

DATA COLLECTION: Following informed consent, research staff will collect detailed contact information and schedule the first data collection session. During the COVID-19 pandemic, data collection will be completed verbally over the phone and/or electronically (emailed survey, video chat) using REDCap. 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.

The data collection for caregivers sampled involves three structured face-to-face sessions with data collectors, each lasting typically 60-90 minutes. Data will be collected at baseline (T1), at 4-6 months (T2) after the 4-week intervention, and at ~~12~~ 4-6 months later (T3). The data collection includes measures of carer health conditions, carer life events, health rating of care recipient, resourcefulness (including financial resourcefulness), dementia symptom severity, caregiving demands, carer responses to perceived stress, depressive cognitions, negative emotions, carer health outcomes, caregiving effort scales, and COVID-19 questions comprising the 158-225 item questionnaire (bereaved caretakers are not asked all study measures since they are no longer actively caring for their family member). 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). The third, and final, data collection session involves the additional measure of an Intervention Evaluation Questionnaire that will ask participants for feedback regarding the intervention they received.

The table below shows which study instruments are administered at each time point:

Data Collection Instrument	**Baseline / T1**	**4-6 months post-intervention / T2**	**~~12~~ 4-6 months post-T2 / T3**
Demographic and Descriptive Data*	X	X	X
Health Rating of Elder Care Recipient**	X	X	X
Cultural Justification for Caregiving	X	X	X
Resourcefulness Scale	X	X	X
Financial Resourcefulness	X		
Revised Social Readjustment Rating Scale	X	X	X
Revised Memory and Behavior Problems Checklist**	X	X	X
Perceived Stress Scale	X	X	X
Depressive Cognition Scale	X	X	X
Negative Emotions Checklist	X	X	X
Caregiver Appraisal of Functional Capacity**	X	X	X
Health Risk Behavior Scale	X	X	X
PROMIS Global Health Measures	X	X	X

Caregiving Effort Scales	X	X	X
~~Financial Stress~~	~~X~~		
COVID-19 Questions	X	X	X
Intervention Evaluation Questionnaire			X
Heart Rate Variability	X	X	X

* Questions 7-13 of the Demographics will NOT be asked to caretakers.

** These scales will NOT be asked to caretakers.

For in-person data collection: 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. Data is collected on an iPad through the REDCap Mobile App – which can be used when there is no wireless connection available. The data is stored securely in the app until it can be uploaded with a secure wi-fi connection (and then is removed from the iPad completely). IPads have a secure connection to login to the device, and another secure login to connect to the REDCap app. IPads are shut down completely at the end of every data collection session. 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.

Heart-rate variability (HRV) data will be collected with a Byteflies or a similar HRV device, used either on the chest or on the wrists. Once a data collection (T1, T2, or T3) is complete, a team member will make an arrangement to collect HRV data at the study participant's home or another agreed upon meeting location at a set day/time.

- Remote HRV data collection: The participant will receive instructions of how to use the HRV device for 10-20 minutes data collection of HRV. The team member will be available to provide support during this time by phone or video call, and participants will be provided written instructions as well. 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 (May 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.

INTERVENTION: Within two weeks of the first data collection session (including study scales and HRV data collection), carers within each of the three caregiving phases (caregivers, care partners, and caretakers) will be randomly assigned using a computer program to one of three treatment groups: 1) Self-management (SM) need, 2) Self-management (SM) preference, or 3) attention control. The SM-need group will receive a self-management intervention tailored to meet their need for resourcefulness training (RT) or biofeedback (BF) as

determined by whichever baseline cut score is lower, the Resourcefulness Scale or the SDNN parameter for age and gender. Carers randomly assigned to the SM-preference will choose to do RT or BF according to their personal preference. However, we will use minimization methods for group assignment to ensure equivalent representation across the three treatment groups, and factors likely to affect variables of interest, including carer age, gender, and race/ethnicity, in order to insure demographic similarity.

Carers in the SM-need and SM-preference groups will receive the training and practice a self-management intervention between the T1 and T2 data collections and may continue to use the intervention between T2 and T3 if they wish. The attention control (AC) condition, which consists of diversional activities, will also take place between T1 and T2 data collections. The RT, BF, or AC will be introduced during a single virtual session (Zoom, or iPad + phone call, depending on study participants ability / preference) during the COVID-19 pandemic, otherwise during a single face-to-face session in a mutually agreed upon private location. These intervention meetings last about 30-60 minutes and include a voice-over PowerPoint presentation, a summary of the information in a print brochure or electronic PDF, and a workbook (print or electronic) to be completed daily over 28 days, as they independently practice the intervention. RT participants will also be given a printed or emailed PDF list of examples (differ depending on caregiving type) from the training. The electronic workbook will be a form that is emailed daily over 28 days, but a print booklet will be provided for those that prefer it, and will be collected after 28 days. They will receive telephone, text or email follow-up (their preference) once per week for the 28-day intervention period while practicing the intervention (or activities) independently and keeping a daily workbook. Interventionists will be carefully trained by PI Zauszniewski and CNS 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 carers 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 the RT, BF, or AC; they will keep field notes and have weekly supervision by CNS Juratovac and PI Zauszniewski, who has been trained in delivering biofeedback and has pilot-tested both interventions for feasibility and efficacy in similar populations. Commonalities during the single session for the RT, BF, or AC are:

1) All carers will keep a progress log, though its content will differ by intervention/condition;
2) All will be taught to indicate day and time of the log entry, with the suggestion to do it at the same time each day; and
3) All will complete a log entry during the training session.

Consistently, during the 4 weeks after the initial session:

1) All carers will perform the assigned intervention (or activities) on their own,
2) All will have access to intervention/activity content for review as they wish,
3) All will receive weekly follow-up calls/emails from interventionists (3-5 minutes) to remind them to follow respective intervention/activity protocols, and
4) All will be encouraged to continue their logs even if days have been missed (although BF data may be missing).

Resourcefulness Training Intervention

Resourcefulness training involves teaching skills constituting personal (self-help) and social (help-seeking) resourcefulness. The proposed method for teaching resourcefulness extends beyond simply teaching the skills to the caregivers of persons with dementia to facilitating the use of resourcefulness skills through self-reinforcement by daily tracking in a tracking log. Therefore, in this unique intervention, a mnemonic device will be used to facilitate recall of specific skills within the repertoire comprising resourcefulness. **Three** mnemonic techniques are used in (RT): acronyms, chunking, and practice. The techniques are explained on the slides.

An **acronym** is formed by the first letter of words or groups of words to form a new word. In the case of RT, the mnemonic device uses the 8 letters spelling **RESOURCE** to prompt recall of specific personal and social resourcefulness strategies as follows:

- **R**ely on family / friends;
- **E**xchange ideas with others;
- **S**eek professionals or experts;
- **O**rganize daily activities;
- **U**se positive self-talk;
- **R**eframe the situation positively;
- **C**hange from usual reaction;
- **E**xplore new ideas.

The second mnemonic technique to be used in RT is **chunking**, which refers to the common rule that an individual can remember between 5 and 9 things at one time. In RT, the word RESOURCE contains 8 letters, which is a reasonable "chunk" of ideas of ideas for study participants to remember. Another way in which chunking is used is that the first three resourcefulness skills refer to social resourcefulness and involve help-seeking behavior, while the last five refer to personal resourcefulness and use self-help behaviors.

The third mnemonic technique involves **practice**. In this clinical trial, practice will be done through keeping a daily tracking log reviewing which strategies were used that day, along with review of a RESOURCE card and Resourcefulness Training pamphlet. Intervention recipients will choose the practice method they want to use.

