Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving

NCT05292248

Study Protocol and Statistical Plan

Updated 8/24/2023

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

INSTRUCTIONS:

- *Use this template to prepare your IRB Protocol.*
- *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.*
- *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:
Include the full protocol title.

Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving

PRINCIPAL INVESTIGATOR:
Name: Kylie Meyer

DATE: 8/24/2023

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: Click here to enter text.

Has this study been disapproved by or withdrawn from any other IRB?
☒ Yes ☐ No
If so, please explain: This study began at UT Heath San Antonio, the investigator's previous institution. It is being transferred to Case Western Reserve University.

Does this study involve cancer research or cancer-related issues?
☐ Yes ☒ No
If yes, indicate the PRMC number: Click here to enter text.

Is this a student led study?
☐ Yes ☒ No
If yes, is the student: ☐ Undergrad ☐ Graduate Student ☐Other Click here to enter text.
If yes, is the project: ☐ Capstone ☐ Master's thesis ☐ PhD dissertation
☐Other Click here to enter text.

Is this work part of a larger collaborative research project where more than one institution is participating in the research? (*In collaborative projects, data/specimens/results are often shared between researchers at the participating institutions, and they will publish together.)*

☐ **No** ☒ **Yes**

If yes, please explain.

We are collaborating with the University of Southern California, where the intervention is being administered as a part of a social service program for caregivers (USC Family Caregiver Support Program). USC may participate in publication of findings, but is not involved in data collection procedures.

1.0 Funding

If this study is grant funded, is the money coming directly to CWRU from the study sponsor?

☐ Yes ☒ No ☐ N/A, not grant funded

2.0 Objectives

Directions: Describe the purpose, specific aims or objectives. Be sure to also include the hypothesis being tested. The *overall objective* of this project is to test the preliminary efficacy that participation in the CONFIDENCE intervention improves caregiver learned resourcefulness and self-efficacy, as well as distal outcomes including monthly out-of-pocket costs of caregiving and financial anxiety/worry. The *central hypothesis* is that caregivers who participate in the CONFIDENCE intervention will report higher levels of learned resourcefulness and self-efficacy following participation in the CONFIDENCE intervention in follow up surveys as compared to levels found at baseline.

A secondary objective of this research (sub-study, modification submitted 8/2023) is to characterize out-of-pocket spending by Latino family caregivers to persons living with dementia on care-related expenses.

3.0 Background

Directions: Describe the relevant prior experience and gaps in current knowledge describing how this study will add to existing knowledge. Include any relevant preliminary data. **Family caregivers to people living with dementia encounter high out-of-pocket caregiving costs that exert long-term material and psychological consequences.** A 2016 report by AARP found that caregivers to people living with dementia spend an average of $10,697 per year on out-of-pocket costs related to caregiving (Rainville, Skufca, & Mehegan, 2016). This is nearly double the out-of-pocket costs experienced by caregivers to individuals who are not living with dementia. Another study found similar levels of out-of-pocket spending by caregivers ($6,194), and also calculated the costs of caregivers' forgone wages each year ($13,188) (Hurd, Martorell, Delavande, Mullen, & Langa, 2013). The effects of disrupted employment related to caregiving accumulate over time, making it still more difficult to pay for caregiving expenses out-of-pocket. A study by the Metlife Mature Market Institute found that women ages 50 and older who provide care to a parent lose an average of $324,000 in wages, pension earnings, and Security in their lifetime (2011). Caregiving can prompt a "vicious cycle of poverty"—women who live below the poverty threshold are more likely to become caregivers, and caregivers are more likely to become impoverished (Lee, Tang, Kim, & Albert, 2015). Further, it is increasingly recognized that financial hardship is

comprised not only of material strain, but also psychological strain (Tucker-Seeley & Thorpe, 2019). Perceived financial strain from caregiving is associated with role overload and burden (Andren & Elmstahl, 2007; Lai, 2012; Liu, Dokos, Fauth, Lee, & Zarit, 2019). For low-income caregivers, out-of-pocket spending on caregiving, combined with periodic or permanent lost wages, can compound financial strain over a lifetime. **Hispanic caregivers have higher out-of-pocket caregiving costs relative to their income than non- Hispanic caregivers.** Whereas out-of-pocket expenditures on caregiving—regardless of the care recipient's cognitive status— consumes 20% of caregivers' annual income and costs $6,954 per year on average, these costs comprise nearly half (47%) the income of Hispanic women who provide care and total $10,704 annually (Rainville et al., 2016). Relative to the average caregiver (i.e., caregiver of any race/ethnicity), Hispanic women who provide care spend $1,849 more on household items (e.g. home modifications for safety, home repairs) and $1,849 on education, legal, and travel expenses (e.g., retrofitting vehicles to accommodate wheelchairs) per year. Higher caregiving costs are in-part due to a preference among Hispanic families for older family members to receive care in the community, rather than in skilled nursing facilities, and often within a shared household (Angel & Berlinger, 2018; Scharlach et al., 2006). A growing number of Hispanic families are likely to care for someone living with dementia. Hispanics are 50% more likely to experience dementia and current projections suggest there will be an 832% grown in the number of Hispanics who live with dementia by 2060 (Alzheimer's Association, 2019; Wu, Vega, Resendez, & Jin, 2016). Given the anticipated growth in the number of Hispanic families living with dementia, financial disadvantages that are already experienced by U.S. Hispanics, and the high costs from caregiving, dementia has been described as "the perfect storm" for financial hardship among U.S. Hispanics (Wu et al., 2016). **Caregivers struggle to access community-based resources and benefits that could be used to displace out-of-pocket expenditures related to caregiving.** Community-based (social support) systems that serve family caregivers and older adults are de- centralized and difficult to navigate (Funk, Dansereau, & Novek, 2019; Meyer, 2017). Although most service-seeking caregivers need at least some assistance with legal and financial matters (e.g., seeking health and non-health benefits), Hispanic caregivers are less likely to use social supports for themselves than non-Hispanic caregivers (Martindale-Adams, Nichols, Zuber, Burns, & Graney, 2016; Shrestha et al., 2011). Qualitative research reveals that Hispanic caregivers know that community-based services exist to support caregivers, but perceive accessing these resources overly burdensome relative to their perceived value (Scharlach et al., 2006). Hispanic caregivers also identify a need for more culturally- relevant services, especially those based on Mexican cultural norms. As such, compared to non- Hispanics, Hispanic caregivers may face more barriers to accessing services and supports like those provided through the National Family Caregiver Support Program that could be used to off-set some of the out-of-pocket costs of caregiving (Lepore, Splaine, Bangerter, & Dawson, 2020). **There is an unmet need for programs to alleviate financial hardship among family caregivers.** On April 15th, 2020 the National Academies of Sciences, Engineering and Medicine held a workshop on intervention programs to better support family caregivers. Implementation science expert Melissa Simon, MD, PhD recommended that the caregiving field develop interventions to address financial hardship using approaches from other fields (2020). In line with this recommendation, the **Confidently Navigating Financial Decisions and Enhancing Financial Wellbeing in Dementia Caregiving (CONFIDENCE)** program draws on successful intervention approaches identified within nursing and gerontological research to lower out-of-pocket caregiving costs and prevent financial hardship among low-income family caregivers. **Given prior research we propose to evaluate an educational program to encourage reduced out-of-pocket spending on caregiving that is developed to be culturally relevant and tailored to the needs of Latino Caregivers. This program will be delivered as a regular service program at the University of Southern California Family Caregiver Support Program. This project is supported by an AARP Foundation grant. Case Western will lead the evaluation of the program to test its preliminary efficacy and feasibility.**

