Study Protocol

TITLE:	A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers (CUIDANDO JUNTOS) (CuidandoJuntos)
PROTOCOL NO.	24-0291-01
SPONSOR:	University of Rochester
INVESTIGATOR:	Julian Montoro-Rodriguez

NCT06394388

Date: 12 Dec 2023

Study protocols and Data Analysis Plan

Screening and Registration protocols

The registration website is hosted by UNCC. The registration website provides information for prospective participants including a brief description of the program, participation requirements, and a link to register to participate in the CUIDANDO JUNTOS research study. The registration link will connect potential participants to a Qualtrics survey including screening questions. The registration website will also contain a link to the Project Website.

We will be using screening procedures. An electronic questionnaire will be used for the screening questions. Participants must provide consent on the screening survey delivered via Qualtrics prior to accessing any of the screening questions. All potential participants must first complete a registration survey administered via a link to the Qualtrics survey on the UNCC website to indicate their interest in participating in the study. In the registration survey, participants will provide basic demographic information including names and contact information including (email addresses, phone numbers) and age and whether they provide care to a family member/friend with ADRD. Participants who meet the age and care for a family member/friend with ADRD will then be directed to a consent form that they must accept electronically, in order to answer the screening questions regarding level of stress. The screening and registration data will be stored on secure UNCC servers in a secure and Password protected Dropbox folder. Only the PI and project coordinator will have access to the identifiable screening and registration data. The security of these electronic data is enhanced by using the UNC encrypted protocol.

Consent Protocol

Eligible participants will receive an email instructing them to complete an electronic consent form accessed through the program website and administered via Qualtrics. All participants who qualify will be sent a link to a Qualtrics survey containing a full consent form minus the signature line as well as a pdf document of the informed consent form minus the signature line for their records. Participants will indicate their consent and receipt of this consent form by indicating their informed consent on the Qualtrics survey. Participants who do not consent to participate will not be contacted further by the research team and all identifying information will be deleted from the records. Once informed consent is obtained, participants will be contacted regarding completion of the first assessment survey. Additionally, participants will be provided with a brief reminder of what participation in this study will entail and their rights as study participants prior to completing the pre-and-post surveys. Participants will be required to indicate their consent to proceed on the Qualtrics survey before the Qualtrics survey will allow them to view or respond to the survey questions. Participants will also be instructed to contact members of the research team with any questions regarding participation in each session.

Assessment and Session Protocols:

Once informed consent is obtained, participants will be contacted regarding completion of the first assessment survey (pre-assessment). Once the consent form and first survey are completed each participant will be assigned to a group led by one of the trained facilitators. Once assigned to a group, participants will be emailed with their zoom invitation. Participants will provide their physical mailing address on the first Assessment (Time 1). The project coordinator at UNC Charlotte will

mail the materials (handouts and slides) to each participant. After completing the CUIDANDO JUNTOS program, participants will be emailed a link to a post assessment Qualtrics survey. Participants will also be mailed a hard copy of their program completion certificate. Participants will also be asked to answer semi structured interview questions after completing the CUIDANDO JUNTOS program.

Data Analysis Plan:

Basic descriptive statistics for all outcome measures assessed both pre- and post-intervention. Internal consistency estimates, minimum and maximum scores, means and standard deviations are computed for each variable. To test for meaningful change over time, the change in mean score from Time 1 to Time 2 for each outcome measure was evaluated. Formal paired samples t-tests were conducted to test for statistical significance. However, given the small sample size and limited power, we also interpret Cohen's *d* as a more meaningful indicator of the magnitude of the observed effects.

Application Type

Instructions

Before moving to the next page, carefully review the application type definitions listed below and then choose the application type that is appropriate for your research. This will populate the required protocol application pages for you to complete.

Application Type Definitions:

Initial Application: This application is for studies that will involve interaction, engagement, intervention, communication, etc. with human subjects. This may be direct or indirect (e.g, online surveys, use of survey panels, etc.) interactions.

Initial Application - Data Only: The application is for studies that will ONLY ever use data or biospecimens and NEVER have any direct interaction, engagement, intervention, communication, etc. with human subjects.

- Existing data refers to data you will receive or obtain from a source other than your study participant.
- Data obtained from secondary sources and not from the data collection procedures being proposed as part of this study.
- For example, if your study will involve existing data for secondary data analysis (e.g., student records, medical records, administrative data, etc.).
- Note, if you are conducting collaborative research and will be conducting data analysis for the larger collaboration, the IRB Reliance Agreement application type may be appropriate.
- Studies that will involve both the use of existing data and will involve additional procedures such as surveys, interviews, etc. do not use this application. Use the Initial Application type instead.

IRB Reliance Agreement: This application is only for use when UNC Charlotte will rely on an external IRB for the review and

Application Type Selection

* **Application Type:**

- (●) Initial Application
- ( ) Initial Application - Data Only
- ( ) IRB Reliance Agreement

General Information

* Protocol #:	* Submission #:	Submission Type:
IRB-24-0291	IRB-24-0291-01	Initial Application

Instructions

- When responding to question #2 below, state the goals of the proposed study as related to the research question(s).
- Provide a clear and succinct summary description of the background information that led to the plan for this project.

Title and Objective

*** 1. Project Title:**

A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers

*** 2. Objective/Aim: Using lay language, provide:**

- Background information and context
- Rationale for why this study is needed
- The study purpose, specific aims, or objectives that will be met by this specific project
- Explanation of research questions and hypotheses being tested

You will be asked to describe the specific procedures in a later section of the application.

Background and Context information: There are several evidence-based interventions for distressed dementia caregivers that focus on skill building to increase resilience. However, few psychoeducational programs target Latino caregivers, and there are no evidence-based interventions promoting “social connectedness and support” in a culturally congruent way for Latinos. The Caregiver Thrive, Learn & Connect (TLC) is a telehealth caregiver educational program that builds upon evidence-based strategies from the "Coping with Caregiving" program (tested in REACH II) to improve caregivers’ psychosocial outcomes. Caregiver TLC incorporates a goal-oriented approach focused on learning effective strategies to seeking support and connecting with caregivers and community resources. Dementia caregivers attend sessions in small groups through Zoom, making the program accessible for caregivers with limited information, time, transportation, and language proficiency. The program website allows caregivers to access information, resources (videos), attend informational activities (webinars) and participate in a virtual community where caregivers learn and connect with others.

Rationale: Several factors including distrust of the health system, language, and differences in cultural values contribute to the underrepresentation of Latinos in intervention research. There is urgency for culturally adapted programs addressing their needs. Our cultural adaptation follows the Barrera’s Cultural Adaptation Behavioral Health Stage Model (2013).

Study Specific Aims: Specific Aim 1. To create a Community Advisory Board to engage Latino caregivers and community leaders to work with us to co-develop the program. Specific Aim 2. To test an early-stage adapted Spanish language of the program. Specific Aim 3. To examine the mechanism of social connectedness as a means to improve clinical outcomes (depression, stress, burden).

Research Questions and Hypotheses: This is a mixed model exploratory study to gather information from Latino bicultural and bilingual caregivers about their caregiving experience, the validity of the Spanish translation and acculturation of Cuidando Juntos program. We will gather qualitative data from Community Advisory Board members on the content and feasibility of the program. We also will collect basic quantitative data from a small pilot demonstration program using pre and post assessment of Latino caregiver participants. Our research questions will address the the level of acculturation and feasibility of the Spanish program Cuidando Juntos, and will provide an initial test for the efficacy of the small pilot study. Therefore, there are no specific quantitative hypothesis due to the descriptive and exploratory nature of the study.

Funding Source

*** 3. Is this activity funded, associated with a proposal/funding request, or will use University funds (e.g., startup, departmental, or discretionary funds)?**

☑ Yes ☐ No

3.1 If your funding source is in Niner Research, locate your grant record using the add button in the table below.

Proposal Name	Sponsor Name	Proposal Number

3.2 Use the table below to list all funding sources and requests that are currently NOT in Niner Research.

Funding Type	Sponsor (FRG, start-up funds, etc.)	Proposal Number (if available)	Department Name	

Please upload the following documents (if available) on the "Study Attachments" page: Grant proposal, Scope of Work, Contract, and/or Agreement.

PI Status

* **What is the primary status of the Principle Investigator (PI)?**

- (●) Faculty
- ( ) Staff
- ( ) Student

Updated By: **Tyler Steven Forgette @ 12-Dec-2023 12:17:33 PM**

INSTRUCTIONS

- To add personnel: click the “Add” button in the top right corner of the Personnel table.
- Use the pop-up box to search by Last Name and First Name of the person you want to add.
- Choose the person from the list and click the "Select" button in the top right corner of the search box.
- Use the "Role" dropdown list to select the role for each person added.
- Important: You need to select a role for all Personnel using the Role dropdown box. For the Primary Investigator you select the "Primary Investigator" checkbox AND choose Primary Investigator in the "Role" dropdown.
- Repeat this process for all research team members.
- Any person listed on this page will be able to view and edit this record/application.
- The “Primary Investigator” checkbox designates the PI and makes that person the Record Owner.
- To remove personnel from an Initial Application, use the "Delete Personnel" link that appears in the bottom right corner of the person's listing. This feature can only be used prior to the approval of a protocol.
- **Members leaving the research team:** The "End Date" field is how you designate an end point for a person's involvement with the study. This field is generally not used when creating a new protocol application. If/when you need to remove personnel, you create an Amendment and as part of the Amendment, set the "End Date" as the effective date that the person would be removed from the study personnel. I.e., the date you are creating the personnel Amendment. For example, this method would be used when a research assistant finishes a semester volunteering in a lab.
- CITI Training documentation: Upload CITI training documentation on the Study Attachments page in the "Training Documents and Other Materials" section IF the CITI training information is not part of the personnel listing.

UNCC Personnel

1. Using the table below, list all UNC Charlotte personnel involved in this project.

Full Name	Address 1	Email	Phone	Department
Montoro-Rodriguez, Julian	9201 University City Blvd	jmontoro@uncc.edu	7046876166	School of Social Work

Primary Investigator	End Date	Role
☑		Primary Investigator

Certifications

Certification	Begin	End
Social & Behavioral Research (IRB)	11-Jan-2021	10-Jan-2025

Instructions

- List all external collaborators who will be involved in this study by recruiting study participants, obtaining informed consent from participants, collecting and/or analyzing data.
- External collaborators at institutions with an IRB should consult with their institution to determine what if any local IRB requirements they must meet.
- An Individual Investigator Agreement is needed for external collaborators who are affiliated with an organization that does not have an IRB. This form is available on the IRB Forms webpage. See the Resource Bar for a link to the IRB Forms page.
- If you are collaborating with community partners who are not functioning as researchers OR if your extended research team includes multiple individuals with limited roles, please consult with the IRB office (uncc-irb@uncc.edu) to determine if these individuals need to be listed as project personnel.