Biofeedback Training Intervention

A proposed method of stress reduction for the family caregivers of persons with dementia disorder involves biofeedback that focuses on heart rate variability (HRV). Through HRV biofeedback, one is able to learn how breathing patterns relate to changes in heart rate. HRV biofeedback has been found to be effective in reducing stress and enhancing relaxation.

The iRelax device is a small hand held device and contains a screen that displays one's heart wave, similar to an EKG tracing. Under each wave appears a bar that shows how well one is breathing in relation to heart rate. With each breath, one can score 1 point or a fraction of it (1/3 or 2/3). The device will beep with a minimum breath score of 2/3. The Interventionist will teach the caregivers:

1) How to turn the iRelax on and off.
2) Insert a finger into the sensor clip that detects their pulse rate.
3) Inhale slowly and gently while observing the waves on the screen
4) Exhale slowly and gently while counting slowly from one to five when a new triangle appears above the wave

5) Begin to inhale when the next wave starts to rise
6) How points are scored to show "heart rhythm coherence" - under each wave appears a bar that shows how well one is breathing in relation to heart rate. With each breath, one can score 1 point or a fraction of it (1/3 or 2/3). The device will beep with a minimum breath score of 2/3.
7) Use of a daily workbook to record daily points earned during the biofeedback session. The caregiver will be asked to describe his/her general emotional state each day and any specific stresses / frustrations he/she experienced in relation to the diagnosed family member. He/she will be asked to do this for the 4-week intervention period (28 days). A Biofeedback breathing card and pamphlet (or electronic PDF) will also be provided to the participant.

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.

The study is approved on ClinicalTrials.gov.
Clinical Trials.gov ID: NCT04603482

List of Data to be Collected

1. *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).

- Demographics
- Questionnaires to measure carer health conditions, carer life events, health rating of care recipient, dementia symptom severity, caregiving demands, carer responses to perceived stress, depressive cognitions, and negative emotions, financial resourcefulness and stress, carer health outcomes, and COVID-19 questions (Listed under site related documents as 'instruments & measures.pdf')
- Intervention evaluation questionnaire
  (Listed under site related documents as 'CCS intervention eval questionnaire.pdf')
- Intervention workbooks
  (Listed under site related documents as 'AC / BF / RT workbook page.pdf'

Data Analysis Plan

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

Prior to testing the study aims, demographic profiles for caregivers, care partners, and caretakers will be created through univariate descriptive statistics, including means, standard deviations, and range of scores, and will be used to assess continuous data; frequencies and percentages will be used to describe categorical data. We will track the health conditions and the life events of all carers and dementia symptoms, level of care, and health rating of the care recipient for those who are not bereaved. However, the primary aim (**Aim 1)** is to test the effects of health self-management interventions (RT or BF) delivered based on need (i.e., cut score) or preference (i.e., personal choice) of dementia carers who have transitioned within six months to a new phase in the caregiving career (to at-home caregiver, to care partner with a facility, or to caretaker following the death of care recipient). **Aim 1** is to compare carers who are randomly assigned to the need (SM-need, preference (SM-preference) group, or an attention control condition over 3 time points (baseline, 6 months, and 12 months) on carer responses (i.e., perceived stress, depressive cognitions, and negative emotions) (**Aim 1a**), and health outcomes (health risk, and physical and mental health) (**Aim 1b**). **Aim 2** will focus on comparing caregivers, care partners, and caretakers. For **Aims 2a and 2b,** we will determine whether differences exist among caregivers, caregivers, care partners, and caretakers in carer responses **(2a)** and health outcomes **(2b)** over time. For all analyses, we will control for the effects of three covariates: months in caregiver, care partner, or caretaker role, dementia symptom severity, and caregiving demands.

For both study aims, we will use a 3 group by 3-time point Repeated Measures Analysis of Variance (RMANOVA), as well as 3 group by 3-time point Repeated Measures Analyses of

Covariance (RMANCOVA) to control for the three covariates on carer responses (i.e., perceived stress, depressive cognitions, and negative emotions) (**Aim 1a and Aim 2a**) and health outcomes (health risk, and physical and mental health) (**Aim 1b and 2b**). We will use both analyses in a two-step process: first, we will use RMANOVA to determine if mean differences exist among the 3 groups over 3 time points. If we find mean differences, for the second step we will run RMANCOVA to identify how the covariates impact the initial findings. This controls for any confounding effects of the covariates on the repeated measures models and will also allow us to determine how much of an impact the covariates have on carer responses and health outcomes.

The RMANOVA and RMANCOVA will allow us to not only assess mean differences across time, group differences, and the interaction of time X group in order to test the trend of the means over time across the SM- need, SM-preference, and attention control condition in **Aim 1** and caregiver vs. care partner vs. caretaker in **Aim 2**. The RMANOVA and RMANCOVA not only can be used to determine if there are mean differences across the three time periods, but can also utilize orthogonal polynomial contrasts to determine whether linear and quadratic trends of the means across time are significant.

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.

   Identifiers in the Screening log (Box.com) and Contact Form (REDCap and CWRU BOX) will be destroyed after data collection is complete, and before the study is closed, by deleting the files.

   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:

2. 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 – Health Research Campus study office

3. 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

2. 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 carer 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 using a workbook about the use of diversional activities (the attention control), resourcefulness skills or breathing techniques, or use of the biofeedback device. If a carer 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, or being recently bereaved, may stimulate emotional responses in the caregiver during the 4 week interventions. All weekly phone call/email/text field notes will be stored in Box or 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.

With regard to the use of the HRV measuring instrument, there have been no reported safety risk with the use of this instrument. 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. However, when analyzing their heart rate data, if the score indicates an irregularity with your heart rate or rhythm (e.g., SDNN <50ms), a study team member will contact the study participant as soon as possible, let the participant know that while the BioRadio reading is not diagnostic, their score indicates they may have some irregularity with their heart rate, and we will recommend that they follow-up with their health care provider at their earliest convenience.

3. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable.
   ☒ N/A
4. If applicable, describe the risks to others who are not research participants.
   ☒ N/A
5. 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 and CWRU Box.

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 virtually or 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 workbook specific to intervention – carers will be provided with a structured workbook (electronic or print) for their use during the four week intervention

between the first (T1) and second (T2) data collection interviews. If provided a print copy, they will be instructed to store the workbook in 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 workbook entries; they may use alternative names if they wish. Interventionists will review the workbooks 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 workbooks 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 10 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 in Box and/or REDCap. 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.

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.)

Gift card incentives will be increased over time: $20 at T1, $25 at T2, and $30 at T3. Carers will also receive a $20 gift card for the face-to-face intervention session and $5 gift cards for each week (up to 4 weeks/ $20) of completion of the workbook, distributed after the 28-day intervention time frame. Thus, each subject may receive up to $115 in gift card compensation for completion of all 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, T3, 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. Martha Sajatovic, Professor of Psychiatry from the CWRU School of Medicine, martha.sajatovic@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 carer emotional distress that required intervention by data collector or interventionist as well as those requiring referral and follow-up and instances where carers 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., carer 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 carer distress and breach of confidentiality (as described above). Carer 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.

Study Information stored in Box.com:

- Screening & Enrollment Log (screening ID, name, phone number and/or email, staff notes regarding eligibility status of individual, Study ID, Screen date, Informed Consent date, T1 date, Intervention date, T2 date, T3 date, End-of-Study date)
- Uploaded HRV data
- Copy of current informed consent form, and current protocol
- Project Manager will keep REDCap back-up files (updated monthly) in Box.com. Files will be in SPSS format, and these separate files will be accessible only to the Project Manager and Data Coordinator.