Background for sub-study (8/2023 modification). In addition to attempting to intervene to reduce out-of-pocket care costs, the authors further wish to deepen current understanding as to what these costs are. In an article published in *The Gerontologist*, the PI collaborated with researchers from the University of Southern California to understand how Latino caregivers manage high out-of-pocket care costs (Mage at al., 2023). We learned about how caregivers described how purchasing everyday items, such as hygiene products accumulated over time. Caregivers also found themselves compromising their own financial wellbeing to cover their family members' costs, such as paying more for high quality items as a show of love for their family member. Prior survey research by AARP demonstrates variation in how much caregivers pay on caregiving that varied by race and ethnicity (Skufca et al., 2021). For example, Hispanic caregivers $225 more annually on household expenses relative to non-Hispanic white caregivers. This research suggests that it is highly likely that sociocultural factors affect purchase decisions, needs, and, ultimately, out-of-pocket costs of caregiving. Still, there is more to be learned about spending patterns among Latino family caregivers related to caregiving. Doing so could partially uncover reasons for financial strain in this population (e.g., paying for household items to avoid residential care), as well as inform culturally relevant measurement and intervention approaches. **The purpose of the proposed sub-study study is, thus, to characterize the out-of-pocket costs of family caregivers among Latino family members to persons living with dementia.**

Please add relevant references at the end of the protocol, not at the end of this section.

4.0 Inclusion and Exclusion Criteria

Directions: Describe how individuals will be screened for eligibility.

Participants will be asked to either complete an online self-administered survey to determine their eligibility, or to complete eligibility questions by telephone. If participants complete the online form, they will receive a telephone follow up to complete any missing questions, check for fraud (e.g., repeat questions to ensure consistent responses), and complete the verbal consent process.

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.	Age range: from 50 to no upper limit (sponsor criteria)
2.	Physician diagnosis of Alzheimer's Disease or related dementia by a physician at least 6 months ago Able to attend 5, 1.5 to 2 hours group-based lessons over 5 weeks
3.	Latino or Hispanic ethnicity
4.	Able to attend 5, 1.5 to 2 hours group-based lessons over 5 weeks

	Exclusion
1.	Unreliable access to email, a computer, and internet access
2.	Does not speak and read English
3.	Previously attended CONFIDENCE program

5.0 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.

Example language that can be used: We will enroll 25 subjects at CWRU and plan to enroll 150 subjects study wide. We will enroll N=60 participants to complete surveys before and after participation in CONFIDENCE, as well as N=15 participants to complete qualitative interviews. Participants in the CONFIDENCE program may be asked to complete qualitative interviews even if they did not complete the survey study, so long as they meet eligibility criteria. In addition to new enrollment of participants at CWRU, the PI will also be bringing data from 4 participants and 22 ineligible individuals over to CWRU. These individuals will be reconsented on the approved CWRU consent document as described in section 10.0 "Consent Process". .

6.0 Special/Vulnerable Populations

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 (e.g. Foster Children)
- ☐ **Pregnant Women** (only if targeted)
- ☐ **Neonates**
- ☐ **Neonates of Uncertain Viability**
- ☐ **Employees**
- ☐ **Prisoners**
- ☐ **Illiterate Individuals**
- ☐ **Non-English Speaking**
- ☐ **Students**
- ☒ **None**

1. If the research involves students or employees, describe how you will recruit so that:
   a) Employers or educators do not know if someone participated (until after grades have been assigned in the case of educators)
   b) Employers or educators do not *directly* recruit their own students or employees, and anything else to prevent feelings of coercion to those subordinate to their employer or educator.
   Click here to enter text.

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. Click here to enter text.

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. Non-English speaking adults are currently excluded, pending translation of program materials, anticipated in October 2022. Persons who are illiterate are excluded due to inability to engage with program materials, such as a written workbook and written materials presented during synchronous program sessions.

7.0 International information

☒ This is **not** an international study – *please leave rest of this section blank.*

☐ We will be conducting this research at the following international sites:
Click here to enter text.