Investigators Outside of UNCC

* **1. Is UNC Charlotte taking or being asked to take responsibility for the oversight of research by individuals, groups, or organizations outside of UNCC or will the external collaborators/entities obtain their own IRB approval? Select the appropriate item.**

- (●) UNC Charlotte IRB will be the lead IRB overseeing the study and external collaborators/entities.
- ( ) Collaborator will obtain IRB review and approval from their IRB.
- ( ) Study does not include outside investigators/collaborators.

Attachment: IRB reliance agreement may be needed for the external organization/collaborator to rely on UNCC if the external organization has its own IRB. Contact uncc-irb@charlotte.edu to request assistance.

Attachment: An Individual Investigator Agreement may be needed if the external collaborator is with an organization that does not have its own IRB. This form is available on the IRB Forms webpage. See the Resource Bar for a link to the IRB Forms page.

Outside Investigators

Investigator Name	Email	Role	Institution/Organization Name	
Jennifer Ramsey	jenniferlramsey888@gmail.com	Other	Independent	
Maria Quinones	Maria_Quinones@urmc.rochester.edu	Co-Investigator	University of Rochester	

Instructions

- Conflicts of interest disclosures are required for all research team members. **Including, Co-Investigators, Research Assistants, and external collaborators.**
- Non-financial conflicts of interest may include, existing relationships between research team members and external entities (e.g., study sites, organizations, institutions) that could potentially affect the integrity of the research. For example, a PI recruiting from a business where the PI's family member is in a position of leadership.

Conflict of Interest

* **1. At any time, will any members of the research team (PI, Co-Is, RAs) or their immediate family members have a financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study?**
AND/OR
Are there other conflicts of interest such as non-financial relationships that have the potential for conflict of interest or have the appearance of compromising the research team's (PI, Co-Is, RAs) objectivity in fulfilling research responsibilities related to the conduct of this study?

☐ Yes ☑ No

Instructions

- Some research involving human subjects may be eligible for an Exemption approval determination.
- Exemption means that the full scope of the regulations do not apply. However, the ethical requirements for Human Subjects Research do apply. (e.g. voluntary, consent is obtained, privacy and confidentiality are protected, etc.)
- Studies involving drugs, devices, medical procedures, experimental interventions or manipulations, or greater than minimal risk are NOT eligible for Exemption.
- Research involving prisoners may not be eligible for Exemption.
- For additional guidance on Exemption categories please check the Resource Bar.

Exemption Screening

* **1. Do you want your study evaluated for possible Exemption determination?**

☐ Yes ☑ No

In order to be eligible for Exemption approval determination, your research must fit an Exemption category. All of the categories will be listed. Only select the applicable category. You MUST complete the explanation narrative for the category you select to provide rationale and justification for why the category applies to your research.

Instructions

- If you are conducting research where participants have a reasonable expectation of privacy (public school, daycare center, medical facility), you must upload a letter of support from the facility administrator.
- Some public school systems have their own research review process. Please check with a school system representative to ensure you are meeting local requirements.
- If you are recruiting participants from other universities, they may require local IRB review. Please check with the institution's IRB office to ensure all local requirements are followed.
- If the location is outside the US, you must provide documentation that you meet requirements for conducting human subjects research based on that country's laws.
- If you will conduct study activities at/on the UNC Charlotte campus, you can list UNCC campus as the Site Location and yourself as the Site Contact. If the study will be conducted entirely online, you can list the location as Online (Zoom, Qualtrics, etc.) with yourself as the Site Contact.
- List the school location if you are conducting the study at school (K-12, University, etc.). List the local community organization if the study will occur at such a site.
- If you will recruit study participants from a business/company/organization, you would list the site location accordingly. The Site Contact would be the person you have approval from to conduct recruitment.

Locations

* **1. Will this study be conducted in locations outside the United States?**

☐ Yes ☑ No

* **2. List the locations where participants will be studied both on and off the UNCC campus.**

Name of Site Location	Name of Site Contact	Healthcare or Non-Healthcare	
On-line	Julian Montoro-Rodriguez	Non-healthcare setting	

* **3. IRB oversight of research activities at the above listed Research Locations AND/OR IRB oversight of external collaborators.**

☐ This study will rely on External IRB (not the UNCC IRB)

☑ UNCC IRB will oversee research activities at external research locations

☐ UNCC IRB will oversee activities conducted by external collaborators

ALERT: Be sure you have listed the external researchers on the Outside Investigators Page.

* **3.1 List the collaborating research locations AND/OR external collaborators that UNCC will serve as the IRB of record. If UNCC will serve as the IRB overseeing multiple research locations AND/OR external collaborators, you will need to use the "Add" button to add each location and/or collaborator.**

Please provide as much information as possible in the table below. For external collaborators state "NA" for Site Name. If the information is unknown, respond "Unknown."

SITE NAME	NA
Site PI Name	Jennifer Ramsey
Role	Collaborator
Activities	☑ Obtain consent and/or assent ☑ Perform research procedures ☑ Administer study interventions or experiment ☑ Obtain, use, or analyze identifiable or coded (has a study ID) data and/or specimens ☑ Obtain, use, or analyze de-identified data and/or specimens ☑ Other participant contact

* **Will the external institution and/or external collaborator defer review and oversight to the UNC Charlotte IRB?**	Yes ☑ No☐
* **Full legal name of external institution:**	NA
* **Federalwide Assurance (FWA) number from external Institution:**	NA
* **OHRP Registration Number of external IRB:**	NA
* **Contact Person at the external institution:**	NA
* **Name, Title, Address, Phone, Email**	Jennifer Ramsey, PhD, 1430 Lonan Drive, Waxhaw, NC 28173, 330-360-3842; jenniferlramsey888@gmail.com
* **External institution signatory official:**	NA
* **Name, Title, Address, Phone, Email**	NA

SITE NAME	University of Rochester
Site PI Name	Maria Quinones
Role	Co-Investigator
Activities	☑ Obtain consent and/or assent ☑ Perform research procedures ☐ Administer study interventions or experiment ☑ Obtain, use, or analyze identifiable or coded (has a study ID) data and/or specimens ☑ Obtain, use, or analyze de-identified data and/or specimens ☑ Other participant contact ☑ Other responsibilities or roles
* **Will the external institution and/or external collaborator defer review and oversight to the UNC Charlotte IRB?**	Yes ☑ No☐
* **Full legal name of external institution:**	NA
* **Federalwide Assurance (FWA) number from external Institution:**	NA
* **OHRP Registration Number of external IRB:**	NA
* **Contact Person at the external institution:**	Maria Quinones
* **Name, Title, Address, Phone, Email**	Maria Quinones, PhD. 225 Crittenden Blvd Rochester, NY 14642. 585-276-3903. Maria_Quinones@urmc.rochester.edu
* **External institution signatory official:**	Director of Human Subject Review Board at Rochester University
* **Name, Title, Address, Phone, Email**	Janice Taylor, Administrator 585-273-4127

Number of Participants

* **1. Total number of participants.** 30

1.1 If this study will occur at multiple Research Locations (as listed on the Research Locations page), please specify the number of participants at each location/site. If this study is not occurring at multiple Research Locations state "Not Applicable."

All study activities will happen virtually using a zoom videoconference platform with HIPPA compliance

2. If the Total Number of participants listed above (question #1) includes multiple groups or cohorts of participants, please explain the number of participants for each group.

Cohort 1 = 10 participants will engage in a demonstration test of the program to further refine the content and design of the program in Spanish
Cohort 2 = 20 participants will engage in a pilot test for program to finalize the final version of the Spanish program.

Vulnerable or Select Populations

3. Do you have specific plans to include participants from these vulnerable or select populations? If so, check all that apply

- ☐ Children (under the age of majority for their location)
- ☑ Non-English-speaking
- ☐ Patients (i.e., have a specific disease, disorder or condition regardless of where they receive their healthcare)
- ☐ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)
- ☐ Decisionally impaired
- ☐ Pregnant women
- ☐ HIV positive individuals
- ☐ UNC Charlotte Employees
- ☐ UNC Charlotte Students
- ☐ People, including children, in studies that might uncover child, elder, or domestic abuse/neglect.
- ☐ Native Americans or non-U.S. indigenous populations

* **4. Describe your plans to provide additional protections for these participants for the populations checked above, including any considerations for cultural concerns or issues. E.g. parental consent, translated study materials, use of an interpreter, privacy protections, debriefing, etc.**

The Community Advisory Board (CAB) is comprised of bilingual, bicultural professionals from the Latino community. They are not participants on the research pilot test study. The CAB members as "experts" will review the program materials. They will provide feedback to improve the translation and acculturation of the program. The CAB members will sign a MOU to acknowledge their understanding and acceptance of the tasks, responsibilities, and compensation. The CAB members are not participants, they will not have to any participant data, and will be compensated for their time and effort.

Age Range

* **5. List the minimum age of the subjects in this study. If there is no minimum age limit, please indicate by writing "NA".** 45

* **6. List the maximum age of subjects enrolled. If there is no maximum age limit, please indicate by writing "NA".** NA

Inclusion and Exclusion Criteria

Participants will be age 45 or older; Spanish speaking Latino caregivers for a loved one with ADRD (and living with or nearby the person with ADRD); elevated caregiving stress (as measured by a score of = 11 or higher on the 10-item Perceived Stress Scale [PSS-10] and/or a score of 5 or greater on the Modified Caregiver Strain Index [MCSI]). Access and use of Zoom and Internet.
The ADRD term is normally used for referring to patients with Alzheimer's disease and/or related dementias. Our study only includes caregivers of persons with ADRD. The study will not include the patients with ADRD.

* **8. Justify any exclusion based on race, gender or ethnicity. If exclusion will not result based on these criteria, please state not applicable.**

This study is to develop a program targeted to Spanish speaking Latino caregivers, since there are limited caregiver programs available for this growing population.

Screening

* **1. Check the applicable item if you will use or obtain any information about your prospective participants for screening, recruiting, or determining the eligibility before you obtain consent. Note: You should only collect the minimal information needed for these purposes. If you will collect more information than is needed for screening/eligibility determinations, you will need to obtain informed consent for the screening/eligibility determination.**

- [x] Obtain information through oral or written communication with the prospective subject or legally authorized representative. This includes online, telephone, or in-person screening questionnaires or interviews.
- [ ] Obtain already collected identifiable private information or records. Examples include review of medical charts, data repositories, and administrative records.
- [ ] Reviewing/testing identifiable biospecimens by accessing stored biospecimens and related information.
- [ ] None of the above

* **Describe the procedures and explain when and how you will destroy the data if the participant declines to participate or is not eligible.**

We will be using screening procedures. An electronic questionnaire will be used for the screening questions. Participants must provide consent on the screening survey delivered via Qualtrics prior to accessing any of the screening questions.