Study Information stored in REDCap:

- Screening form (criteria questions answered, verbal study consent~~, and consent for future research~~), Contact Form (name, address, phone number, preferred contact methods and times), eConsent (signed copies saved in File Repository, automatically includes IP address), Enrollment form confirming enrollment date, consent form signed digitally or paper copy; Randomization form with intervention assignment and-End-of-Study forms. Study team members, depending on role, have access to different forms.
- Interventions and Weekly meetings (different staff, depending on role, have access to different forms): Intervention tracking (date of intervention, weekly follow-up contact).
- Surveys Project: All study instruments

Stored on Network drives:

- No PHI is stored on network drives
- Internal study files such as grant proposal, IRB folder, marketing materials.

References

1. Alzheimer's Association. (2016). Alzheimer's disease facts and figures. *Alzheimer's & Dementia,*12(4), 22. http://dx.doi.org/10.1016/j.jalz.2016.03.001
2. Gaugler, J.E., & Teaster, P. (2006). The family caregiving career for community-based long-term care practice and policy. *Journal of Aging & Social Policy, 18*(3/4), 2006, 141-154. doi: 10.1300/J031v18n03_10
3. Peacock, S.C., Hammond-Collins, K., & Forbes, D.A. (2014). The journey with dementia from the perspective of bereaved family caregivers: A qualitative descriptive study. *BMC Nursing, 13*, 42. doi: 10.1186/s12912-014-0042-x
4. Prince, M., Wimo, A., Guerchet, M., Ali, G.C., Wu, Y.T., & Prina, M. (2015). *World Alzheimer Report 2015 The Global Impact of Dementia An analysis of prevalence, incidence, cost and trends: Executive Summary.* London: Alzheimer's Disease International
5. Chiao, C.Y., Wu, H.S., & Hsiao, C.Y. (2015). Caregiver burden for informal caregivers of patients with dementia: A systematic review. *International Nursing Review, 62*, 340-250. doi: 10.1111/inr.12194

6. Gaugler, J.E., Anderson, K.A., Zarit, S.H., & Pearlin, L.I. (2004). Family involvement in nursing homes: effects on stress and well-being. *Aging & Mental Health, 8*(1), 65–75. doi: 10.1080/13607860310001613356
7. Romero, M.M., Ott, C.H., Kelber, S.T. (2014). Predictors of grief in bereaved family caregivers of persons with Alzheimer's Disease: A prospective study. *Death Studies, 38,* 395–403. doi: 10.1080/07481187.2013.809031
8. Bangerter, L.R., Liu, Y., & Zarit, S.H. (2017, online). Longitudinal trajectories of subjective care stressors; The role of personal, family, and dyadic resources. *Aging and Mental Health*. doi: 10.1080/13607863.2017.1402292
9. Von Kanel, R., Mills, P.J., Mausbach, B.T., Dimsdale. J.E., Patterson, T.L., Ziegler, M.G., Ancoli-Israel, S., Allison, M., Chattillion, E.A., & Grant, I. (2012a). Effects of Alzheimer's caregiving on circulating levels of c-reactive protein and other biomarkers relevant to cardiovascular disease risk: A longitudinal study. *Gerontology, 58*, 354-365. doi: 10.1159/000334219.
10. Von Kanel, R., Mausbach, B.T., Dimsdale. J.E., Mills, P.J., Patterson, T.L., Ancoli-Israel, S., Ziegler, M.G., Roepke, S.K., Chattillion, E.A., Allison, M., & Grant, I. (2012b). Effect of chronic dementia caregiving and major transitions in the caregiving situation on kidney function: A longitudinal study. *Psychosomatic Medicine, 74*, 214-220. doi: 10.1097/PSY.0b013e3182408c14.
11. Von Kanel, R., Mausbach, B.T., Ancoli-Israel, S., Dimsdale. J.E., Mills, P.J., Patterson, T.L., Ziegler, M.G., Roepke, S.K., Chattillion, E.A., Allison, M., & Grant, I. (2012c). Sleep in Alzheimer's caregivers: A longitudinal study with a focus on the effects of major patient transitions on sleep. *Sleep, 35*(2), 247-255. doi: 10.5665/sleep.1632.
12. Gaugler,J.E., Kane, R.L., & Newcomer, R. (2007). Resilience and transitions from dementia caregiving. *Journal of Gerontology: Psychological Sciences, 62*(1), 38-44.
13. Collins, F.S., & Varmus, M.D. (2015). A new initiative on precision medicine. *New England Journal of Medicine, 372*, 793-795. doi:10.1056/NEJMp1500523.
14. The White House (2015). *Fact sheet: President Obama's Precision Medicine Initiative*. Retrieved from https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative.
15. Ryan, P., & Sawin, K. (2009). The individual and family self-management theory: Background and perspectives on context, process, and outcomes. *Nursing Outlook, 57*, 217-225. doi:10.1016/j.outlook.2008.10.004.
16. UWM Self-Management Science Center Working Group. (2011). Individual and Family Self-management Theory: Definition of self-management. Retrieved from http://www4.uwm.edu/smsc/framework/
17. Zauszniewski, J.A., Eggenschwiler, K., Preechawong, S., Roberts, B.L., & Morris, D.L. (2006). Effects of teaching resourcefulness skills in elders. *Aging and Mental Health, 10*(4), 1-9. doi:10.1080/13607860600638446.
18. Zauszniewski, J.A., Eggenschwiler, K., Preechawong, S., Roberts, B.L., & Morris, D.L. (2006). Effects of teaching resourcefulness and acceptance on affect, behavior, and cognition of chronically ill elders. *Issues in Mental Health Nursing, 28*(6), 575-592. doi:10.1080/01612840701354547.
19. Zauszniewski, J.A., Musil, C.M., Au. T.Y., Burant, C.J., & Standing, T.S. (2014). Resourcefulness training for grandmothers raising grandchildren: Establishing fidelity. *Western Journal of Nursing Research, 36*(2), 228-244. doi:10.1177/0193945913500725.
20. Zauszniewski, J.A., Musil, C.M., Burant, C.J., & Au, T.Y. (2014). Evidence for preliminary effectiveness of resourcefulness training interventions for grandmothers raising grandchildren. *Research in Nursing and Health, 37*(1), 42-52. doi: 10.1002/nur.21574.