☐ We are recruiting participants outside of the US from the following locations:
Click here to enter text.

☐ We are sending data outside of the US to the following locations:
Click here to enter text.

☐ We are receiving data from outside of the US from the following locations:
Click here to enter text.

8.0 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.)

   ☒ I attest that advertisements will only be placed **with permission**

   ☒ Social media

   - Indicate the platform(s): Facebook

   ☒ I attest that recruitment information will only be posted **with permission**

   ☒ Other. *Please specify:* The research assistant or PI will contact participants who enroll in the Eventbrite page to register for the program with the USC Family Caregiver Support Program. Participants are asked about their interest in participating in a research study when they sign up to attend CONFIDENCE. Those who indicate an interest in the study will receive a follow up phone call and/or email from the study team to tell them more about the study and check eligibility if interested. Participants who began participation at UT Health San Antonio will also be contacted to ask about continuing their participation in the study at Case Western. We will reconsent these participants prior to their continuing to engage in study activities. *ADDITIONAL METHODS OF RECRUITMENT SUBMITTED 10/2022*: To hasten the pace of recruitment, the study team is also requesting to submit an article to *La Presna*, a Spanish/English newspaper in the northern Ohio and southeast Michigan regions that describes the program and study. We also prepared talking points that USC FCSC family care navigators can share about the program and the study if they wish to. Lastly, the PI, with permission of the USC FCSC will also send an individual email and/or phone call to likely eligible participants (50+, Latino). The USC FCSC will send a password-protected file with caregivers' name, email, and phone number to the PI, who will contact caregivers directly to learn if they may be interested in participating in the program and/or the study. ADDINTIONAL METHODS OF RECRUITMENT SUBMITTED 11/2022: We will also work with Banner Health Institute's Alzheimer's Prevention Registry to identify potential participants. Individuals identifying as a caregiver sign up to receive email blasts from Banner Health and may review information about studies they may be interested in a website. Persons who are interested then indicate their interest, and provide the study team their name, email, and phone number to reach them. This information is made available in a portal where the study team will whether they contacted the participant.

2. Describe when, where, how and by whom potential research participants will be recruited. Individuals involved in recruitment should be identified by role and not by name (e.g. study coordinator, co-investigator, research assistant).
   See above. Participants will also be able to contact the study team directly, such as by calling or emailing the research assistant after seeing a study flyer or social media post. If this occurs, the study team member will not only complete study eligibility procedures,

but register participants in the Eventbrite system to reserve a CONFIDENCE spot for them. For those caregivers who receive a letter or phone call from the PI or who sign up on the Banner Health Institute site, the PI will contact the participant by telephone and/or email up to 3 times to share more information about the study and/or enroll the participant.

3. 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?
   USC will complete 12 cohorts of the CONFIDENCE intervention from September 2022 to June 2023, where cohorts will be held monthly except for 3 months where USC will run 2 cohorts simultaneously. We expect to enroll N=5 caregivers per cohort, or about 1/3 of caregivers who sign up to attend the program, to reach our recruitment goal N=60 caregivers.

9.0 Setting

Directions: Describe the sites and locations where your research team will conduct the research.

All research will be conducted at Case Western Reserve University where the study team has lab space to collect data by telephone, REDCap, and Zoom in a private space.

10.0 Consent Process

Indicate whether you will be obtaining consent:

☒ Yes ☐ No

If yes, answer the following questions:

1. Describe who will consent the subjects and where the consent process will take place: Consent processes will be completed by the PI and research assistant over the phone in a private space.

2. The time that will be devoted to the consent discussion: We anticipate that the consent process will take no more than 10 minutes to complete

3. Any waiting period available between informing the prospective subject and obtaining the consent: There is no waiting period between informing the participant of their eligibility and the consenting process.

4. Steps that will be taken to ensure the research participants' understanding: Participants will be asked whether they have any questions about what is involved in the study. We will also send a copy of the study information reviewed by phone by email to participant.

5. Any process to ensure ongoing consent: We will assume ongoing consent if the participant chooses to complete surveys. At the top of each survey, participants will be reminded that participation is voluntary. Participants whose data is being transferred from UT Health San Antonio will be reconsented using the approved

Case Western document to ensure they remain aware of changes in the study location and how this affects study risks and benefits.

6. Steps that will be taken to minimize the possibility of coercion or undue influence to the subjects: While consenting participants, we will remind them that participation is voluntary, and that they are welcome to participate in CONFIDENCE regardless of their choice to participate in the research 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, or written consent will not be documented)

☒ Yes ☐ No

If yes, explain how the research involves no more than minimal risk. Likely risks involved in this research include psychological burden, such as due to the added time to participate in the program and stress in response to discussion about financial wellbeing topics. Other possible but unlikely risks include break of confidentiality. We minimize this risk by collecting as few identifiers as possible and using protocols to limit the likelihood of a breach, such as collecting data using the secure REDCap portal and separating the collection of identifiers in the eligibility survey with study data

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.

1. Give the rationale for the request of a waiver of signed consent. Rational for requesting an alteration of consent to exclude the signature component is due to feasibility concerns. Participants will be recruited nationally, and will only interact with the researchers by phone, email, or Zoom.

2. Please describe how you will be documenting that a participant has consented. Verbal consent from the participant will be marked in the participant's REDCap eligibility survey

3. Indicate if the subjects will be provided with written information about the study, and provide justification if you will not be providing a written explanation of the research. Participants will be emailed written information described during the telephone consent process

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

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

If you are requesting an alteration of consent, or a waiver of consent, please answer the following:

1. Give the rationale for the request of a waiver or alteration of the consent process. Click here to enter text.

2. Explain why the waiver or alteration of consent will not adversely affect the rights and welfare of the participants. Click here to enter text.

3. Explain why the research could not practicably be carried out without the waiver or alteration of consent. Click here to enter text.

4. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

**Be sure to upload a consent script or information sheet with your study protocol*

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: This is a pilot study to test the preliminary efficacy of CONFIDENCE, as well as the feasibility of delivery and acceptability. The study team is currently translating intervention materials into Spanish, and plan to submit an amendment to enroll Spanish speakers by October 2022

☐ I will be targeting non-English speaking adults

1. Describe the process to ensure that the oral and written information provided to those research participants will be in that language during initial consent as well as throughout the study. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

☐ 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. Click here to enter text.

2. List the language(s) other than English that will be targeted: Click here to enter text.

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: Click here to enter text.

☐ There is NOT an anticipated direct benefit to the subject. Explain: Click here to enter text.

1. Describe the process to determine whether an individual is capable of consent. Click here to enter text.

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). Click here to enter text.

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. Click here to enter text.
   ☐ N/A

4. Describe the process for assent of the research participants. Indicate:
   - Which subjects that are unable to consent will be required to give assent? If not all, explain why. Click here to enter text.

   - Describe whether assent of the research participants will be documented and the process to document assent. Click here to enter text.

   ☐ 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:
   a. Indicate how you will be documenting the permission:

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

b. 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. Click here to enter text.

If a waiver of parental permission is being requested:

a. 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. Click here to enter text.

b. Describe how the research could not practicably be carried out without the waiver of parental permission. Click here to enter text.

c. Indicate if the subjects will be provided with additional information about the study after participation. Click here to enter text.

2. 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. Click here to enter text.

   If assent will be obtained from none of the children, indicate the rationale. Click here to enter text.

   When assent of children is obtained, describe how it will be documented. Click here to enter text.

3. For children who are pregnant, describe how assent and permission are obtained. Click here to enter text.
   ☐ N/A

11.0 Sharing of Results with Research Participants

Individual test or research results will be shared with research participants (this is not referring to sharing through standard academic channels, e.g., publishing, presentation, etc.):

☒ Yes ☐ No

If yes, describe how the results will be shared. Participants will be invited to review their daily spending surveys to help monitor spending on out-of-pocket costs of caregiving. Recording daily spending is a part of the intervention itself, regardless of study participation. (Non-study participants receive a worksheet to monitor spending.) By sharing daily spending survey,

participants can use information they already shared in surveys for this activity. Spending surveys will be emailed to participants using PDF downloads from REDCap of their daily surveys. We will also share aggregate findings with participants at the end of this study

Individual test results will be shared with others (e.g., lab results given to a primary care physician):

☐ Yes ☒ No

If yes, describe with whom and how the results will be shared. Click here to enter text.

12.0 Study Design/Procedures

Directions:

1) Describe the overall study design (e.g.: single visit, single-blind, double-blind, non-randomized, randomized, blood draw, investigational drug, device etc.).
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.
5) Include a description of any device being used to collect data (e.g., eye tracker, step counter). If the device itself is being studied, include additional information in Section 29.

Overall. This study uses a single arm pre- and post-test design with three data collection points (baseline and two follow up) to evaluate the preliminary efficacy, acceptability, and feasibility of delivering an intervention to lower the out-of-pocket spending on caregiving for Latino caregivers to persons living with dementia. Data will be primarily collected using survey research methods, including "daily diary" methods (N=60). We also plan to collect qualitative semi-structured interviews with participants (N=15), as well as fidelity information about the delivery of the intervention. Participation will take approximately 10 weeks from baseline to completion. **Enrollment.** Participants will enroll in the CONFIDENCE program using an Eventbrite link that will be shared as a part of regular services offered by the University of Southern California Family Caregiver Support Center. When a participant registers for the CONFIDENCE program, they will be asked if they are interested in participating in the research study. Participation in the research study is optional; caregivers do not need to enroll in the study to attend the program. If a caregiver indicated interest in this research, the research assistant or PI will reach out by phone and email (up to 4 contacts) to tell the caregiver more about the study and determine eligibility. The participant may choose to complete the eligibility form online or by phone. Even if the participant completes the eligibility form online, they will receive a follow up call to ensure they understand the study activities and verbally consent to participate. **Intervention.** Enrolled participants will be asked to attend once weekly group-based sessions for the CONFIDENCE program by Zoom for 5 weeks. Each session will last approximately 1.5 hours each and will require participants to complete up to 1 hour of take-home activities per week. Each session will focus on a different topic (e.g., seeking community resources to displace out-of-pocket spending) meant to help caregivers displace out-of-pocket care costs and reduce financial strain. There are five sessions (5 weeks) total to the CONFIDENCE program. Sessions will be led by 2 facilitators with experience in caregiver intervention or else trained by someone with this experience. Up to 15 caregivers may register for each sessions, though we anticipate no more than 10 caregivers to attend each session due to absences. **Survey Administration.** Enrolled study participants will receive a baseline survey up to 2 weeks prior to the first intervention session and will be asked to complete the survey within 7 days. The baseline survey will ask about spending on out-of-pocket care costs, financial strain, resourcefulness, self-efficacy, as well as information about the caregiving context and use of supports. It is anticipated this survey will take no more than 20 to 30 minutes to complete. Once the baseline survey is complete, participants will begin to receive daily surveys by phone or email, depending on their preferences. Daily surveys will ask about spending on caregiving that day and are to be completed from 7 pm to 11 pm each consecutive day for 5 days. These surveys will serve two purposes: 1) daily spending habits reported in surveys will be summarized and shared with back with participants as a part of the intervention and 2) data from surveys will be used to determine average daily spending, our primary outcome of interest. Daily spending surveys will take no more than 10 minutes to complete. We anticipate some participants will not meet the requested