All potential participants must first complete a registration survey administered via a link to the Qualtrics survey on the UNCC website to indicate their interest in participating in the study. In the registration survey, participants will provide basic demographic information including names and contact information including (email addresses, phone numbers) and age and whether they provide care to a family member/friend with ADRD. Participants who meet the age and care for a family member/friend with ADRD will then be directed to a consent form that they must accept electronically, in order to answer the screening questions regarding level of stress.

The screening and registration data will be stored on secure UNCC servers in a secure and Password protected Dropbox folder. Only the PI and project coordinator will have access to the identifiable screening and registration data. The security of these electronic data is enhanced by using the UNC encrypted protocol.

Methods of Recruitment

* **2. Check all the following means or methods of participant recruitment to be used.**

- [ ] In person
- [ ] SONA Pools (Psychological Science and Political Science)
- [ ] Research Panels (Qualtrics, You.Gov, MTurk, etc.)
- [ ] Research Participant registry or database
- [ ] Presentation to classes or other groups
- [ ] Letters
- [x] Flyers
- [ ] Radio, TV recruitment ads
- [ ] Newspaper recruitment ads
- [x] Website recruitment ads
- [ ] Social Media (Facebook, Twitter, LinkedIn, YouTube, etc.)
- [ ] Telephone script
- [ ] Email or listserv announcements
- [x] Follow up to initial contact (e.g., email, script, letter)
- [ ] Other

* **3. Please explain the procedures that will be used for each item selected above.**

Prospective participants will be recruited by advertisement of the study among community partners and organizations. Recruitment flyer will be developed based on feedback from CAB members to ensure cultural appropriateness of the

The community partners and organizations will be decided upon and contacted later based on advise from the CAB. The community partners/organizations will not be contacted until the program and all materials has been translated and acculturated for Latino dementia caregivers. This will be prior to the pilot study, but after the first six months of the study when the CAB had completed their review of the program materials and documents. Currently, the program materials and documents are only available in English. The main goal of this study is the translation and acculturation of the English version of the program.

The study will be advertised on the UNC Charlotte program website and the CaregiverTLC. org website, Both Websites are still under development pending advise and feedback from the CAB regarding the cultural appropriateness for the Latino dementia caregivers.
The community partners and organizations will be emailed fliers detailing the participation requirements, general overview of the study, and registration instructions that they will share with their members. The recruitment flyers are still under development pending advise and feedback from the CAB regarding the cultural appropriateness for the Latino dementia caregivers. The protocol will be amended to reflect finalized content and procedures following the advise of the CAB.

* **4. Describe how you will protect the privacy of potential subjects during recruitment.**

- Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, if the study involves sensitive topics, vulnerable populations, etc.
- If the study's recruitment process does not pose a threat to privacy, state "Not Applicable."

All identifiable information will be stored on secure UNCC servers in password protected and secure Dropbox folders. Only members of the research team will have access to potential participants' information. Any participant information related to participants who are not eligible will be deleted from the database

Instructions

Informed Consent Process:

- Ethical implementation of research requires respect for persons and informed consent.
- Participants should be told all relevant information needed to make an informed decision about participation.
- If relevant, describe any steps that will be taken to minimize coercion or undue influence during the consent process (this may arise with children in a school setting, patients in a medical setting, clients in a community program, etc.). Some methods might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician, teacher, course instructor).
- Waivers of consent may be requested. The IRB will evaluate whether the rationale and justification for a waiver meet the applicable waiver approval criteria.
- Child and youth assent are appropriate in many circumstances. Researchers should consider appropriate assent procedures for children age 7 and older. Waiver of child/youth assent must be requested.
- Please attach in the Study Attachment page, all consent forms and assent forms that will be used.

Informed Consent Process Screening

* **1. Please review the waiver definitions below and select all that apply.**

Waiver of Written Documentation of Informed Consent:
The default is for participants to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary or in circumstances where a signed consent form creates a risk for the participant.

Full or Partial Waiver of Consent:

- The standard is for participants to give informed consent.
- There are times in which the consent form can be waived in full (not just the waiver of signature) or waived in part.
- A waiver may be requested for research involving only existing data or human biological specimens.
- More rarely, it may be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception).
- In limited circumstances, parental permission may be waived.

☑ Waiver of documentation of consent

☐ Full or partial waiver of consent

☑ None of the above

Consent Process

***For Data Only applications, a waiver of consent may be needed. In this case, the questions in this section may not apply.**

* **1. Explain the process (step by step) for obtaining consent from the participant.**

Eligible participants will receive an email instructing them to complete an electronic consent form accessed through the program website and administered via Qualtrics.
All participants who qualify will be sent a link to a Qualtrics survey containing a full consent form minus the signature line as well as a pdf document of the informed consent form minus the signature line for their records. Participants will indicate their consent and receipt of this consent form by indicating their informed consent on the Qualtrics survey.
Participants who do not consent to participate will not be contacted further by the research team and all identifying information will be deleted from the records. Once informed consent is obtained, participants will be contacted regarding completion of the first assessment survey.
Additionally, participants will be provided with a brief reminder of what participation in this study will entail and their rights as study participants prior to completing the pre and post surveys. Participants will be required to indicate their consent to proceed on the Qualtrics survey before the Qualtrics survey will allow them to view or respond to the survey questions.
Participants will also be instructed to contact members of the research team with any questions regarding participation in each session.
At the beginning of each virtual program session, trained facilitators will also summarize what is expected of participants during participation in each session. Participants can choose to withdraw from the study at any time. Only eligible participants who have provided informed consent will be provided access to the full virtual program sessions (password protected), links to the Qualtrics surveys, and links to the HIPPA compliant Zoom meeting invites.
It is our understanding that using a sophisticated electronic program such as DocuSign may not be feasible for some potential participants who may not be familiar with such programs. Participants will however, be required to indicate their consent on

Additionally, qualifying and consented participants will also indicate consent on each electronic survey prior to accessing any survey questions. Participants who do not indicate their agreement to proceed with each electronic survey will not be directed to respond to any survey questions and will also be asked if they would like to withdraw from the study and receive no further contact from the research team.
Participants who indicate they would like to completely withdraw will no longer be contacted by members of the research team. All participants will also be emailed a PDF version of the program consent form for their records.

We have included the English text for all consent forms (screening consent, program consent, survey consent) which will be translated into Spanish pending advise and feedback from the CAB. The screening consent and survey consent form will be included in each of the respective surveys such that participants can not access survey questions until providing electronic consent. These surveys are still under development pending feedback from the CAB members. We will not contact potential participants until all program documents and surveys are fully translated and acculturated. These documents and surveys will be added to the IRB when they are developed. We expect this process will take about six months.

* **2. Will decisionally-impaired participants be enrolled in your study? (includes some developmental dementia-related, and or psychiatric disorders, others who lack capacity to give consent)**

☐ Yes ☑ No

* **3. Are you planning to obtain consent from any Non-English speaking participants? If yes upload the consent document translation on the Study Attachments Page.**

☑ Yes ☐ No

* **3.1 Describe how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their legally authorized representative (LAR).**

All study materials will be available to participants in both English and Spanish. A bilingual members of the research team will be available to discuss the consent process and documents and any questions in the participant preferred language (English or Spanish).

* **4. Will children under the age of majority in their locale (18 years in NC) be enrolled?**

☐ Yes ☑ No

* **5. Describe who will be obtaining consent.**

Participants will be instructed to complete the electronic consent form by a bilingual member of the research team via an email written in English and Spanish. Participants can contact a bilingual member of the research team via phone or email in their preferred language to ask any questions.

Waiver of Written Documentation of Informed Consent

* **1. Choose which of the following consent approaches apply.**

☐ Consent form minus the signature lines

☑ Online consent form

☐ Verbal consent obtained in person or via the phone

☐ Other

Attach the relevant documentation on the Study Attachments page

* **2. Choose which one of the following justifies the waiver of written documentation.**

☐ The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). Participants should be asked whether they want documentation linking them with the research and their wishes will govern whether they sign the form. Note: This justification cannot be used in FDA-regulated research. This justification may not be applicable if incentives are offered.

☑ The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. (e.g., many phone or mail surveys, man in the street interviews, etc.).

☐ The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

where obtaining written (paper-pen signed or digital signature) consent is not practical.

* **3. If your request for a waiver of written documentation applies to some but not all of your participant groups and or consent forms, please describe and justify. If this doesn't apply write "NA".**

NA

Protected Health Information (HIPAA)

Protected Health Information (PHI) is any identifiable information about the participant's health that relates to their participation in this research and is obtained from sources other than the participant, such as medical records, health care providers, insurance plans, etc.

* **1. Will you need access to PHI for the purpose of the study? For example, to identify or screen potential participants, to obtain study data or specimens, or for follow-up.**

☐ Yes ☑ No

Instructions

- Provide a description of the study's methods and procedures.
- **The description should provide sufficient details such that the IRB will have a good understanding of what, when, why and how the study will be implemented and what participants will experience.**
- Describe the study's design and sequence of procedures.
- Experimental procedures and/or interventions should be clearly described and labeled as such.
- If the study uses control or intervention/experimental groups, clearly describe what participation will be like for each of the groups or study arms.
- If the study includes measures, survey instruments and questionnaires (including the collection of demographic data), identify each and, if available, provide references for the measures.
- Describe what they intend to measure (relate to purpose/hypothesis).
- Identify any that were specifically created for the study.
- If your study uses data and/or biospecimens only, describe the procedures you will use to conduct your research. E.g., how you will use and/or process the data and/or specimens.

Screening

* **Will you be using any methods or procedures commonly used in biomedical or clinical research (this would include but not be limited to drawing blood, performing lab tests, biological monitoring, conducting physical exams, collecting physiological information, administering drugs, or conducting a clinical trial)?**

☐ Yes ☑ No

Methods and Procedures

A *clinical trial* is a study in which one or more human subjects are prospectively assigned to one or more biomedical or behavioral interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. There are two main types of clinical studies: clinical trials and observational studies.

* **1. Is this study a clinical trial? Do NOT check yes merely because you are conducting research in a clinical setting or using clinical data.**

☐ Yes ☑ No

2. Will this study use any of the following methods? Check all that apply.

☐ Audio recording.

☑ Video recording or filming.

☐ Behavioral observation eg. naturalistic, classroom & experimental observations.

☐ Pencil and paper questionnaires or surveys

☑ Electronic questionnaires or surveys

☐ Telephone questionnaires or surveys

☐ Interview questionnaires or surveys where researcher records participant responses.

☐ Asking participants to watch a video, performance, etc.

☐ Interviews: individual

☐ Computer based task, testing, measure, etc.