21. Zauszniewski, J.A., Lekhak, N., Morris, D.L., Burant, C., & Underwood, P. (2016). Resourcefulness training for women caregivers of elders with dementia: Establishing fidelity. *Western Journal of Nursing Research, 38*(12), 1554-1573. doi: 10.1177/0193945916655798.
22. Zauszniewski, J.A., Lekhak, N., Burant, C., & Morris, D.L. (2016). Preliminary evidence for effectiveness of resourcefulness training for women dementia caregivers. *Journal of Family Medicine, 3*(5), 1069-1078.
23. Alzheimer's Association. (2011). *Advocacy Center Federal Policy Priorities: National Alzheimer's Project Act (NAPA)*. Available at http://www.alz.org/advocacy/federal-priorities.asp#napa. Last accessed May 18, 2019.
24. National Institute on Aging. (2012). *Alzheimer's Disease Research Summit 2012: Path to Treatment and Prevention.* Available at https://www.nia.nih.gov/about/events/2012/alzheimers-disease-research-summit-2012-path-treatment-and-prevention. Last accessed May 18, 2019.
25. National Institute on Aging. (2012). *Alzheimer's Disease Research Summit 2012: Path to Treatment and Prevention.* Available at https://www.nia.nih.gov/about/events/2012/alzheimers-disease-research-summit-2012-path-treatment-and-prevention. Last accessed May 18, 2019.
26. Obama calls on Congress to fund 'precision medicine' studies (2015, January 30). Available at http://medicalxpress.com/news/2015-01-obama-precision-medicine-one-size-fitsall.html. Last accessed May 18, 2019.
27. Tom, S.E., Hubbard, R.A., Crane, P.K., Haneuse, S.J., Bowen, J., McCormick, W.C., McCurry, S., & Larson, E.B. (2015). Characterization of dementia and Alzheimer's Disease in an older population: Updated incidence and life expectancy with and without dementia. *American Journal of Public Health, 105*(2), 408-413. doi: 10.2105/AJPH.2014.301935
28. Hurd, M.D., Martorell, P., Delavande, A., Mullen, K.J., Langa, K.M. (2013). Monetary costs of dementia in the United States. *New England Journal of Medicine, 368*(14), 1326-1334. doi: 10.1056/NEJMsa1204629
29. Cooke, D.D., McNally, L., Mulligan, K.T., Harrison, M.J., & Newman, S.P. (2001). Psychosocial interventions for caregivers of people with dementia: A systematic review. *Aging and Mental Health, 5*(2), 120-135. doi: 10.1080/713650019
30. Dam, A. E., de Vugt, M. E., Klinkenberg, I. P., Verhey, F. R., & van Boxtel, M. P. (2016). A systematic review of social support interventions for caregivers of people with dementia: Are they doing what they promise?. *Maturitas, 85*,117-130. doi:10.1016/j.maturitas.2015.12.008
31. Elvish, R., Lever, S.J., Johnstone, J., Cawley, R., & Keady, J. (2013). Psychological interventions for carers of people with dementia: A systematic review of quantitative and qualitative evidence. *Counselling and Psychotherapy Research, 13*(2), 106-125. doi:10.1080/14733145.2012.739632
32. Huis, J.G., Verkaik, R., Mistiaen, P., vn Meijels, B., & Francke, A.L. (2014). The effectiveness of interventions in supporting self-management of informal caregivers of people with dementia: A systematic review. *BMC Geriatrics, 15*(147), 1-10. doi: 10.1186/s12877-015-0145-6
33. Li, R., Cooper, C., Austin, A., & Livingston, G. (2013). Do changes in coping style explain the effectiveness of interventions for psychological morbidity in family carers of people with dementia? A systematic review and metaanalysis. *International Psychogeriatrics, 25*(2), 204-214 doi: 10.1017/S1041610212001755
34. McKechnie, V., Barker, C., & Stott, J. (2014). Effectiveness of computer-mediated interventions for informal carers of people with dementia systematic review. *International Psychogeriatrics, 26*(10), 1619-1637. doi: 10.1017/S1041610214001045
35. Petriwskyj, A., Parker, D., O'Dwyer, S., Moyle, W., & Nucifora, N. (2015). Interventions to build resilience in family carers of people living with dementia: a systematic review protocol.

JBI Database Of Systematic Reviews & Implementation Reports, 13(7), 44-61. doi: 10.11124/jbisrir-2015-1994

36. Scott, J. L., Dawkins, S., Quinn, M. G., Sanderson, K., Elliott, K. J., Stirling, C., & ... Robinson, A. (2016). Caring for the carer: A systematic review of pure technology-based cognitive behavioral therapy interventions for dementia carers. *Aging & Mental Health, 20*(8), 793-803. doi: 10.1080/13607863.2015.1040724
37. Tang, W.K., & Chan, C.Y.J. (2016). Effects of psychosocial interventions on self-efficacy of dementia caregivers: A literature review. *International Journal of Geriatric Psychiatry, 31*, 475-493. doi: 10.1002/gps.4352
38. Gitlin, L.N., Belle, S.H., Burgio, L.D., Czaja, S.J., Mahoney, D., Gallagher-Thompson, D., Burns, R., Hauck, W.W., Zhang, S., Schulz, R., & Ory, M.G. (2003). Effect of multicomponent interventions on caregiver burden and depression: The REACH multisite initiative at 6-month follow-up. *Psychology and Aging, 18*(3), 361-374. doi: 10.1037/0882-7974.18.3.361
39. Shulz, R., Burgio, L., Burns, R., Eisdorfer, C., Gallagher-Thompson, D., Gitlin, L.N., & Mahoney, D.F. (2003). Resources for Enhancing Alzheimer's Caregiver Health (REACH): Overview, site-specific outcomes, and future directions. *The Gerontologist, 43*(4), 514-520. doi: 10.1093/geront/43.4.514
40. Wisniewski, S.R., Belle, S.H., Coon, D.W., Marcus, S.M., Ory, M.G., Burgio, L.D., Burns, R., & Schulz, R. (2003). The Resources for Enhancing Alzheimer's Caregiver Health (REACH): Project design and baseline characteristics. *Psychology and Aging, 18*(3), 375-384. doi: 10.1037/0882-7974.18.3.375
41. Burgio, L., Stevens, A., Delois, G., Roth, D. L., & Haley, W. E. (2003). Impact of two psychosocial interventions on white and African American family caregivers of individuals with dementia. *Gerontologist, 43*(4), 568-579. doi: 10.1093/geront/43-4/568
42. Burns, R., Nichols, L.O., Martindale-Adams, J., Graney, M.J., & Lummus, A. (2003). Primary care interventions for dementia caregivers: 2-year outcomes from the REACH study. *The Gerontologist,43*(4), 547-555. doi: 10.1093/geront/43.4.547
43. Chee, Y.K., Gitlin, L.N., Dennis, M.P., & Hauck, W.W. (2007). Predictors of adherence to a skill building intervention in dementia caregivers. *The Journals of Gerontology: Medical Sciences,62*(6), 673-678.
44. Eisdorfer, C., Czaja, S. J., Loewenstein, D. A., Rubert, M. P., Arguelles, S., Mitrani, V. B. et al. (2003). Effect of family therapy and technology-based intervention on caregiver depression. *Gerontologist, 43*(4), 521-531. doi: 10.1093/geront/43.4.521
45. Gitlin, L.N., Hauck, W.W., Dennis, M.P., & Winter, L. (2005). Maintenance of effects of the home environmental skill-building program for family caregivers and individuals with Alzheimer's disease and related disorders. *The Journals of Gerontology: Medical Sciences, 60*(3), 368-374.doi: 10.1093/gerona/60.3.368
46. Gitlin, L. N., Winter, L., Corcoran, M., Dennis, M. P., Schinfeld, S., & Hauck, W. W. (2003). Effects of the home environmental skill-building program on the caregiver-care recipient dyad: 6-month outcomes from the Philadelphia REACH initiative. *Gerontologist, 43*(4), 532-546. doi: 10.1093/geront/43.4.532
47. Mahoney, D. F., Tarlow, B. J., & Jones, R. N. (2003). Effects on an automated telephone support system on caregiver burden and anxiety: findings from the REACH for TLC intervention study. *Gerontologist, 43*(4), 556-567. doi: 10.1093/geront/43.4.556
48. Sarabia-Cobo, C.M. (2015). Heart coherence: A new tool in the management of stress on professionals and family caregivers of patients with dementia. *Applied Psycholophysiology and Biofeedback*, *40*, 75-83. doi:10.1007/s10484-015-9276-y.