timeline for the Baseline survey. If so, we will continue to allow them to participate in the study without complete they daily spending surveys, so long as the Baseline survey is completed prior to the first intervention session. This will enable us to still collect data about outcomes besides out-of-pocket costs of care. A follow up survey will be sent immediately after the participant completes the intervention (within 48 hours) and will also ask about participant satisfaction with CONFIDENCE. A second follow up survey will be sent 8 weeks after the intervention is complete. After the participant completes the second follow up survey, they will receive a second set of daily spending diaries administered in the same way as the first set of diaries. Follow up surveys are expected to take approximately 20 to 30 minutes to complete. Participants will receive up to 5 reminders to complete the baseline and follow up surveys, include 3 emails prompts and up to 2 phone calls. Participants will receive a text message reminder, if they choose, reminding them to complete daily spending surveys each night. **Qualitative interviews.** Up to 15 participants will also be asked to participate in a one-on-one qualitative, in-depth, semi-structured interview as well about their experiences with the program, which is expected to take approximately 45 minutes depending on how much the participant would like to share. Selection of interview participants will be based on purposeful sampling, with the goal of recruiting a qualitative sample that includes a range of care experiences according to participant gender, age, employment status, and kin relationship to the person to whom care is provided. Interviews will be completed over Zoom and recorded and later transcribed. Participants will be invited to complete this interview after completing the CONFIDENCE program. If the participant agrees to participate, they will receive a study information sheet by email prior to attending the interview and will review this information sheet before completing the interview. **Payment for surveys and qualitative interviews.** Amazon gift cards will be sent to participants by email for each study activity (surveys and interviews). We will pay participants for the baseline and first set of diaries surveys within a week of when the first set of diaries are due. A second payment will be administered within a week of the first follow up survey being completed. The remaining payments will be sent the week of the second set of diary surveys are due/completed. Payment for interviews will be sent within 1 week of completing the interview. Participants may earn up to $125 for participating, or $150 if they complete the qualitative interview. Participants may earn $25 for each study activity. **Fidelity.** Fidelity will be monitored by an observer (PI or research assistant) and the CONFIDENCE program facilitators. We will monitor one randomly selected CONFIDENCE lesson for each cohort. The selected lesson will be based on Stata's random number generator. The facilitators will know in advance of each lesson if selected for monitoring so they may record lesson. The facilitator will be sent a survey within 24 hours of completing selected sessions to self-monitor delivery. Fidelity surveys will be sent by the PI using REDCap. Session recordings will be stored in the USC CONFIDENCE Office 365 Shared folder and deleted once fidelity forms are completed. The research assistant or PI will watch the recording and complete the fidelity survey within 2 weeks of the lesson taking place. **Attendance**. The USC facilitator will monitor attendance at CONFIDENCE sessions and will store this information in a shared Office 365 folder. The study team will extract information about attendance from study participants from Excel files where attendance is marked and enter it into REDCap for study participants. **Comparison of registrant demographics and study participants.** In addition to data collected from surveys, we will compare the demographic characteristics of individuals who register for CONCIDENCE to participate in the educational program alone with those of study participants. This information can help to inform future recruitment methods by helping the study team understand differences in the characteristics of those who choose to participate in research and those who do not. As a part of their funder's requirements, USC must report on demographic characteristics of program participants to the sponsor. They currently collect this information using the Eventbrite registration page. The Case Western investigators will already have access to the Eventbrite form information to identify participants who are interested in participating in the research study. To compare the characteristics of study participants to non-study participants, we will download Excel files directly from Eventbrite onto an encrypted university Box folder, and add an indicator variable to indicate whether or not individual registrants were in the research study. Once this occurs, all identifiable information will be removed from Excel files and the file will be saved so we can conduct analyses and compare characteristics of study and non-study participants. **Participant safety and monitoring adverse events.** ***Adverse events.*** Adverse events and protocol deviations will be recorded on an adverse event form by the study team member (PI or RA) who first observes this event. Adverse events pertaining to participant safety and confidentiality will be promptly reported by the PI by phone. Where the RA or PI suspects risk of harm to self or others, this will be reported to USC PI Donna Benton, PhD, who is a licensed clinical psychologist with extensive experience working with caregivers. Dr. Benton is the director of the USC Family Caregiver Support Program where CONFIDENCE is being administered. She will reach out to the participant by phone to conduct further assessment and a safety plan. All protocol deviations and adverse events will be promptly reported to the Institutional Review Board by the PI. Serious adverse events will be reported within 24-hours. ***Data and Safety Monitoring.*** The PI will complete a Data Safety Monitoring Report every 6 months of the study. The Data Safety Monitoring Report will include the following core elements: a) Progress towards enrollment and participant retention; b) Participant characteristics for enrolled and retained participants (e.g., age, race, ethnicity, gender, aspects of the caregiving situation) according to intervention status; and c) Documentation of adverse events, serious adverse events, and unanticipated problems, as defined below, including resolution of these events and study protocol modifications. This report will not contain any participant identifiers. This report will be shared with the USC PI for review.

Sub-study (8/2023 Modification): To complete the sub-study objective, the research team will draw upon existing de-identified qualitative interview data from N=14 family caregivers collected by collaborators at USC. (An Exempt approval, information sheet, interview guide, and notice indicating no need for a DUA are attached.) We will conduct a content analysis of the types of expenditures covered by participants, wherein we will report the frequency with which each expense was described. This will be reported alongside baseline data that asks about out-of-pocket spending on caregiving collected in the parent study, including frequencies and estimated costs. These survey data were informed by responses collected during qualitative interviews, which helped the researchers to generate ideas about what to ask about in surveys. By reporting out on these data in tandem using a mixed methods approach, we can provide a holistic picture of what out-of-pocket spending on care looks like for Latino family caregivers.

13.0 Study Timeline (optional)

	Pre-Screening	Visit 1	Visit 2	Visit 3	Six week Follow up
Estimated time requirement of visit					
Data Collection					
Study Procedure 1					
Study Procedure 2					
Study Procedure 3					
Phone Call Questionnaire					

14.0 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.