☑ Focus groups

☐ Diaries or journals

☐ Photovoice

☐ Photography and/or imaging (Still photos, thermal images)

☐ Mobile Applications (development, testing, using mobile apps)

☐ Physical Activity

☐ Wearable technology (fitness, virtual reality and other devices)

☐ Other

* **3. Describe the study methods and procedures, including a sequential description of what participants will be asked to do including follow-up procedures when relevant.**

- **Please explain the procedures listed in question #2 that will be used for each item selected above.**
- **Describe the specific data that you will collect using the collection methods listed in question #2.**

Website:

Registration website:

The registration website will be hosted by UNCC. The registration website is under development and none of the components of the website that are part of the research will go-live until this protocol is modified to provide the complete website details. All survey and data collected will be stored solely on UNCC systems and servers. The registration website will provide information for prospective participants including a brief description of the program, participation requirements, and a link to register to participate in the Cuidando Juntos research study. The registration link will connect potential participants to a Qualtrics survey including screening questions and questions regarding the potential participants willingness to participate. The registration website will also contain a link to the Project Website.

Project Website:

The Project Website will be hosted by Photozig. No data will be collected from the website. The website is under development and none of the components of the website will go-live until this protocol is modified to provide the complete website details. A project website will be built to support the implementation of the pilot study. The website will contain all materials, instructions, and relevant resource links. The main features are: 1) provide information for prospective participants, active participants, facilitators, project team members 2) deliver content such as information sheets, training slides, and program session materials and resources. The website will contain general content and resource information including contact information for the PI and other members of the research team brief description of the program, session slides and resource materials and links. The website will not be used for data collection.

Community Advisory Board: A community advisory board will be established. Advisory board members will consist of community professionals who are bicultural and bilingual and who have experience working with Latino dementia caregivers and/or were dementia caregivers themselves. Members of the CAB will be identified through contacts at local organizations serving Latino dementia caregivers. Potential CAB members will be contacted by email or phone from contact information provided by local community organizations and informed of the required tasks and compensation for CAB members and asked to sign a MOU indicating their intention to act as a CAB member for the Cuidando Juntos research project. CAB members will be asked to attend up to 10 virtual meetings over Zoom throughout the duration of the 1-year study. During these meetings, CAB members will review all project materials including session materials, recruitment materials, scripts, and assessment measures and asked to provide feedback regarding the cultural appropriateness of the materials, resources for Latino dementia caregivers, and barriers faced by Latino dementia caregivers. The research team will use this feedback to modify study and session materials accordingly. CAB members will be compensated $200 for each meeting attended.

Recruitment:

Upon modifying recruitment materials based on CAB feedback, the research team will contact potential participants via recruitment adds on the project website and recruitment adds emailed to local organizations serving Latino dementia caregivers. The adds will include a brief overview of the Cuidando Juntos Program,

Registration and Consent:

All potential participants must complete a registration/screening questionnaire administered via a link to the Qualtrics survey on the registration website to indicate their interest in and qualifications to participate in the study. Participants will provide basic demographic information including names, age, race/ethnicity, languages spoken, contact information including email addresses, phone numbers, location, general availability, and the nature of the care provided to the family member with dementia. The registration/ screening questionnaire will also contain the Perceived Stress Scale [PSS-10] and the the Modified Caregiver Strain Index [MCSI] as participants must experience elevated caregiving stress (as measured by a score of = 11 on the 10 item Perceived Stress Scale [PSS10] and/or a score of 5 or greater on the Modified Caregiver Strain Index [MCSI]).

Members of the research team will review the registration information to determine eligibility as all participants must be 45 years of age or older and provide care to a family member or friend with dementia and must experience elevated caregiving stress (as measured by a score of = 11 on the 10 item Perceived Stress Scale [PSS10] and/or a score of 5 or greater on the Modified Caregiver Strain Index [MCSI]). Participants who qualify will be contacted with instructions (via email or phone: preference to be indicated by potential participants on the initial registration/screening questionnaire) to complete the informed consent, indicate again their availability for participation in the group sessions, and complete the first assessment. In sum, once the potential participant is at the registration website, they will complete a registration/screening survey if they wish to be considered for participation. Then, qualifying participants will be contacted by a member of the research team and will be provided with further instructions regarding completion of the informed consent form. All participants who qualify will be sent a link to a Qualtrics survey containing a full consent form minus the signature line as well as a pdf document of the informed consent form minus the signature line for their records. Participants will indicate their consent and receipt of this consent form by indicating their informed consent on the Qualtrics survey. Participants who do not consent to participate will not be contacted further by the research team and all identifying information will be deleted from the records.

Assessment and Cuidando Juntos Sessions:

Once informed consent is obtained, participants will be contacted regarding completion of the first assessment survey (pre-assessment). Once the consent form and first survey is completed each participant will be assigned to a group led by one of the trained facilitators based on the indicated availability. Once assigned to a group, participants will be emailed their zoom invitation from the facilitator. After completing the Cuidando Juntos program, participants will be emailed a link to a post assessment Qualtrics survey. Participants will also be required to indicate their consent on each electronic survey (pre and post) prior to accessing any survey questions. Participants who do not indicate their agreement to proceed with each electronic survey will not be directed to respond to any survey questions and will also be asked if they would like to withdraw from the study and receive no further contact from the research team. Participants will also be asked to participate in a focus group and answer semi-structured interview questions after completing the Cuidando Juntos program. Participants will indicate their consent to participate in the semi-structured interview on the initial consent form and will also be emailed a link to an electronic survey administered via Qualtrics and will be required to indicate their consent tom participate in the semi-structured interview focus group prior to being emailed the link to the Zoom meeting. Participants who do not indicate their agreement to participate in the focus group will also be asked if they would like to withdraw from the study and receive no further contact from the research team. Participants who indicate they would like to completely withdraw will no longer be contacted by members of the research team. Participants can choose to withdraw from the study at any time.

Confidentiality and Program Access:

program information on the Project Website and can choose to complete the registration/screening form on the registration website. Only eligible participants who have provided informed consent will be provided access to the full modules (password protected), links to the Qualtrics surveys, and links to the HIPPA compliant Zoom meeting invites. All survey data will be collected via Qualtrics and will be stored on the UNC Charlotte servers and systems. Additionally, all recordings of the sessions and focus groups will be stored on the UNCC servers and systems. All assessment data and recordings will only be able to be accessed by members of the research team.

"Cuidando Juntos" is the name of the Spanish intervention for Latino dementia caregivers.

The CAB members are only reviewing and providing feedback on program materials, assessments, and documents. They are not functioning as participants, and will not have access to any participant data.

The links were met to direct IRB members to the Caregiver TLC Website in English as the Caregiver TLC program is the program on which the Spanish version will be based. The links have been removed. The Caregiver TLC program was evaluated in a previous study already approved by the UNC Charlotte IRB.

The content of the surveys has not been yet fully developed. The first goal of this study is to develop a program and assessment that are culturally adapted for Latino dementia caregivers. The development of such materials is expected to take about six months. Once the materials are developed they will be added to the IRB for approval. Participants will not be contacted until materials are developed.

Members in the focus groups will be asked to submit written feedback and complete semi-structured focus group sessions, thus semi-structured interviews will be the means of data collection for the focus groups. The semi-structure questions has not yet been fully developed. The development of such materials is expected to take about six months. Once the materials are developed they will be added to the IRB for approval. Participants will not be contacted until materials are developed.

* **4. Duration of participation: Describe the 1) Total time commitment for the participant and 2) time commitment for each activity or component if applicable. E.g., duration for each survey, interview, follow-up, debriefing, etc.**

We will assess caregivers approximately one week prior to the training one week after completing
the program. These measures are standard in the caregiving literature, and focus on both the positive and potential negative aspects of caregiving. At each occasion, they would require approximately an hour to complete. In addition to these assessments, caregivers will attend 6 weekly sessions to complete
the program. Participants will also answer semi-structure interview questions as part of focus group discussions after completing the six week sessions.
The estimated duration of participation is approximately 2 months.
After qualifying participants are consented they will be assigned to participate in the "Cuidando Juntos" program group. Once assigned, participants will complete a pre assessment survey approximately one week before beginning the program. The pre-assessment survey will be completed virtually using Qualtrics and will take approximately 40 minutes to complete. Participants will then complete the six weekly "Cuidando Juntos" program sessions, each lasting two hours. One week after completion of the sessions participants will complete a post assessment survey virtually using Qualtrics, which will take approximately 40 minutes to complete. Between one and two weeks after completing the program sessions, all participants in the program group will be invited to participate in a virtual focus group via HIPAA zoom platform. Participants will be ask to respond to semi-structured questions about the program during the focus group. The group will be lead by a bilingual/bicultural member of the research team. The focus group will last two hours. Total participation for the duration of the study will be approximately ten week for participants.

* **5. Does your study involve incomplete disclosure or deception?**

☐ Yes ☑ No

* **6. Data Analysis: Describe the analytical techniques the researcher will use to answer the study questions.**

Descriptive, bivariate and basic multivariate quantitative analyses (pre and post controlling by sociodemographic information). Data from focus groups will be analyzed using a content analysis approach.

* **7. If there are procedures or methods that require specialized training, describe who (role and qualifications) will be involved and how they will be trained. e.g., cognitive assessments, specialized intervention or technique, blood draws, etc. If not, state not applicable.**

Facilitators will have a social work, case management or other human development or clinical background. Drs. Dolores Gallagher-Thompson and Ann Bilbrey of the Optimal Aging Institute will train facilitators.

Identifiers

* **1. Check the identifying information below that you have access to, already have, or will have, and or will receive, even if it is not retained with the research data. This includes any identifiers you may have at any point, even if only temporarily and even if the identifiers are never linked to the study data.**

- [x] Names
- [x] Telephone numbers
- [x] All dates related to the subject (e.g. birth date, admission/discharge date, test date)
- [ ] Geographic subdivision smaller than a State (e.g. address, city, county, precinct, zip and geocode)
- [ ] Fax numbers
- [x] Electronic mail addresses
- [ ] Social Security numbers
- [ ] Student or Employee ID numbers
- [ ] Device identifiers and serial numbers (e.g., implanted medical device)
- [ ] Certificate or license numbers
- [ ] Biometric identifiers, including finger and voice prints
- [ ] Account numbers (this could be any type of account that is unique to the participant)
- [ ] Health plan beneficiary numbers
- [x] Full face photographic images and any comparable images
- [ ] Internet protocol (IP) address numbers
- [ ] Medical record numbers
- [ ] Vehicle identifiers and serial numbers (VIN), including license plate numbers
- [ ] Web universal resource locators (URLs)
- [ ] Any other unique identifying number, code or characteristic
- [ ] None of the above

Identifier Details

* **2. For each of the items checked above, explain why this information will be collected and how it will be used.**

The research team will need the names, ages, phone numbers, and email addresses of participants to contact them regarding the session participation and complexion of assessments and focus groups. Ages of the participants is needed by the research team because participants mush be at least 45 years of age. Upon complexion of data collection all data be de-identified. Only members of the research team identified by the PI will have access to de-identified data. Full face images in the form of video recording of the participants during the program zoom sessions and focus group zoom sessions will be reviewed by members of the research team to identify issues related to program delivery, acceptability and to conduct content analysis for the focus group sessions. These recordings will be store on secured UNCC systems and servers and only members of the research team identified by the PI will have access to these recordings. These recordings will be stored separately from survey data.