49. Vernooji-Dassen, M., Draskovic, I., McCleery, J., & Downs, M. (2011). Cognitive reframing for carers of people with dementia. *Cochrane Database Systematic Reviews, 11*, Art. No.: CD005318. doi: 10.1002/14651858.CD005318.pub2
50. Werner, P., Goldstein, D., Karpas, D.S., Chan, L., & Lai, C. (2014). Help-seeking for dementia: A systematic review of the literature. *Alzheimer Disease and Associated Disorders, 28*(4), 299-310. doi: 10.1097/WAD.0000000000000065
51. Nolan, M., Ingram, P., & Watson, R. (2002). Working with family carers of people with dementia: Negotiated coping as an essential outcome. *Dementia, 1*(1), 75-93. doi: 10.1177/147130120200100104
52. Bekhet, A.K., Zauszniewski, J.A., & Matel-Anderson, D. (2012). Resourcefulness Training Intervention: Assessing critical parameters from relocated older adults' perspectives. *Issues in Mental Health Nursing, 33(7),* 430-435. doi: 10.3109/01612840.2012.664802
53. Gonzalez, E. W., Polansky, M., Lippa, C. F., Gitlin, L. N., & Zauszniewski, J. A. (2014). Enhancing resourcefulness to improve outcomes in family caregivers and persons with Alzheimer's Disease: A pilot randomized trial. *International Journal of Alzheimer's Disease*, 2014, Article ID 323478, 10 pages. doi: 10.1155/2014/323478.
54. Musil C.M., Zauszniewski, J.A., Burant, C.J., Toly, V.B., & Warner, C. (2016). Evaluating an Online Resourcefulness Training Intervention Pilot Test Using Six Critical Parameters. *International Journal of Aging and Human Development, 82*(1), 117-135. doi: 10.1177/0091415015623552
55. Toly, V., Musil, C.M., & Zauszniewski, J.A. (2014). Resourcefulness Training Intervention: A Promising Approach to Improve Mental Health of Mothers with Technology-Dependent Children. *Applied Nursing Research, 27*(1), 87-90. doi: 10.1016/j.apnr.2013.11.003
56. Zauszniewski, J.A., Bekhet, A.K., Lai, C.Y., McDonald, P., & Musil, C.M., (2007). Effects of teaching resourcefulness and acceptance on affect, behavior, and cognition of chronically ill elders. *Issues in Mental Health Nursing, 28*(6), 575-592. doi: 10.1080/01612840701354547
57. Zauszniewski, J.A., Lekhak, N., Au, T.Y., Yolpant, W., & Morris, D.L., (2015). Need for resourcefulness training for women caregivers of elders with dementia. *Issues in Mental Health Nursing, 36*(12), 1007-
58. Zauszniewski, J.A., Morris, D.L., Lekhak, N., Au, T.Y., & Napoleon, B. (2016). Resourcefulness Training for women dementia caregivers: Acceptability and feasibility of two practice methods. *Issues in Mental Health Nursing,* 37(4), 249-256. doi: 10.3109/01612840.2015.1119222
59. Aneshensel, C.S., Pearlin, L.I., Mullan, J.T., Zarit, S.H., & Whitlatch, C.J. (1995*). Profiles in Caregiving: The Unexpected Career*. San Diego: Academic Press.
60. Lindgren, C.L. (1993). The caregiving career. *Journal of Nursing Scholarship, 25*(3), 214-219. doi: 10.1111/j.1547-5069.1993.tb00784.x
61. Pearlin, L. I., & Aneshensel, C. S. (1994). Caregiving: The unexpected career. *Social Justice Research, 7*(4), 373-390. doi: 10.1007/BF02334863
62. Pearlin, L. I., & Aneshensel, C. S. (1996). Profiles in caregiving: The unexpected career. *Social Justice Research, 33*(10), 5733-5748
63. Gaugler, J.E., Wackerbarth, S.B., Mendiondo, M., Schmitt, F.A., & Smith, C.D. (2003). Characteristics of dementia caregiving onset. *American Journal of Alzheimer's Disease and Other Dementias*,18(2), 97-104. doi: 10.1177/153331750301800208
64. Robinson, C.A., Bottorff, J.L., Pesut, B., Oliffe, J.L., & Tomlinson, J. (2014). The male face of caregiving: A scoping review of men caring for a person with dementia. *American Journal of Men's Health, 8*(5) 409–426. doi: 10.1177/1557988313519671
65. Ducharme, F., Levesque, L., Lachance, L., Kergoat, M.J., Coulombe, R. (2011). Challenges associated with transition to caregiver role following diagnostic disclosure of Alzheimer

disease: A descriptive study. *International Journal of Nursing Studies 48*(2011), 1109–1119. doi: 10.1016/j.ijnurstu.2011.02.011
66. Adams, K.B. (2006). The transition to caregiving, *Journal of Gerontological Social Work, 47*,(3-4), 3-29. doi: 10.1300/J083v47n03_02
67. Kramer, B.J., & Lambert, J.D. (1999). Caregiving as a life course transition among older husbands: A prospective study. *The Gerontologist*, *39*, 658-667. doi: 10.1093/geront/39.6.658
68. Seltzer, M.M., & Li, L.W. (2000). The dynamics of caregiving: Transitions during a three-year prospective study. *The Gerontologist*, *40*, 165-178. doi: 10.1093/geront/40.2.165
69. Wuest, J., Ericson, P.K.,&Stern, P.N. (1994). Becoming strangers: The changing family caregiving relationship in Alzheimer's disease. *Journal of Advances in Nursing*, *20* (3), 437-443. doi: 10.1111/j.1365-2648.1994.tb02378.x
70. Skaff, M.M., Pearlin, L.I., & Mullan, J.T. (1996). Transitions in the caregiving career: Effects on sense of mastery. *Psychology and Aging, 2*(2), 247-257. doi:10.1037/0882-7974.11.2.247
71. Gaugler, J.E., Anderson, K.A., Leach, C.R., Smith, C.D., Schmitt, F.A., & Mendiondo, M. (2004). The emotional ramifications of unmet need in dementia caregiving. *American Journal of Alzheimer's Disease and Other Dementias, 19*(6), 369-380. doi: 10.1177/153331750401900605
72. Rose, K.M., & Lopez, R.P. (2012). Transitions in dementia care. *Online Journal of Issues in Nursing, 17*(2), 1-17. doi:10.1177/1054773811431883
73. Niksad-Terhune, K.A., Newcomer, R., & Gaugler, J.E. (2010). Do trajectories of at home dementia caregiving account for burden after nursing home placement? A growth curve analysis. *Social Work Health Care, 49*(8): 734–752. doi: 10.1080/00981381003635296
74. Orzeck, P., & Silverman, M. (2008). Recognizing post-caregiving as part of the caregiving career: Implications for practice. *Journal of Social Work Practice 22(*2), 211–220. doi: 10.1080/02650530802099866
75. Pearlin, L. I. (1992). The careers of caregivers. *The Gerontologist, 32*(5), 647.
76. Bertrand, R.M., Fredman, L., & Saczynski, J. (2006). Are all caregivers created equal? Stress in caregivers to adults with and without dementia. *Journal of Aging and Health, 18*(4), 534-551. doi: 10.1177/0898264306289620
77. Eifert, E.K., Adams, R., Dudley, W., & Perko, M. (2015). Family caregiver identity: A literature review. *American Journal of Health Education, 46*, 357-367. doi: 10.1080/ 19325037.2015.1099482
78. Lindauer, A., & Harvath, T.A. (2015). The meanings caregivers ascribe to dementia-related changes in care recipients: A meta-ethnography. Research in Gerontological Nursing, 18(1), 39-48. doi: 10.3928/19404921-20141121-01
79. Schultz, R., & Martire, L.M. (2004). Family caregiver of persons with dementia: Prevalence, health effects, and support strategies. *American Journal of Geriatric Psychiatry, 12*(3), 240-249. doi:10.1097/00019442-200405000-00002
80. Brodaty, H. (2007). Meaning and measurement of caregiver outcomes. *International Psychogeriatrics, 19*, 363–381. doi: 10.1017/S1041610207005182
81. Brodaty, H., Draper, B., & Low, L. (2003). Nursing home staff attitudes towards residents with dementia: strain and satisfaction with work. *Journal of Advanced Nursing, 44*(6), 583–590.
82. Butcher, H. K., Holkup, P. A., Park, M., & Maas, M. (2001). Thematic analysis of the experience of making a decision to place a family member with Alzheimer's disease in a special care unit. *Research in Nursing and Health, 24*(6), 470–480 doi: 10.1002/nur.10005