This study has been registered on ClinicalTrials.gov. This entry was transferred to Case Western, NCT05292248

15.0 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: Click here to enter text.

2. 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).
   Baseline, Follow Up 1, and Follow Up 2 Survey; Daily spending surveys; Qualitative interviews; Intervention fidelity, including CONFIDENCE session recordings; Characteristics of study participants and non-study participants (Eventbrite registration)

16.0 Online Data Collection

☐ We will not collect data through an online platform.

1. List the online platform to be used. The preferred platforms are REDCap and Qualtrics, as these provide good data security and have options for collecting data without individually identifiable information.
   All survey data will be collected through REDCap. Qualitative interview data will be collected on an institutional Zoom account and recorded. Eventbrite data will also be downloaded on registrants, regardless of study participation

2. If your intent is to collect the data without identifiers linked to an individual (including IP addresses), describe how you will ensure that no identifiable information will be associated with the data.
   - ☐ Qualtrics: enable Anonymize Responses setting (removes IP addresses and location data)
   - ☐ REDCap: use of the Public Survey Link
   - ☐ REDCap: use of a Participant List without a Participant Identifier field
     (Note: this does maintain a connection between the data and the individual, but it is only accessible to REDCap support personnel and not the researchers. Data collected in this manner should not be referred to as anonymous, but rather as data that is deidentified to the researchers).
   - ☒ Other: Study data will be collected in two separate REDCap projects where participants will have separate IDs for eligibility and research data. These will be connected by a study key stored on an encrypted university Box folder.. The first REDCap project will be used to determine eligibility and will include participant identifiers required to administer payments and contact participants. The second REDCap project will exclude participant's names but will include email and cell

phone number to administer surveys and reminders. These data will be marked as "identifiers" in REDCap and will be excluded from data downloads when we go to analyze data.

17.0 Data Analysis Plan

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

Participant characteristics, including age, gender, race, ethnicity, educational attainment, income, employment status, kin relationship to recipient, length of time caregiving, hours of caregiving, and whether the care recipient and caregiver live together will be reported using frequencies, percentages, means, and standards of deviation. *Comparison of Study and non-study participants.* Demographic characteristics of study and non-study participants collected from Eventbrite will be compared using t-test and chi-squared bivariate analyses, as well as frequencies and percentages. **Outcome Measures** *Self-Efficacy (primary outcome).* Self-efficacy is measured using the Caregiver Self-Efficacy Scale. This 8-item scale combines domains of self-efficacy (e.g., managing behavioral symptoms, accessing respite, and controlling upsetting thoughts. It demonstrates high reliability (alpha=0.89) and good test-retest reliability (0.73). Participants rate the extent to which they are "Not confident at all" (1) to "Totally confident" (10). Scores range from 8 (lowest) to 80 (highest).[35] *Resourcefulness (primary outcome).* Resourcefulness is measured using the 19-item learned resourcefulness scale designed for family caregivers (alpha=0.81). This scale has two factors: one focused on help-seeking and another on self-help. Caregivers are asked the frequency at which they use different strategies to manage challenges, and may respond: . Items are added together to create a total score. Scores range from 0 to 24. Permission was received by the scale's author to use this tool on April 21, 2022. *Psychological Financial Strain (secondary outcome).* Our measure for psychological financial strain is derived from multiple scales, which were selected according to relevance to our caregiving population. Items 1 to 11 ask about financial anxiety and is based on the 10-item scale from Shapiro & Burchell (2012).[36] Item 1 is modified such that the question asks about feeling overwhelmed instead of bored. We also added an item based on another related to caregiving (i.e., "I find planning for my caregiving expenses to be unpleasant"). Items 12 to 14 are based on those used by Novilitis et al., (2003), and address additional components of financial anxiety than those items introduced by Shapiro (e.g., arguments with others; alpha=0.74).[37] Lastly, we included the 1-item question from Shim et al. (2010) that asks about financial worry ("I worry constantly about money"; CFA factor loading was 0.79 for this item).[38] *Monthly Spending Report (out-of-pocket costs of caregiving, secondary outcome).* Our measure for monthly out-of-pocket costs of caregiving is based on the tool used by the AARP Public Policy Institute in their 2016 report on the out-of-pocket costs of caregiving. We will calculate estimated daily costs using both period survey and daily survey. Period surveys (i.e., baseline and the second follow up surveys) ask about spending: in the last month (30 days) and in the last 12 months but not the last month. When a caregiver indicates paying for an item in the last month, they are asked to provide an estimated cost. (We do not ask about cost in the last year given the likelihood the participant will not be able to accurately recall this cost and may forget some expenses.) The costs for yearly/monthly item are those believed to occur irregularly, such as purchase of devices and rent payments. Daily costs are those anticipated to occur regularly, and are asked about on daily surveys, such as groceries and recreation items for the care recipient. To calculate monthly spending, we will multiply daily spending by 6 to approximate 30