* **2.1 How will these identifiers be stored in relationship to the research data:**

- [x] with the research data. -- i.e., in the same data set/same file (whether electronic or hardcopy data)
- [x] separate from the research data. -- i.e. coded with a linkage file stored in a different location. The location must be physically separate, whether it's a physical location (different cabinet, room, etc.) or electronic location (different folder with access restrictions, different network drive, etc.

* **Provide details about the option you selected above.**

A separate secure dropbox folder will be created for the sessions recordings and the focus group recordings. This will be a different dropbox folder than the one used for assessment or registration data. We acknowledge that video data cannot be separate from all identifiers.

Instructions - In your description be sure to explain the following:

- How will participant identifiers be handled?
- Will data be identifiable or anonymous? Note: Anonymous means that no one, not even the Researcher will know the identity of the participant.
- Describe if and/or how data will be coded. Will a study ID be assigned, a pseudonym, etc?
- Will a master list be used that links participant identity to assigned code/ID/pseudonym?
- How will audio or video recordings be handled?

* **1. Describe procedures for maintaining privacy of the participant (identity) and the confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).**

The data will be de-identified by the research team. Each participant caregiver will be given an ID number that will be used for the entire data available for each participant. Only the PI and Project Coordinator will have access to the Master list linking the participant ID with identifiable data. Video recordings will be stored in a separate Dropbox folder from survey data.

* **2. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child abuse or physical abuse, immigration status, etc?**

☐ Yes ☑ No

* **3. If this study is limited to data collection by survey or interview, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs). State "Not Applicable" if this does not apply to this study.**

Personal information will be associated with an ID number. We will use the ID number to link the individual with the data. A master list linking ID numbers to participant information will be stored securely on UNCC systems and servers and accessible only to the PI and the project coordinator via a secure Dropbox folder. Electronic data will be stored on a secure and encrypted network at the University of NC Charlotte campus, with password required for access. Native windows encryption will be used to maintain secure the data. Any hard copy data will be stored in locked cabinets in the office of the principal investigator at CHHS office #481

Data reports will not include reference to individual participants. Data will be reported for the aggregate information of all participants. No unique or singular data traceable to a participant will be included.

* **4. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?**

☐ Yes ☑ No

Data Storage

Instructions:

- Please refer to OneIT Guidelines for Data Handling for Level 2 and/or Level 3 data.
- Consult with your College Data Security Officer as needed.

* **1. Describe the procedures for storing the data. Including, your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe how and when linkage codes and/or identifiers will be done destroyed.**

All video recordings recorded via the HIPPA compliant Zoom platform will be stored on secure UNCC servers in a secure and Password protected Dropbox folder. The audio and video files will be kept for three years and then destroyed. Participants who consented to participate in the study will be emailed a link to a password protected Qualtrics survey to complete the pre- and post-assessments. These data will be stored on secure UNCC servers in a secure and password protected Dropbox folder. Only the PI and project coordinator will have access to identifiable data. The security of these electronic data is enhanced by using the UNC encrypted protocol. All video recordings will be destroyed three years following the closure of the project. These recordings will be stored on secure UNCC servers in password protected drobox folders for the duration of the study and up to two years following the closure of the project. All other identifiable data including Master lists and data obtained from Qualtrics surveys will also be destroyed upon closure of the study. These data will be stored on secure UNCC servers in password protected Dropbox folders for the duration of the study and up to two years following the closure of the project.

Information collected from Individuals who do not qualify for the study will be destroy and no record will be saved.

Data Transfer and Sharing

Instructions:

- Please refer to OneIT Guidelines for Data Handling for Level 2 and/or Level 3 data.
- Consult with your College Data Security Officer as needed.

* **1. Describe how data will be shared among research team (i.e., personnel listed on this application).**

be stored on secure UNCC servers in a secure and Password protected Dropbox folder. Participants who consented to participate in the study will be emailed a link to a password protected. Qualtrics survey to complete the pre- and post-assessments. These data will be stored on secure UNCC servers in a secure and Password protected Dropbox folder. Only the PI and project coordinator will have access to identifiable data. The security of these electronic data is enhanced by using the UNC encrypted protocol.

* **2. Will identifiable data be shared with individuals outside of the research team?**

☐ Yes ☑ No

Benefits

Instructions

- Do not cite monetary payment or other compensation as a benefit.

* **1. Describe the benefit to society based on scientific knowledge to be gained.**

This study will contribute to the Latino community since currently there are no psychoeducational program for Latino caregivers of PLVD in Spanish.

* **2. Describe the direct benefit to individual participants in this study. If there are no direct benefits to the individual participant, say so here and in the consent form if there is a consent form.**

Participants attending the Cuidando Juntos program may experience potential benefits including decrease levels of depression, stress, and an increase of social connectedness and social support. These mental health and skill care building benefits are possible but not guaranteed.

Risks

Instructions

- For each of the following categories of risk, describe the potential risk and what will be done to minimize the risks.
  - Psychological risk (e.g., emotional distress or embarrassment)
  - Social risk (e.g., loss of reputation/standing, harms to a larger group or community, etc.)
  - Economic risk (e.g., loss of income, loss of employment or insurability, loss of professional standing, etc.)
  - Legal risk (e.g., disclosure of illegal activity, disclosure of negligence, etc.)
  - Physical risk (e.g., medication side effects, pain, discomfort, injurty, etc.)
- Where possible, describe the likelihood of the risks occurring, using the following terms:
  - Very Common (approximate incidence >50%)
  - Common (approximate incidence > 25%)
  - Likely (approximate incidence 10-25%)
  - Infrequent (approximate incidence 1-10%)
  - Rare (approximate incidence <1%)

1. Describe any potential risks - physical, psychological, economic, social, legal, discomforts, hazards, or other - and assess the likelihood and seriousness for each risk described.

We anticipate no psycho-social or economic harm, legal jeopardy, or risk of pain or injury to the participants in this study. There is no medication involved in this study. However, participants may experience some embarrassment or emotional distress when confronting issues inherent in providing care to family members with dementia as one on the main goals of the intervention is to help caregivers identify and better manage difficult behaviors exhibited by the care recipient as well as the caregiver's response to such behaviors and stressful situations.

2. Describe the procedures for protecting against or minimizing any potential risks.

Facilitators will provide information to caregivers about available counselling services in the community. We do not expect any breach of confidentiality, but in the case that happens we will follow a protocol where the facilitator or Research Assistant is instructed to report immediately to the Principal Investigator. A report will be kept of any potential events. If needed professional services will be recommended for participants. The data from the assessment interviews and the program sessions will be kept under the supervision of the Principal investigator and subject to de-identification.

Data and Safety Monitoring

* **1. Are there criteria that will be used to withdraw an INDIVIDUAL PARTICIPANT from this study or halt the research intervention. E.g., abnormal lab tests, allergic reactions, failure or inability to comply with study procedures, etc?**

☐ Yes ☑ No

* **2. Are there criteria that will be used to stop the ENTIRE STUDY prematurely? E.g., safety, efficacy, unexpected adverse events, large number of unanticipated events, inability to recruit sufficient number of participants, etc.**

☐ Yes ☑ No

* **3. Will this study involve a data and safety monitoring board or committee? A DSMB monitors the progress of the research and safety of participants.**

☐ Yes ☑ No

Instructions

- Complete the questions below that pertain to the use of existing records/data or human biological specimens.
- Existing data refers to data you will receive, obtain, or access from a source other than your study participant.
- Data obtained from secondary sources that was not collected for the purposes of your study.

Data Sources

* **Will you use or obtain any records, data, or human biological specimens that have already been collected?**

☐ Yes ☑ No

Instructions

- Please refer to Financial Services Human Subjects Payments, How to Pay guide. Link available in the Resource Bar.

Incentives and Costs

* **1. Are there incentives (monetary or non-monetary) for participants to participate or are you reimbursing participants for study-related costs (e.g., travel, parking, hotel accommodations or childcare)?**

☐ Yes ☑ No

* **2. Will there be any financial costs that participants will incur related to participation in the study?**

☐ Yes ☑ No

Updated By: **Tyler Steven Forgette @ 12-Dec-2023 12:17:33 PM**

Instructions

- Use this page to upload any supporting documents that are relevant to your protocol.
- Before uploading, carefully review the e-file title of each document. The e-file should clearly identify the content of the document (e.g., Social Media Recruitment, Interview Questions, Parental Consent, etc.).
- Each table contains different document types. To add an attachment click the "Add" button in the appropriate table. If you can't find the specific document type you need, each table has an "other" option that you may choose.
- If you have a document that doesn't "fit" one of the table categories, use the "Other" table and select "other" as the document type.
- After clicking Add and selecting a Document Type, click the upload icon (upwards arrow). This opens a pop-up box for you to search and select your document.
- If you successfully uploaded the document, the document name and date and time of upload will appear next to the upload icon in the table.

Attachments

Master Protocols, Grants, Proposals

Document Type	Upload protocols, grants, proposals	
Grant Application	OtherClinicalTrialRelatedAttachments_Project9TLC.pdf 21-Oct-2023 12:08:18 PM	
Other Study Protocol	SESSION by SESSION OUTLINE Draft for CAB to Review 10_18_23.docx 21-Oct-2023 12:19:36 PM	

Data Collection Materials

Document Type	Upload Data Collection Materials	
Online Survey	Project 9 Measures.docx 21-Oct-2023 12:10:23 PM	

External IRB/Multi-Site Studies

Document Type	Upload External IRB/Multi-Site Studies	

Sponsor-Related Materials (monitoring, regulatory)

Document Type	Upload Sponsor-Related Materials	

Consent Related Materials

Document Type	Upload Consent Materials	
	Program Consent Form Cuidando Juntos Consent form November 2023.docx 15-Nov-2023 01:37:42 PM	

Recruitment Materials

Document Type	Upload Recruitment Materials	
Flyer	cuidando juntos flyer (1).docx 04-Nov-2023 11:46:33 AM	

Other Approvals and Agreements

Document Type	Upload Other Approval/Agreements	
Other Approval or Agreement	IRB Cuidando Juntos CAB MOU.docx 21-Oct-2023 12:33:53 PM	
Individual Investigator Agreement	Individual-Investigator-Agreement Ramsey (1).docx 04-Nov-2023 11:40:22 AM	
Individual Investigator Agreement	MQ Individual-Investigator-Agreement (1) (1).docx 04-Nov-2023 11:41:43 AM	