83. Coehlo, D.P., Hooker, K., & Bowman, S. (2007). Institutional placement of persons with dementia: What predicts occurrence and timing? *Journal of Family Nursing, 13*(2), 253-277. doi: 10.1177/1074840707300947
84. Cohen, L.W., Zimmerman, S., Reed, D., Sloane, P.D., Beeber, A.S., Washington, T., Cagle, J.G., & Gwyther, L.P. (2014). Dementia in relation to family caregiver involvement and burden in long-term care. *Journal of Applied Gerontology, 33*(5), 522-540. Doi:10.1177/0733464813505701
85. Gaugler, J. E., Kane, R. L., Kane, R.A., & Newcomer, R. (2005). Unmet care needs and key outcomes in dementia. *Journal of American Geriatric Society, 53*(12), 2098-2105. doi: 10.1111/j.1532-5415.2005.00495.x
86. Gaugler, J.E., Zarit, S.H., & Pearlin, L.I. (2003). The onset of dementia caregiving and its longitudinal implications. *Psychology and Aging,18*(2):171–80. DOI: 10.1037/0882-7974.18.2.171
87. Rowles, G.D., & High, D.M. (1996). Individualizing care: Family roles in nursing home decision-making. *Journal of Gerontological Nursing, 22*(3), 20–25. doi: 10.3928/0098-9134-19960301-08
88. Zarit, S.H., Whitlatch, C.J. (1992). Institutional placement: Phase of transition. *Gerontologist, 32,* 665–672. doi: 10.1093/geront/32.5.665
89. Bramble, M., Moyle, W., & Shum, D., (2011). A quasi-experimental design trial exploring the effect of a partnership intervention on family and staff well-being in long-term dementia care. *Aging & Mental Health, 15*(8), 995–1007. doi: 10.1080/13607863.2011.583625
90. Ryan, A.A., & Scullion, H.F. (2000). Family and staff perceptions of the role of families in nursing homes. *Advanced Nursing, 32*(3), 626-634. doi: 10.1046/j.1365-2648.2000.01521.x
91. Gaugler, J.E., & Kane, R.L. (2007). Families and assisted living. *Gerontologist, 47*(Suppl 1),83–99. doi: 10.1093/geront/47.Supplement_1.83
92. Majerovitz, S.D. (2007). Predictors of burden and depression among nursing home family caregivers. Aging and Mental Health, 11(3), 323-329. doi: 10.1080/13607860600963380
93. Whitlatch, C.J., Schur, D., Noelker, L.S., Ejaz, F.K., & Looman, W.J. (2001). The stress process of family caregiving in institutional settings. *Gerontologist, 41*(4), 462–473. doi: 10.1093/geront/41.4.462
94. Williams, S.W., Williams, C.S., Zimmerman, S., Munn, J., Dobbs, D., & Sloane, P.D. (2008). Emotional and physical health of informal caregivers of residents at the end of life: The role of social support. *Journals of Gerontology – Psychological and Social Sciences, 63B*(3), S171–S183.
95. Schultz, R., Boerner, K., Shear, K., Zhang, S., & Gitlin, L.N. (2006). Predictors of complicated grief among dementia caregivers: A prospective study of bereavement. *American Journal of Geriatric Psychiatry, 14*(8), 650-658. doi: 10.1097/01.JGP.0000203178.44894.db
96. Meleis, A. I., Sawyer, L. M., Im, E. O., Messias, D. K. H., & Schumacher, K. L. (2000). Experiencing transitions: An emerging middle-range theory. *Advances in Nursing Science, 23*(1), 12-28. doi: 10.1097/00012272-200009000-00006
97. Rosswurm, M.A., Larrabee, J.H., & Zhang, J. (2002). Training family caregivers of dependent elderly adults through on-site and telecommunication programs. *Journal of Gerontological Nursing, 28*, 27-38. doi: 10.3928/0098-9134-20020701-07
98. Zauszniewski, J.A., & DiMarco, M. (2004). [A pilot test of the use of journals to reinforce the teaching of resourcefulness in older adults with chronic conditions]. Unpublished raw data.
99. Zauszniewski, J. A., & Rosswurm, M.A. (2003). Resourceful caregiving. *Journal of Gerontological Nursing 29*(1): 5; author reply 6.
100. Zauszniewski, J.A., & Suresky, M.J. (2012). [A pilot study to test resourcefulness training in family members of adults who use substances]. Unpublished raw data.

101. Zauszniewski, J.A., & Suresky, M.J. (2005). [A pilot study of two methods for reinforcing resourcefulness skills in mothers of children with challenging behaviors]. Unpublished raw data.
102. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2012). Resourcefulness training for grandmothers raising grandchildren: Is there a need? *Issues in Mental Health Nursing, 33*(10), 680-686. doi: 10.3109/01612840.2012.684424
103. Vaschillo, E., Lehrer, P., Rishe, N., & Konstantinov, M. (2002). Heart rate variability biofeedback as a method for assessing baroreflex function: a preliminary study of resonance in the cardiovascular system. *Applied Psychophysiology and Biofeedback, 27*(1), 1–27. doi:10.1023/A:1014587304314.
104. Lehrer, P.M., Vaschillo, E.G., Vaschillo, B., Lu, S., Eckberg, D.L., & Edelberg, R. (2003). Heart rate variability biofeedback increases baroreflex gain and peak expiratory flow. *Psychosomatic Medicine, 65*, 796–805. doi:10.1097/01.PSY.0000089200.81962.19
105. Prinsloo, G.E., Rauch, H.G.L., Lambert, M.I., Muench, F., Noakes, T.D., & Derman, W.E. (2011). The effect of short duration heart rate variability (HRV) biofeedback on cognitive performance during laboratory induced cognitive stress. *Applied Cognitive Psychology, 25*(5), 792-801. doi: 10.1002/acp.1750
106. Siepmann, M., Aykac, V., Unterdorfer, J., Petrowski, K., & Mueck-Weymann, M. (2008). A pilot study on the effects of heart rate variability biofeedback in patients with depression and in healthy subjects. *Applied Psychophysiology and Biofeedback, 33,* 195-201. doi: 10.1177/0193945906298607
107. Helicor (2007). *Stresseraser® Owner's Manual*. New York, NY: Helicor Inc.
108. McCraty, R., & Tomasino, D. (2004, November). Heart rhythm coherence feedback: A new tool for stress reduction, rehabilitation, and performance enhancement. Paper presented at the First Baltic Forum on Neuronal Regulation and Biofeedback, Riga, Latvia. Retrieved from website: http://www.heartmath.com/health/professional/hrv_biofeedback.pdf.
109. Ebben, M.R., Kurbatov, V., & Pollak, C.P. (2009). Moderating laboratory adaptation with the use of a heart-rate variability biofeedback Device (StressEraser®). *Applied Psychophysiology and Biofeedback*, *34*, 245–249. doi: 10.1007/s10484-009-9086-1.
110. Heilman, K.J., Handelman, M., Lewis, G., & Porges, S.W. (2008). Accuracy of the StressEraser® in the detection of cardiac rhythms. *Applied Psychophysiology and Biofeedback, 33*(2), 83–89. doi: 10.1007/s10484-008-9054-1.
111. Muench, F. (2008). The portable StressEraser heart rate variability biofeedback device: Background and research. *Biofeedback*, 36(1), 35-39.
112. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2013). Biofeedback in grandmothers raising grandchildren: Effects on stress, emotions, and cognitions. *Biofeedback, 41*(3), 144-149. doi:10.5298/1081-5937-41.3.06.
113. Zauszniewski, J.A., Musil, C.M., & Au, T.Y. (2013). Heart rate variability biofeedback versus resourcefulness training interventions. *Applied Psychophysiology and Biofeedback, 38*(213-238).
114. Zauszniewski, J.A., & Musil, C.M. (2014). Interventions for grandmothers: Comparative effectiveness of resourcefulness training, HRV biofeedback, and journaling. *Biofeedback, 42*(3), 121-129. doi:10.5298/1081-5937-42.3.03
115. Bilchick, K.C., & Berger, R.D. (2006). Heart rate variability. *Journal of Cardiovascular Electrophysiology, 17*, 691–694. doi:10.1111/j.1540-8167.2006.00501.x.
116. Nunan, D., Sandercock, G.R.H., & Brodie, D.A. (2010). A quantitative systematic review of normal values for short term heart rate variability in healthy adults. *Pacing Clinical Electrophysiology, 33*, 1407-1417. doi:10.1111/j.1540-8159.2010.02841.x.