days in a month and add all monthly expenses. While the measure is subject to recall bias and fluctuations in spending, it balances 1) the need to efficiently collect data and 2) reduces recall bias by relying on monthly recall alone. Analysis of Baseline and Follow Up Measures We will used two sets of paired t-tests to examine changes in scores between baseline and follow up surveys. If we discover a p-value of <0.05 after running tests, this will indicate there was a statistically significant difference between scores. We will compare scores from baseline until the first follow up survey and from baseline until the second follow up survey. In addition, we will examine mean scores at each time point, as well as the standard of deviation for all summed scores on each scaled. **Handling of Missing Data** ***Missing daily surveys.*** If participants miss a survey, we will adjust the monthly formula such that we will multiply according to the number of days for which surveys are completed to reach 30. For example, if a participant completed 4/5 surveys, we will multiply by 7.5 instead of 6. We will exclude participants who miss more than 2 daily surveys from analyses when examining monthly costs. ***Missing data on follow up surveys.*** Although data from all participants will be reported in sample descriptives, for all analyses using t-tests, we will use a complete case analysis such that participants with any missing data will be removed from the analytic sample. Although this approach risks missing data bias, multiple imputation and maximum likelihood estimation are not feasible to conduct with bivariate analyses. We will conduct bivariate analyses using a "dummy" variable to identify potential differences between those with complete and incomplete data and will also report the extent of missingness using frequencies and percentages. **Satisfaction Surveys** Satisfaction surveys, included in the first follow up survey sent to participants, will be used to examine participant satisfaction with the CONFIDENCE intervention. Participants will be asked about the program's relevance to their care situation, quality of information presented, satisfaction delivery, and enjoyment of the program overall. Each question is asked as a statement to which participants can indicate the extent to which they agree on a 5-point Likert scale. To analyze scale items, we will provide a percentage of each response (e.g., 80% of caregivers "Agreed" or "Strongly Agreed" with this statement). **Fidelity Reports** Fidelity reports will be evaluated using total scores averaged across all CONFIDENCE Lessons observed. We will be report these in aggregate and separated by facilitator and observer reports. We will divide reports by scores for adherence and quality. Scores will be reported using a percentage, as prior reports indicate 80% or more on fidelity scores indicates acceptable levels of fidelity. In addition—to examine variability in scores—we will also report this information using means and standards of deviation. **Qualitative Interviews** Qualitative interviews will be transcribed verbatim and identifying information removed. For interviews conducted in Spanish, interviews will be translated by a native speaker. To conduct our thematic analysis, at least two members of the research team will read at least 2 transcripts and will decide on a preliminary codebook.[39] The codebook will be applied to an interview and refined further prior to applying codes to the remaining interviews. At least two coders will analyze each transcript independently and will meet to compare codes and discuss differences in coding until agreements met. A second round of coding will be conducted to integrate new codes added during coding. **Statistical Power and Same Size** Our goal is to recruit at least N=60 of these caregivers into a research study to test preliminary efficacy. This *N* supports our ability to detect a small to moderate effect size in a two-tailed t-test at alpha=0.05 at 80% power.

Sub-study (8/2023 Modification): To analyze data in the sub-study, we will conduct a content analysis of the types of expenditures covered by participants, wherein we will report the frequency with which each expense was described. At least two coders will independently review codes in NVivo 12; when there are disagreements over coding, an agreement will be reached through discussion. Data on out-of-pocket spending will be analyzed using frequencies

and percentages to describe each type of cost, as well as means and standards of deviation to describe estimated expenditures for each cost. Survey data will be analyzed in Stata 17. (Note that data collection for surveys is ongoing, such that the total sample is not yet available.)

18.0 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.

   ☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

   ☐ Other- please explain: Click here to enter text.

   Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. All study identifiers will be removed from REDCap survey files and we will also delete the study key once findings are published. Session recordings will be deleted once fidelity monitoring is complete for that session.

   ☒ I attest that any recordings (audio or video) saved to a portable device will be deleted by formatting the device's storage memory.

How are you storing your electronic data?

☒ CWRU Redcap
☐ CWRU Secure Research Environment (SRE)
☒ CWRU Box
☐ OnCore
☐ CWRU Secure Network Drive
☐ Zoom Cloud
☒ Portable device (must be encrypted, not just password protected)
☒ Other - List storage method and provide justification: Data about participant attendance and session recordings used for fidelity monitoring will be temporarily stored in an Office 365 Folder shared by partners at USC, wherein folders must be shared by USC for others to access contents.

Please note: if you're storing or entering your electronic data in any system other than an approved system listed above, please contact the CWRU IRB (cwru-irb@case.edu).

2. ☐ I acknowledge that paper research data and documents will be stored in a double-locked secure environment in the following **location:** Click here to enter text.

   ☒ We will not have paper research documents.

3. Will data be shared?

   ☒ Yes

   - List the exact data elements that will be shared: De-identified survey data from the baseline, follow up, and diaries surveys will be shared, as well as de-identified qualitative interview transcripts with USC

- Describe how data will be sent: De-identified data will be shared by email

☐ No

☐ N/A

If sharing data, please complete a request to ensure the proper contracts/agreements are in place: https://case.edu/research/faculty-staff/technology-transfer/material-transfer-data-use-agreements

18.0 HIPAA Authorization

Does this study collect, access, use, or distribute any Protected Health Information (PHI)?
Protected Health Information (PHI) is (1) any individually identifiable health information transmitted or maintained in a medical record, paper or electronic, or (2) designated data set that was created, disclosed, or used in the course of providing a health care service such as diagnosis, payment or treatment.

☐ Yes ☒ No

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

- ☐ HIPAA authorization is in the consent form
- ☐ I am receiving a Limited Data Set under a Data Use Agreement (DUA)
- ☐ 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*

19.0 FERPA Authorization

Does this study collect, access, use, or distribute any personally identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education)? This includes, but is not limited to, classroom assignments and course evaluations.

☐ Yes ☒ No

If yes, how do you plan to get written authorization from the student (or parent if the student is a minor)?

- ☐ I will incorporate FERPA language* into the consent and obtain written and dated signature or authorized electronic signature using REDCap
- ☐ I will incorporate FERPA language* into a separate form and obtain written and dated signature or authorized electronic signature using REDCap

20.0 Risks to Research Participants

* FERPA language: 1. Specify the educational records that may be both accessed and used in the research. 2. State the purpose of the access and use of records. 3. Identify to whom the records disclosure may be made.