Updated By: **Tyler Steven Forgette @ 12-Dec-2023 12:17:33 PM**

Document Type	Upload Training and Other Materials
CITI Training Documentation	Ramsey citiCompletionReport3321039.pdf 21-Oct-2023 12:26:53 PM
CITI Training Documentation	CITI JMR.pdf 21-Oct-2023 12:29:20 PM
CITI Training Documentation	MQ citiCompletionCertificate_1399471_50532615 (1).pdf 04-Nov-2023 11:49:20 AM

Instructions

- **The Primary Investigator listed on this protocol must complete this page.**
- **If this submission was created by/drafted by someone other than the Primary Investigator, the creator must not complete this page.**
- **If this submission is submitted by someone other than the Primary Investigator, it will be routed to the PI first for certification prior to being routed to the IRB office.**

Certification Statements

I CERTIFY THAT I AGREE TO THE FOLLOWING STATEMENTS:

- As the Primary Investigator listed on this submission, I certify that all information given in this form is accurate and complete.
- Further, the research team members listed on this submission have disclosed all conflicts of interest in which financial or other personal considerations, circumstances, or relationships may compromise, involve the potential for compromising, or have the appearance of compromising a researcher's objectivity in fulfilling research responsibilities.
- As the Primary Investigator, I will personally conduct or supervise this research study.
- I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research.
  I will obtain IRB approval before making any changes or additions to the project, including personnel changes.
- I will provide progress reports to the IRB annually (if required), triennially, or as requested.
- I will promptly report all adverse events or unanticipated problems involving risk to human subjects.
- I will follow the IRB approved consent process for all subjects.
- I will adhere to research data security Level 2 requirements or a Data Security Plan if one is applicable to this study.
- I assume responsibility for ensuring that all personnel listed on the protocol are informed about the above obligations.
- If the PI is a Student, the Faculty Advisor is ultimately responsible for ensuring that this study complies with all the obligations listed above for the Student PI.

☑ * **PI Certification**

Updated By: **Tyler Steven Forgette @ 12-Dec-2023 12:17:33 PM**

Niner Research System Administrator
ninerresearch@uncc.edu

Appendix 1

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload protocols, grants, proposals
File Name: OtherClinicalTrialRelatedAttachments_Project9TLC.pdf

ROYBAL
Center For
Translational
Research

Version Last Updated: 3/3/2021

Other Clinical Trial- Related Attachments (Roybal Specific):

Instructions: Please use this document to ensure all Roybal specific required materials are submitted for each pilot when completing the RPPR and ASSIST. In this document, you will find templates as well as links to NIH guidance and policies.
Please Submit this document in section 5.1 "Other Clinical Trial- Related Attachments" in each study under ASSIST. Please note, that section 5.1 will only appear if you select "Yes" to all the questions in the "Clinical Trial Questionnaire".

- [x] Roybal Pilot Facesheet
- [x] Specific Aims
- [x] Research Design
- [x] Background Questions
- [x] Data and Resources Sharing Plan**
- [ ] Multiple PI/PD Leadership Plan, applicable if there is more than one pilot PI
- [ ] Letters of Support, If applicable

**If a master plan is approved for all pilots conducted at the Roybal site, it can be used/cited here rather than creating a new one. If specific pilots need to deviate from master plan, then PI should submit a new plan.

Roybal Pilot Facesheet for TLC (RocSTAR Project 9):

General information:

P30 Grant #	P30AG064103		
P30 Full Title	Rochester Roybal Center for Social Ties & Aging Research		
Brief Title	A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers		
Pilot PI	Julian Montoro-Rodriguez	Pilot PI Email	jmontoro@uncc.edu

Regulatory Information:

Human Subjects: ☑ Yes If No,please do not submit this pilot. It is not a Clinical Trial)

IRB Status: Choose an Option

Name of IRB (organization)	The University of North Carolina at Charlotte
PI listed on IRB	Julian Montoro-Rodriguez

FDA License(s): None applicable.

IND:	☐ No	☐ Yes
IDE:	☐ No	☐ Yes
BLA:	☐ No	☐ Yes
NDA: N	☐ No	☐ Yes
ANDA:	☐ No	☐ Yes

Classification of Study on Translational Continuum:

NIH Stage Model For Behavioral Intervention Development

- ◉ I (Generation/refinement/modification/adaptation/pilot testing)
- ○ II (Traditional efficacy testing)
- ○ III (Efficacy testing with real-world providers)
- ○ IV (Effectiveness research)
- ○ None of these

Keywords (max 30 characters each)

Latino dementia caregivers

Psycho-educational intervention

Cultural adaptation

Is this a Multi-site Study: ☐ Yes ☑ No

Foreign Component: ☐ Yes ☑ No

Specific Aims & Abstract: (One page or less)

In no more than one page, please include: an Impact Statement with public health relevance (50 words or less), an abstract with a succinct and accurate description of the proposed work (250 words or less) and your specific aims for the project.

HEFFNER + VAN ORDEN_FY23_PILOT#9_ MONTORO-RODRIGUEZ_TLC

Impact:

In 2021 Latinos accounted for 19% of US population and are the largest contributor to population growth. Compared to other sociocultural groups, Latinos have higher prevalence of dementia and less access to services; caregivers report high depression and less family support. Culturally appropriate interventions are needed to address this issue.

Abstract:

There are several evidence-based interventions for distressed dementia caregivers that focus on skill building to increase resilience. However, few psychoeducational programs target Latino caregivers, and there are no evidence-based interventions promoting “social connectedness and support” in a culturally congruent way for Latinos. Several factors including distrust of the health system, language, and differences in cultural values contribute to the underrepresentation of Latinos in intervention research. There is urgency for culturally adapted programs addressing their needs. The Caregiver Thrive, Learn & Connect (TLC) is a telehealth caregiver educational program that builds upon evidence-based strategies from the "Coping with Caregiving" program (tested in REACH II) to improve caregivers’ psychosocial outcomes. Caregiver TLC incorporates a goal-oriented approach focused on learning effective strategies to seeking support and connecting with caregivers and community resources. Dementia caregivers attend sessions in small groups through Zoom, making the program accessible for caregivers with limited information, time, transportation, and language proficiency. The program website allows caregivers to access information, resources (videos), attend informational activities (webinars) and participate in a virtual community where caregivers learn and connect with others. Our cultural adaptation follows the Barrera’s Cultural Adaptation Behavioral Health Stage Model (2013).

Specific Aim 1. To create a Community Advisory Board to engage Latino caregivers and community leaders to work with us to co-develop the program.
Specific Aim 2. To test an early-stage adapted Spanish language of the program.
Specific Aim 3. To examine the mechanism of social connectedness as a means to improve clinical outcomes (depression, stress, burden).

Research Design: (2 Pages or Less)

The Research Design section is the nuts and bolts of your pilot application, describing the rationale for your research and the trial you will accomplish. Though how you organize this is largely up to you, NIH does want you to: provide a clear overall aim, description of intervention, hypothesis and design, justification for identified Stage of BI development, primary outcome and power analysis.

1. Rationale: Latino older adults are disproportionately more likely than Whites to have Alzheimer's or other dementias (14% compared to 10%; Alzheimer's Disease Facts & Figures, 2023). Latino family caregivers report more time-intensive caregiving situations due to concurrent medical conditions (e.g., diabetes and cardiovascular disease) which add additional burden. They also report more depression and less family support compared to other racial/ethnic groups. Yet, they are under-represented in caregiver' intervention research programs, which have typically enrolled well-educated non-Hispanic white caregivers.

2. Scientific Premise: Awareness of, and access to, existing dementia-related services varies across racial/ethnic groups, with Latinos being among the lowest to access formal care, due in part to reliance on family members to provide this care (National Alliance on Caregiving and AARP, 2015). However, adhering to this cultural value can be stressful or supportive, depending on actual support availability and extent of stress among family members. The proposed project will culturally adapt an existing brief, evidence-based psychoeducational program for Latino caregivers by incorporating cultural values such as familism to tailor the intervention and teach effective strategies to improve social connectedness among family members.

3. Describe Intervention: The existing Caregiver TLC program will be culturally tailored by including a focus on addressing cultural values to promote social connectedness and translated into Spanish. Caregiver TLC consists of 8 modules: stress management; behavioral activation; building resilience; building self-care skills; managing difficult emotions; reducing isolation; and two on understanding and responding to difficult behaviors of the PLWD. It is currently offered (over a HIPAA-compliant zoom teleconferencing platform) for 1.5 hrs/wk for 6-weeks to small groups of caregivers (6-10). Leaders are generally agency-based staff trained in social work who complete a 20 hr. zoom-based training program and need to show competency to deliver the program. In addition to the workshop itself, there is a comprehensive website offering complete slide sets, home practice forms, local and national resources, and recordings of webinars by program directors.

4. Innovation: Social Connectedness and Family Support: Framed within the goal-oriented theory of Selection, Optimization and Compensation (Baltes & Baltes (1990) that identifies the intervention principles, the Caregiver TLC workshop will introduce the idea of identifying and using effective strategies to overcome stress, increase support, and seek help from others by setting goals. Throughout the sessions, facilitators will teach Latino caregivers to develop effective strategies to increase family support and social connectedness. Caregivers will identify their unmet needs for services and family support, and will select/optimize goals to expand their social connectedness. At the complexion of the program, caregivers will master the ability to set goals for themselves and use effective strategies to seek support. Research suggest that caregivers who select goals and use effective strategies to attain them, report less depression and better overall psychosocial adjustment (Montoro-Rodriguez et al., 2021; 2019).

5. Study Design: To meet Aim 1 (initial program adaptation) a Community Advisory Board (CAB) will be created consisting of community leaders serving Latino caregivers, and Latino caregivers themselves (bilingual), from the three geographic regions: Rochester, San Diego, and Charlotte. This aspect of the project is considered 'preparatory to research'. This group will meet regularly with the investigators to co-design the culturally adapted version. They will be given a fully translated set of workshop

materials; each initial meeting will focus on one workshop session and feedback will be obtained on: how content is presented; appropriateness of examples and action plans; how to increase social connectedness -particularly with family members – within the context of that workshop's focus. The CAB will also review the program Website that is in English, and make recommendations to make it user-friendly for Latino caregivers. The CAB will recommend ways to use this website to increase social connectedness. CAB members need to identify as Latino, be bilingual, and have the necessary time and skills to participate. To meet Aim 2 (Stage 1B trial), based on this feedback, a preliminary adapted version will be tested in an Stage 1B trial (pre- post design). We will recruit 20 Latino caregivers and all will receive the intervention (with n=10 in each group, run sequentially). We will make refinements (if needed) based on participant and CAB feedback between the first and second group. We will collect qualitative and quantitative data with several metrics (described below). Caregivers need to be men and women, 45 years and older, who identify as primary caregivers of a PLWD with whom they co-reside or live close by. A stress rating will be used so that at least a moderate level of stress related to caregiving is endorsed. Willingness to complete interviews and surveys and provide feedback are also necessary. To address Aim 3, (mechanisms) we will assess changes in loneliness and social support and anticipate that Latino caregivers who demonstrate decreases in loneliness and increases in social support will experience lower stress levels, burden and depression.