117. Zauszniewski, J.A. (1997). Evaluation of a measure of learned resourcefulness in older adults. *Journal of Nursing Measurement, 5*, 71-86.
118. Zauszniewski, J.A. (2012). Intervention development: Assessing critical parameters from the intervention recipient's perspective. *Applied Nursing Research, 25*(1), 31-39. doi: 10.1016/j.apnr.2010.06.002
119. Zauszniewski, J.A., Lekhak, N., & Musil, C.M. (2018). Caregiver reactions to dementia symptoms: Effects on coping repertoire and mental health. Issues in Mental Health, Epub ahead of print. doi:10.1080/01612840.1424974.
120. Zauszniewski, J.A., Musil, C.M., Herbell, K., & Givens, S. (2017). Heart Rate Variability Biofeedback in Grandmothers: Evaluation of Intervention Parameters. *Issues in Mental Health Nursing, 38*(6), 493-499.
121. Zauszniewski, J.A., Musil, C.M., & Variath, M. (2015). Effects of biofeedback on stress, emotions, and cognitions in grandmothers: Correlations between subjective and objective measures. *Biofeedback, 43*(4), 193-199.
122. Ohio Alzheimer's Association. (2016). Fact Sheet on Alzheimer's Disease. Available at http://www.alz.org/documents_custom/facts_2016/statesheet_ohio.pdf?type=interior_map&facts=undefined&facts=facts. Last accessed May 18, 2019.
123 U.S. Census Bureau: State and County QuickFacts. (2015). *American Community Survey.* Available at http://www.census.gov/acs/www/data/data-tables-and-tools/index.php. Last accessed May 18, 2019.
124. Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation, regression analyses, and repeated measures analysis of variance. *Behavior Research Methods*, *41*, 1149-1160. doi:10.3758/BRM.41.4.1149
125. Zauszniewski, J.A., Lai, C.Y., & Tithiphontumrong, S. (2006). Development and testing of the Resourcefulness Scale for older adults. *Journal of Nursing Measurement, 14*(1), 55-66. doi: http://dx.doi.org/10.1891/jnum.14.1.57
126. Great Lakes Neurotechnologies, Inc. (2014). *User Manual for BioRadio for Heart Rate Variability Measurement*. Valley View, OH, USA: Author
127. Vivonoetics, Inc. (2016). *VivoSense: User Manual – Heart Rate Variability (HRV) Professional Edition Version 3.0.* San Diego, CA, USA: Author.
128. CleveMed Research, 2007. Bioradio 150 and Bioradio Capture Lite™ (Version 1.02.07.0601) [Apparatus and Software]. CleveMed Medical Devices Inc, Cleveland, Ohio, USA: Author.
129. Nachar, N., Lavoie, M.E., Marchand, A., O'Connor, K.P., & Guay, S. (2014). The effect of talking about psychological trauma with a significant other on heart rate reactivity in individuals with posttraumatic stress disorder. *Psychiatry Research, 219*, 171-176. doi:10.1016/jpsyres.2014.05.006.
130. Billman, G.E. (2011). Heart rate variability: A historical perspective. *Frontiers in Physiology, 2*, 1-12. doi: 10.3389/fphys.2011.00086. PMCID:PMC3225923
131. Pumprla, J., Howorka, K., Groves, D., Chester, M., & Nolan, J. (2002) Functional assessment of heart rate variability: Physiological basis & practical applications. *International Journal of Cardiology, 84*, 1-14. doi:10.1016/S0167-5273(02)00057-8.
132. Acharya, U.R., Joseph, K.P., Kannathal, N., Lim, C.M., & Surit, J.S. (2006). Heart rate variability: A review. *Medical & Biological Engineering & Computing, 44*, 1031-51. doi:10.1007/s11517-006-0119-0.
133. Thayer, J.F., Ahs, F., Fredrikson, M., Sollers, J.J. , & Wager, T.D. (2012). A meta-analysis of heart rate variability and neuroimaging studies: Implications for heart rate variability as a

marker of stress and health. *Neuroscience and Biobehavioral Reviews, 36*, 747-756. doi: 10.1016/j.neubiorev.2011.11.009.

134. Cohen, H., & Benjamin, J. (2006). Power spectrum analysis and cardiovascular morbidity in anxiety disorders, *Autonomic Neuroscience*, 128(1–2), 1-8. doi:10/1016/j.autneu.2005.06.007.
135. Friedman, B.H. (2007). An autonomic flexibility-neurovisceral integration model of anxiety and cardiac vagal tone. *Biological Psychology 74*, 185–199. doi:10.1016/j.biopsycho.2005.08.009.
136. MindHow (2018). *Twelve Best Brain Stimulating Activities for Seniors.* Retrieved from website: http://www.mindhow.com/best-brain-stimulating-activities-for-seniors/. Last accessed May 18, 2019.
137. Zauszniewski, J.A., & Bekhet, A. (2011). Measuring use of resourcefulness skills: Psychometric testing of a new scale. *ISRN Nursing 1-7*. doi:10.5402/2011/787363. doi:10.5402/2011/787363.
138. Trogdon, J.G., Murphy, L.D., Khajvou, O.A., Li, R., Maylahn, C.M., Tangka, F.K., Nurmagambetov, T.A., Ekwueme, D.U., Nwaise, I., Chapman, D.P., & Orenstein, D. (2015). Costs of chronic disease at the state level: The chronic disease cost calculator. *Preventing Chronic Disease, 12*, 1-9. http://dx.doi.org/10.5888/pcd12.150131
139. Ward, B.W., Schiller, J.S., & Goodman, R.A. (2014). Multiple chronic conditions among U.S. adults: A 2012 update. *Preventing Chronic Disease, 11*, 1-4. http://dx.doi.org/10.5888/pcd11.130389
140. Holmes, T.H., & Rahe, R.H. (1967). The Social Readjustment Rating Scale. *Journal of Psychosomatic Research, 11*, 213-218. http://dx.doi.org/10.1016/0022-3999(67)90010-4
141. Hobson, C.J., Kamen, J., Szostek, J., Nethercut, C.M., Tiedmann, J.W., & Wojnarowicz, S. (1998). Stressful life events: A revision and update of the Social Readjustment Rating Scale. *International Journal of Stress Management, 5*(1), 1-23. doi: 10.1023/A:1022978019315
142. Barreto, M.L., & Frazier, L.D. (2012). Coping with life events through possible selves. *Journal of Applied Social Psychology, 42*(7), 1785-1810. doi: 10.1111/j.1559-1816.2012.00918.x
143. Gerst, M.S., Grant, I., Yager, J., & Sweetwood H. (1978). The reliability of the Social Readjustment Rating Scale: Moderate and long term stability. *Journal of Psychosomatic Research, 22*, 519-623. doi:10.1016/0022-3999(78)90008-9
144. Scully, J.A., Tosi, H., & Banning, K. (2000). Life events checklists: Revisiting the Social Readjustment Rating Scale after 30 years. *Educational and Psychological Measurement, 60*(6), 864-876. doi: 10.1177/00131640021970952
145. Ball, J.M. (1977). Stressful life events and coping methods in mental illness and wellness behaviors. *Nursing Research, 26*(2), 136-141.
146. Roca, M., Gili, M., Garcia-Campayo, J., Armengol, S., Bauza, N., & Garcia-Toro, M. (2013). Stressful life events severity in patients with first and recurrent depressive episodes. *Social Psychiatry and Psychiatric Epidemiology, 48*(12), 1963-1969. doi: 10.1007/s00127-013-0691-1
147. Teri, L., Trax, P., Logsdon, R., Uomoto, J., Zarit, S., & Vitaliano, P.P. (1992). Assessment of behavioral problems in dementia: The revised memory and behavior problems checklist. *Psychology and Aging, 7*(4), 622-631. doi:10.1037/0882-7974.7.4.622
148. Gitlin, L.N., Roth, D.L., Burgio, L.D., Lowenstein, D.A, Winter, L., Nichols, L., Arguelles, S., Corcoron, M., Burns, R., & Martindale, J. (2005). Caregiver appraisals of functional dependence in individuals with dementia and associated caregiver upset. Journal of Aging and Health, 17(2), 148-171. doi: 10.1177/0898264304274184