1. List the reasonably foreseeable risks such as breach of confidentiality, discomforts, hazards, or inconveniences to the research participants related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Include the physical psychological, social, legal, and economic risks.
   Breach of confidentiality. There is small risk that data confidentiality could be breached so that others outside the research team view private study information (e.g., participants' income), though the study team will follow all study protocols to prevent this from occurring. It is also possible that other caregivers could share information they learn about others during the CONFIDENCE program. We will ask all participants to keep information shared during the program private. *Psychological discomfort*. There is some risk of psychological discomfort, such as from discussing challenging with caregiving and the high costs of caregiving. The risk and impact of psychological discomfort will vary among participants. It is no more than what might be expected in caregiver education programs conducted outside of research.

2. If applicable, indicate which experimental procedures may have risks to the research participants that are currently unforeseeable. We cannot identify any unforeseeable risks to participation
   ☐ N/A
3. If applicable, describe the risks to others who are not research participants. Click here to enter text.
   ☒ N/A
4. Describe the availability of medical or psychological resources that research participants might need. As a part of the CONFIDENCE intervention, participants are provided with multiple resources to help with caregiving, including information about how to accesses counseling, support groups, and respite care for caregiver stress
   ☐ N/A

21.0 Provisions to Protect the Privacy Interests of Research Participants

Directions: Indicate the measures that will be taken to protect research participants' privacy interests. Select all that apply:

☐ In person interactions will be conducted in a private space where conversations would not be overheard by others -- this could be at a specific location determined by the research team or at a location that the participant chooses.

☒ For online/remote data collection, participants will be advised to choose a location that would be private.

☐ Researchers will only contact participants if permission has been given to do so.

☐ Other: Click here to enter text.

22.0 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. *Do not list compensation.* Participants may find information shared with them during the CONFIDENCE intervention useful for their caregiving situation

☐ There is **no** direct benefit to research participants.
If no direct benefit, state the potential benefit to society or others. *Do not list compensation.* Click here to enter text.

23.0 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.
Participants will be removed from the study if the study team believes the participant is fraudulent (e.g., inconsistencies in study information provided), submits surveys that are excessively incomplete (e.g., more than 50% of responses are missing), or is not longer eligible (e.g., care recipient passes away). Participants will be notified by email if they are removed from the study.
☐ N/A

24.0 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.
Participants may still participate in the CONFIDENCE program, regardless of study participation
☐ The alternative is for research subjects not to participate.

25.0 Costs to Research Participants

☐ There are **no** costs to research participants or their insurance companies (there are no clinical visits or billable procedures.) – *please leave rest of this section blank*

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. Participants, if they choose to receive text messages, will be responsible for costs based on applicable charges from their carrier

2. Explain who will be responsible for payment of provided services in the event of insurance denials. Not applicable

3. List what procedures, drugs, devices, supplies will be paid by the study sponsor or covered by other funding. List the other funding source. None

26.0 Research Participant Compensation

☐ There is no compensation or reimbursement 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.) Amazon gift cards will be sent to participants by email for each study activity (surveys and interviews). We will pay participants for the baseline and first set of diaries surveys within a week of when the first set of diaries are due. A second payment will be administered within a week of the first follow up survey being completed. The remaining payments will be sent the week of the second set of diary surveys are due/completed. Payment for interviews will be sent within 1 week of completing the interview. Participants may earn up to $125 for participating, or $150 if they complete the qualitative interview. Participants may earn $25 for each study activity.

☐ 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.) Click here to enter text.

27.0 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

28.0 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. All baseline and follow up surveys will be visually assessed for completeness and unusual responses (e.g., "straightline" responses) within 1 week of completion. In addition, the investigator team will complete a Data Safety Monitoring Report every 6 months of the study. The Data Safety Monitoring Report will include the following core elements: a) Progress towards enrollment and participant retention; 2) Participant characteristics for enrolled and retained participants (e.g., age, race, ethnicity, gender, aspects of the caregiving situation) according to intervention status; and 3) Documentation of adverse events, serious adverse events, and unanticipated problems, as defined below, including resolution of these events and study protocol modifications. Weekly team meetings will also provide a time and space to identify and discuss non-adherence to study protocols.

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. Click here to enter text.

29.0 Additional Information

If you have any additional information regarding your study not covered in the template, please include it here. This protocol was previously reviewed and approved as an expedited study by the University of Texas Health Science Center at San Antonio IRB.

The approach to submit the modification for 8/2023 was discussed with Erin Zaletel before submitting given the unique nature of this requested modification. All materials related to the qualitative data have been uploaded, including USC's IRB approval letter as well as a notice that a DUA is not required to transfer the qualitative de-identified data.

30.0 Devices

Does the study include the use of a device that is integral to the study question?

☐ **Yes –** *Answer the questions below.*
☒ **No –** *Leave the rest of this section blank.*

☐ There is an active IDE (Investigational Device Exemption) for the proposed study.
Attach an official letter of support or proof of approval which identifies the IDE holder and IDE number to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device has obtained a 501k clearance.
Attach 501k documentation to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device meets the criteria for an IDE Exemption.
Download the IDE Exemption Form from the SpartaIRB library (HRP-580) and attach to the SpartaIRB smartform.
List devices: Click here to enter text.

☐ The device (and its use) is a non-significant risk device for the proposed study design.
List devices here and provide the PI's rationale for the non-significant risk device determination. Click here to enter text.

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. Click here to enter text.

31.0 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.

Click here to enter text.

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.

32.0 MULTI-SITE RESEARCH (when 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: Click here to enter text.
2. PI of relying site: Click here to enter text.
3. Name of IRB contact: Click here to enter text.
4. Phone number of IRB contact: Click here to enter text.
5. Email address of IRB contact: Click here to enter text.

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.* Click here to enter text.
2. *Describe the methods that will be used to identify potential research participants.* Click here to enter text.
3. *Describe the materials that will be used to recruit research participants.* Click here to enter text.

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:* Click here to enter text.
2. *Interim results:* Click here to enter text.
3. *The closure of the study:* Click here to enter text.

33.0 References

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