6. Analytic Plans: We will collect qualitative and descriptive quantitative data using mixed methods: 1. Individual semi-structured interviews with members of the CAB to ask them about caregivers' needs, supportive services, cultural views and normative expectations about care. 2. Data from Focus Group participants on feasibility and acceptability of the adaptation and refinement. 3. Descriptive pre-post data from the early developmental trial (20 caregivers). Data Analytics.
a. Metrics to assess acceptability of the adapted Caregiver TLC program at conclusion of the early stage trials studies: - Number of "hits" to website and program materials; - % completed action plans; - 6 point self-report Likert scales for: program satisfaction; new skills learned; usefulness of skills; helpfulness of skills; likelihood of using skills in future. b. To measure the mechanism of social connectedness, we will administer the following before & after intervention. - Lubben Social Network Scale-6, Spanish translation (culturally adapted as well as translated into Spanish; Vilar-Compte, Vargas-Bustamante & Lubben, 2018). It is a measure of social isolation (by identifying and counting people in the network including family/ friends and identifying who to talk with about private matters"); -To measure Loneliness we will use the UCLA Loneliness Scale (full version, 20 items). Feelings of loneliness maybe inversely related to feeling connected and supported by family and friends (Russell, Peplau & Cutrona, 1980). c) Clinical outcomes: to be collected before & after early intervention trials: - Perceived Stress Scale, 10 item version (Cohen et al., 1983), available in Spanish; - Zarit Caregiver Burden 6-item version (Higginson, et al., 2010), translated into Spanish (Martin-Carrasco et al., 2010), and PHQ-9 to assess depressive symptoms (Kroenke & Spitzer, 2002; available in Spanish). d) We also assess for the role of Familism and Acculturation using the scales developed by Marin, Sabogal et al. (1987). Highly acculturated Latino dementia caregivers are likely to more extensively use support services outside the home (and rely less on family) to care for PLWD.

7. Future Directions/ Next Steps: This work is regarded as preliminary to development of an Stage II efficacy trial grant proposal to submit in 2024 which will test the acceptability of the culturally adapted Caregiver TLC in a rigorous controlled trial. We aim to develop an RO1 level multi-site Stage III-IV trial to test the efficacy of this virtual adapted Caregiver TLC program with Latino caregivers in different parts of the US.

Background Questions:

Please answer the questions below in regard to your project. Not to exceed 1 page.

What is the important public health issue ultimately to be addressed by this research?	The proposed research addresses the important public health issue of social disconnectedness, which confers high risk for poor mental and physical health, and earlier mortality. Effective, culturally appropriate interventions that promote social connection, and ultimately, caregiver well-being, are needed. The proposed study aims to conduct stage 1b intervention development research to culturally tailor and test the capacity of a caregiver intervention to increase social connectedness in Latino family caregivers. Understanding how to target social connectedness in Latino caregivers should lead to highly effective approaches that protect caregivers' well-being.
Does this issue affect a specific population? If yes, please describe the population.	Yes. We focus on Latino family members who provide care for a family member with Alzheimer's disease or related dementia (ADRD). Social disconnection – that is, loneliness and/or isolation -- is a common experience among family caregivers, with estimates indicating that up to 80% of caregivers will report feeling socially disconnected due to caregiving responsibilities. Compared to other sociocultural groups, Latinos have higher prevalence of dementia and importantly, Latino caregivers report less family support, increasing risk for social disconnectedness and poor well-being.
What is/are the hypothesized principle(s) of the proposed intervention?	The intervention is proposed to work by helping caregivers create goals that are suitable to their life circumstances (per the Selection, Optimization, and Compensation model of lifespan development; Baltes & Baltes, 1990) and that address Latino cultural values. In particular, familism, a Latino cultural value underscoring prioritization of family above self, underlies a reliance on family members to provide dementia care, resulting in Latinos', among racial/ethnic groups, being among the lowest to access formal dementia care and support services. Familism can also contribute to caregiver depression, via behavioral disengagement (Parveen et al., 2013), or foster connectedness, when family support is strong. Familism is posited to be a necessary guiding principle in the development of interventions that can effectively target social connectedness (mechanism) to promote Latino caregiver well-being (health outcome). For example, psychoeducation to increase knowledge and priorities for social connectedness require attention to how familism may play a role in caregivers' resistance to rely on supports outside of the family.
How will the hypothesized mechanism(s) of behavior change be measured? How will the principles and mechanisms be tested?	The hypothesized mechanism underlying caregiver well-being is social connectedness. We will use social connectedness measures validated with Latino adults (PROMIS social isolation, PROMIS emotional support, Lubben Social Network Scale-6; UCLA-loneliness scale). To test the role of familism in intervention outcomes, we will examine (1) whether familism is associated with less social connectedness at baseline, and, (2) regardless of familism, whether the extent of change in social engagement (measured as uptake of social opportunities afforded by the intervention platform), explains social connectedness outcomes.
Are there existing efficacious interventions for this issue in any population?	There are few efficacious interventions that target social connectedness in any population. The intervention to be tested in this proposal will add to the Roc STAR Center portfolio of interventions that target social connectedness, specifically for Latino caregivers. This will be the first group-based intervention for Latinos added to our portfolio; given heterogeneity in contributors to social disconnectedness and preferences for addressing it (including group versus individual modalities), diversifying our portfolio of interventions in this way will promote personalization and greater acceptability and eventual uptake outside of research settings.
Do efficacious interventions for this issue exist in a closely related population?	No, there are few efficacious interventions to reduce loneliness in Latino or other populations of dementia care partners.
If this proposed pilot is successful, what are your anticipated next steps? That is, what is the anticipated pathway through the Stages of intervention development? Also, what are the future plans for the study in terms of funding (e.g, a second Roybal pilot, an R01 proposal, an R21 proposal, etc.)?	The long-term objective of this research is to ensure the social connectedness and health of Latino caregivers of a family member with ADRD. Given that familism can contribute to caregiver psychological distress as well as less accessing of services that could alleviate burden and distress, subsequent, larger-scale studies will address the pathway linking social engagement/connectedness to dementia support services and care use and, ultimately, well-being. Toward this end, we will follow the current stage 1a and 2b work with a Stage II efficacy study to test effects of Caregiver TLC on social connectedness, dementia care services and supports use, and longer-term caregiver psychological well-being. Following that, a multi-site Stage III-IV clinical trial is envisioned, to evaluate the efficacy of this program with Latino caregivers in different regions of the US.
How will this pilot advance science within the portfolio of Alzheimer's Disease & Related Dementias?* * Specific to AD/ADRD Roybal Centers	Social disconnection – that is, loneliness and/or isolation -- is a common experience among family AD/ADRD caregivers, with estimates indicating that up to 80% of caregivers will report feeling socially disconnected due to caregiving responsibilities. Yet, there remains a lack of effective loneliness interventions for caregivers. This early stage clinical trial will advance understanding of culturally-informed and tailored approaches that can substantially foster social connectedness and health and well-being among Latino caregivers.

Data and Resource Sharing

The STAR Center Data and Resource Sharing Plan will be used for this project.

Appendix 2

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload protocols, grants, proposals
File Name: SESSION by SESSION OUTLINE Draft for CAB to Review 10_18_23.docx

Caring Together (Cuidando Juntos)
Session by Session Outline- Draft 10/18/23 based on current CG TLC

Session 1: Stress & Frustration

10m Greetings/ informal conversation

20m Introductions of facilitators, of participants, of workshop & expectations

20m T1. Stress

What is stress, why it is not good for caregivers physically and mentally, cg & stress

How to recognize **you** are stressed – ask CGs to identify where in their body (and mind or feelings) they experience stress – and share with the group

What to do about stress - Relaxation Skills / Breathing is the key!

Practice Activity - Deep Breathing & Visualization

20m T2. What to do when your frustrated

Getting frustrated is normal but it increases our feelings of being stressed

Knowing where you are on the continuum of frustration …..anger

Practice Activity- How do you know?

Tips and Strategies

10 Breaths, Are you feeding your frustration?, STOP (will need a different acronym in Spanish as this doesn't translate well)– PRACTICE in session

10m Summary: review of session

25m Goal planning for following week – explain process & help CG set up individual goals

Active goals (instrumental; getting formal/informal help)

Connecting goals (emotional; connecting w/someone)

15m Last Questions / POLL/ Resource Sharing(informal sharing (i.e. recipe, podcast etc.)/ Close

Session 2: Asking for Help

10m Greetings

20m Goal Check-In – interactive – review progress/ discuss obstacles/ problem solve

Check in on instrumental goals

interactive discussion followed by brief **poll** (do you think you reached, yes/no, if no why) to collect data for the research

Check in on connecting goals

interactive discussion followed by brief **poll** to collect data

20m T1. Care checklist – each person asked to do this privately & share if comfortable

Who is in your network? What do they do for you?

Where are the gaps/ What do you need?

Activity - creating a task list & support list: who can you ask for help/ support?

20m T2. Getting the Family involved – interactive (breakout sessions to increase discussion)

Getting help from friends and family, Using the tasks and support list, HOW TO ASK FOR HELP in such a way that you're likely to get it!

Family communication & family meetings family conflict strategies

10m Summary: review of session

20m Goal planning for following week – each CG creates at least one goal in each area
Active goals (instrumental)
Connecting goals (emotional)
15m Last Questions / POLL/ Resource Sharing / Close

<u>Session 3: Challenging Behaviors</u>
10m Greetings
20m Goal Check-In- interactive - review progress/ discuss obstacles/ problem solve
Check in on instrumental goals
interactive discussion followed by brief **poll** to collect data
Check in on connecting goals
interactive discussion followed by brief **poll** to collect data
10m T1. Challenging Behaviors that cause stress to the CG (statement to normalize stress, frustration, anger)
What are they and why they occur
10m T2. Breaking Down the Behavior
Triggers - what they are and why they're important
Behavior – just the facts
Reactions – how you or the person you are caring for reacts
30 m Examples (done together) Identify behavior, triggers, & reactions unique to each CG
Good one to start off with: PWD wants to drive, no longer has license – trigger: sees key On kitchen table, grabs it & starts out the door. CG reacts: you can't do that anymore, You don't have a license – maybe she runs after him to try & stop him & they argue
10m Summary: review of session
20m Goal planning for following week –
Active goals (instrumental)
Connecting goals (emotional)
10m Last Questions / POLL/ Resource Sharing/ Close

<u>Session 4: Handling Challenging Behaviors with Less Distress</u>
10m Greetings
20m Goal Check-In -
Check in on instrumental goals
interactive discussion followed by brief poll to collect data
Check in on connecting goals
interactive discussion followed by brief poll to collect data
30m T1. Review their experiences identifying triggers / behaviors/ reactions
Interactive – important to rule out medical issues – as cause of behavior
Strategies for Change, Based on Trigger, Based on CG Reaction –
Strategies for CG to RESPOND to difficult behaviors – not "react" to them
30m T2. Some known successful strategies – interactive -
General strategies: CG RELAXATION / Mindful breathing/ taking "time out"
What you can try: Agitation & Aggression, Wandering, Losing Inhibition, Sundowning, Sleep Disturbances, Hoarding, Paranoia & Accusing