149. Cohen, S., Kamarck, T., & Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24*, 385-396.
150. Cohen, S., & Williamson, G. (1988). Perceived stress in a probability sample of the United States. In S. Spacapan & S. Oskamp (Eds.), *The Social Psychology of Health.* Newbury Park, CA: Sage.
151. Schwartz, K.A., & Dunphy, G. (2003). An examination of perceived stress in family caregivers of older adults with heart failure. *Experimental Aging Research, 29*(2), 221–235. doi: 10.1080/03610730303717
152. Wright, R.J., Finn, P., Contreras, J.P., Cohen, S., Wright, R.O., Staudenmayer, J., Wand, M., Perkins, D., Weiss, S.T., & Gold, D.R. (2004). Chronic caregiver stress and IgE expression, allergen-induced proliferation, and cytokine profiles in a birth cohort predisposed to atopy. The *Journal of Allergy and Clinical Immunology, 113*(6), 1051-1057. doi: 10.1016/j.jaci.2004.03.032
153. Zauszniewski, J.A. (1995). Development and testing of a measure of depressive cognitions in older adults. *Journal of Nursing Measurement, 3*(1), 31-41.
154. Zauszniewski, J.A. (1997). The Depressive Cognition Scale: Further psychometric evaluation. *Journal of Nursing Measurement, 5*(2), 191-200.
155. Zauszniewski, J.A., & Bekhet, A.K. (2012). Developing a screening measure for early detection of depressive symptoms: The Depressive Cognition Scale. *Western Journal of Nursing Research, 34*(2), 228-242. doi:10.1177/0193945910396731. doi: 10.1177/0193945910396731
156. Zauszniewski, J.A., Picot, S.J.F., Debanne, S., Wykle, M., & Roberts, B.L. (2002). Psychometric characteristics of the Depressive Cognition Scale in African American women. *Journal of Nursing Measurement, 10*(2), 83-95. doi:10.1891/jnum.10.2.83.52557
157. Zauszniewski, J.A., Chung, C., Krafcik, K., & Sousa, V. (2001). Psychometric testing of the Depressive Cognition Scale in women with type 2 diabetes. *Journal of Nursing Measurement, 9*(1), 61-72.
158. Zauszniewski, J.A., & Suresky, M.J. (2010). Psychometric testing of the Depressive Cognition Scale in women family members of seriously mentally ill adults. *Issues in Mental Health Nursing, 31*(7), 483-490. doi:10.3109/01612841003602687. doi: 10.3109/01612841003602687
159. Sousa, V.D., Zauszniewski, J.A., & Jaber, A.F. (2010). Confirmatory factor analysis of the Depressive Cognition Scale among adults from the United States general population. *Archives of Psychiatric Nursing, 24*(6), 397-407. doi:10.1016/j.apnu.2010.03.004. doi: 10.1016/j.apnu.2010.03.004
160. Zauszniewski, J.A., Krafcik, K., Preechawong, S., Chung, C. Airey, T., Wilke, P. et al. (2004). Focused reflection: Reminiscence for elders using specific themes and visual images. *Journal of the Applied Gerontology, 23*(4), 429-442 doi:10.1891/jnum.14.1.57
161. Zauszniewski, J.A. (2007). [Analysis of 6-week test-retest reliability of the Negative Emotions Checklist, Depressive Cognition Scale, and Resourcefulness Scale in older adult members of the control condition of the PIs former clinical trial]. Unpublished raw data.
162. Burton, L. C., Newsom, J. T., Schulz, R., Hirsch, C. H., & German, P. S. (1997). Preventive health behaviors among spousal caregivers. *Preventive Medicine, 26*, 162–169. doi: 0.1006/ pmed.1996.0129
163. Perlick, D.A., Miklowitz, D.J., Lopez, N., Chou, J., Kalvin, C., Adzhiashvili, V., & Aronson, A. (2010). Family-focused treatment for caregivers of patients with bipolar disorder. *Bipolar Disorder*, 12, 627–637. doi: 10.1111/j.1399·5618.2010.00852.x. PMCID:PMC2947337
164. Gonzalez, J.M., Holman, C.S., Marcus, T., & Perlick, D.A. (2011). Health risk behaviors in caregiving for bipolar disorder. *International Society for Bipolar Disorders Global*, 12(4), 1, 12-13.

165. Hays, R.D., Bjorner, J.B., Revicki, D.A.., Spitzer, K.L., & Cella, D. (2009). Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Quality of Life Research, 18,* 873-880. doi:10.1007/s11136-009-9496-9. doi: 10.1007%2Fs11136-009-9496-9.
166. Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J.G. (2009). Research electronic data capture (REDCap): A meta-driven methodology and workflow process for providing translational research informatics support. Journal of Biomedical Informatics, 42(2), 377-381. doi:10.1016/j.bi.2008.08.010.
167. Roberts, B.L., Madigan, E., Anthony, M., & Chen, Y. (1997). Data management: Cleaning and checking. *Nursing Research, 46*(6), 350-352. http://dx.doi.org/10.1371%2Fjournal.pmed.0020267
168. Youngblut, J.M., Loveland-Cherry, C.J., & Horan, M. (1990). Data management issues in longitudinal research. *Nursing Research, 39*(3), 188-189.
169. Field, A.P. (2013). Discovering statistics using IBM SPSS statistics: And sex and drugs and rock and roll (4th Edition). London: Sage Publications.
170. Sainani, K.L. (2013). Avoiding careless errors: Know your data. Physical Medicine and Rehabilitation, 5, 228-229. doi: 10.1016/j.pmrj.2013.01.012.
171. Hair, J.F., Anderson, R.E., Tatham, R.L., & Black, W.C. (1998). Multivariate Data Analysis with Readings (4th Edition) Upper Saddle River, NJ: Prentice Hall.
172. Field, A.P. (2013). Discovering statistics using IBM SPSS statistics: And sex and drugs and rock and roll (4th Edition). London: Sage Publications.

Please reference the Investigator Manual for local institutional requirements.