10m Summary: review of session

20m Goal planning for following week - each CG creates at least one goal in each area

Active goals (instrumental)

Connecting goals (emotional): goal for diffusing situation, try it for next week

10m Last Questions / POLL/ Resource Sharing/ & Close

<u>Session 5: Doing things together</u>

10m Greetings

20m Goal Check-In - interactive - review progress/ discuss obstacles/ problem solve

Check in on instrumental goals

interactive discussion followed by brief poll to collect data

Check in on connecting goals

interactive discussion followed by brief poll to collect data

30m T1. Staying Happy/ Having Joy in your Life Despite the Dementia

For the caregiver: Positive Activities – Intro – discover your unique activities

List, Plan, Schedule, Execute

Importance of writing down activities/ keeping a diary

For your loved one: using BA with them, similarities & differences, flexibility –

Importance of shared positive activities with loved one AND FAMILY/ NETWORK

30m T2. Creating a strong foundation for staying strong as new challenges occur

Four pillars of resilience/ strength to continue: Physical, Mental, Spiritual, Social

Why is sleep important and tips to help (sleep hygiene)

Why staying active is one of the best things you can do to build a strong foundation

Overcoming barriers to staying active

What you can do for your mental health

Connecting spiritually

Connecting socially

10m Summary: review of session

20m Goal planning for following week - each CG creates at least one goal in each area

Active goals (instrumental)

Connecting goals (emotional)

10m Last Question / POLL/ Resource Sharing/ & Close

<u>Session 6: Putting New Skills into Action - Celebratory "tone" -</u>

10m Greetings

15m Goal Check-In - interactive - review progress/ discuss obstacles/ problem solve

Check in on instrumental goals

interactive discussion followed by brief poll to collect data

Check in on connecting goals

interactive discussion followed by brief poll to collect data

30m T1. Review skills learned by session – interactive

Session by session, review skills taught;

ask CGs to self-identify their strength –"I feel more empowered"

30m T2. Planning for the Future: Making change work for you – each CG develops his/her own Action Plan, with prompts from the facilitators & assistance if needed

Action Plans: What is an action plan?

Anticipate future challenging situations/ do any skills taught apply to them

What to do if things get overwhelming?? Where to turn for assistance, support?

20m Summary: Fiesta/ CELEBRATE their Success!

Celebrate each person's success:

Facilitators award certificates, share something positive about each caregiver, each caregiver shares a growth/achievement b/c of what they learned (i.e., better advocate, because of skills they learned)

Opportunity for conversation and sharing of contact information if they want.

Leave with action plan

10m Final thoughts/ POLL (overall evaluation of program)

Appendix 3

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Data Collection Materials
File Name: Project 9 Measures.docx

Analytic Plans: Measures (English/Spanish)

We will collect qualitative and descriptive quantitative data using mixed methods:

1. **Focus groups & Individual semi-structured interviews with members of the CAB to ask them about caregivers' needs, supportive services, cultural views and normative expectations about care.**

   Sample questions (English/Spanish):

A) What are the main environmental demands for Latino caregivers providing care to PLVD in the community? ***SPANISH***: Indicar las necesidades y retos que los Latinos experimentan como cuidadores de familiares con demencia en la comunidad

B) What are the main competencies and skills that Latino caregivers need to care for their relatives with dementia in the community? ***SPANISH***: Indicar las habilidades y destrezas más importantes que los Latinos necesitan para mejorar el cuidado a familiares con demencia.

C) What are the main sources of informal and formal support available for Latino caregivers providing care to PLVD in the community? ***SPANISH***: Indicar los servicios de apoyo informal y formal disponibles para Latinos que cuidan de familiares con demencia en la comunidad.

D) What are the main cultural barriers/opportunities for Latino caregivers providing care to PLVD in the community? ***SPANISH***: Indicar los aspectos culturales que son barreras o facilitadores para Latinos que cuidan a familiares con demencia en la comunidad.

2. **Focus Group to included program facilitators and consented participants in the pilot demonstration to report on the feasibility and acceptability of the adaptation:**

   Sample questions (English/Spanish):

A) What are the main difficulties Latino caregivers may encounter with the Caring Together educational program regarding content topics, activities, structure, design, resources, and use of technology? ***SPANISH***: Indicar las dificultades con diversos aspectos del programa para Latinos que cuidan de familiares con demencia (sobre el contenido, actividades, estructura, diseño, recursos y uso de la tecnología)?

B) What are the expected levels of satisfaction and acceptability of the Caring Together educational program among Latino caregivers of PLVD in the community? ***SPANISH***: Indicar las expectativas de aceptación y satisfacción con el programa para Latinos que cuidan de familiares con demencia en la comunidad.

C) What are the main values recognized/ignored by the Caring Together educational program for Latino caregivers of PLVD in the community? ***SPANISH***: Indicar los valores culturales adoptados/ignorados por el programa para Latinos que cuidan de familiares con demencia.

3. Descriptive pre-post data from the early developmental trial (20 caregivers). Measures to assess the feasibility and acceptability of the program by participants in the pilot study.

Sample questions (English/Spanish):

A) Percentage of Completed action plans. ***SPANISH***: Indicar porcentaje de Latinos que completan el plan de acción del programa.

B) Likert six-point self-report scales for: program satisfaction; new skills learned; usefulness of skills; helpfulness of skills; likelihood of using skills in future. ***SPANISH***: Uso de escalas de tipo Likert para medir los niveles de satisfacción sobre el programa, el uso y utilidad de las habilidades y destrezas aprendidas, las estrategias y uso anticipado de las mismas.

C) Measures of Social Connectedness, we will administer the following before & after intervention.

Lubben Social Network Scale-6, Spanish translation (culturally adapted as well as translated into Spanish; Vilar-Compte, Vargas-Bustamante & Lubben, 2018). It is a measure of social isolation (by identifying and counting people in the network including family/ friends and identifying who to talk with about private matters".

UCLA Loneliness Scale by Vazquez Morejon, A.J., Jimenez Garcia-Boveda, R. 1994. RULS: Escala de Soledad UCLA Revisada. Fiabilidad y Validez de una version Española.

SPANISH: **Items que componen la escala:**

1.- Sintonizo (me llevo bien) con la gente que me rodea
2.- Me falta compañía
3.- No tengo a nadie con quien yo pueda contar
4.- Me siento solo/a
5.- Me siento parte de un grupo de amigos/as
6.- Tengo muchas cosas en común con la gente que me rodea
7.- No tengo confianza con nadie
8.- Mis intereses e ideas no son compartidos por las personas que me rodean
9.- Soy una persona abierta (extrovertida)
10.- Me siento cercano/a de algunas personas
11.- Me siento excluido/a, olvidado/a por los demás
12.- Mis relaciones sociales son superficiales
13.- Pienso que realmente nadie me conoce bien
14.- Me siento aislado/a de los demás
15.- Puedo encontrar compañía cuando lo necesito
16.- Hay personas que realmente me comprenden
17.- Me siento infeliz de estar tan aislado/a
18.- La gente está a mi alrededor pero no siento que esté conmigo
19.- Hay personas con las que puedo charlar y comunicarme
20.- Hay personas a las que puedo recurrir

Goal Setting and Attainment (SOC strategies)

D) Clinical outcomes: to be collected before & after early intervention trials:

Perceived Stress Scale, 10 item version (Cohen et al., 1983), available in Spanish

Zarit Caregiver Burden 6-item version (Higginson, et al., 2010), translated into Spanish (Martin-Carrasco et al., 2010)

PHQ-9 to assess depressive symptoms (Kroenke & Spitzer, 2002; available in Spanish).

E) Control factors such as:

Familism & Acculturation measures using the scales developed by Marin, Sabogal et al. (1987).

Appendix 4

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Consent Materials
File Name: Program Consent Form Cuidando Juntos Consent form November 2023.docx

IRB#: 24-0291-01

College of Health & Human Services, School of Social Work
9201 University City Boulevard, Charlotte, NC 28223-0001

Consent to Participate in a Research Study

Title of the Project:	Cuidando Juntos: A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers
Principal Investigator:	Julian Montoro-Rodriguez, Ph.D., Professor of Gerontology
Study Sponsor:	Rochester Roybal Center for Social Ties and Aging Research (the STAR Center) Pilot Program Award

You are invited to participate in a research study. Participation in this research study is voluntary. The information provided is to help you decide whether to participate. If you have any questions, please ask. Please contact the research team with any questions at 704-687-6166 or jmontoro@charlotte.edu

Important Information You Need to Know

- The purpose of this study is to develop an ONLINE support program for caregivers providing care to people with dementia. Specifically, we will develop an evidence-based educational program for caregivers (Cuidando Juntos) to help them to reduce stress and depression and improve social support. We will invite you to attend a Zoom video conference workshop over six weekly sessions. In addition to the workshop program, we will ask you to answer a few surveys at various points throughout the 2-month duration of the program.
- Some of the questions we will ask you are personal and sensitive. For example, we will ask you about the types of stressful caregiving experiences you have had questions about your relationship with your care recipient. These questions are personal, and you might experience some mild emotional discomfort. You may experience a reduction in your level of stress and gain better mastery and skills in providing care for your family members with dementia. These gains are not guaranteed. Please read this form and ask any questions you may have before you decide whether to participate in this research study.
- Your total time commitment if you participate in this study will be approximately 2 months.

Why are we doing this study?
The purpose of this study is to develop an ONLINE support program for caregivers providing care to people with dementia.

Why are you being asked to be in this research study?

You are being asked to be in this study because you are a Spanish-speaking Latino caregiver to a family member or loved one with dementia and are aged 45 and older.

What will happen if I take part in this study?

- If you choose to participate you will complete surveys two times. These questionnaires will be completed once prior to the workshop program and once up to one week after completing. Surveys will be completed online. The research team will email you a link to each survey. The

survey will ask questions about caregiving outcomes (anxiety, depression, burden, etc.) and quality of life (well-being, satisfaction with life).

- You will be asked to participate in an online evidence-based educational program for caregivers. It consists of 6 weekly sessions led by a trained facilitator via a Zoom teleconferencing platform for 120 minutes per session. The sessions will be recorded (audio and visual). Only members of the research team will have access to these recordings.
- The **first** component of this study includes completing a pre and post assessment questionnaire (2) online regarding caregiving outcomes (anxiety, depression, burden, self-efficacy) and quality of life (well-being, satisfaction with life). We will email you with a link to access the questionnaire online via the email you provided. Surveys will take approximately 1 hour to complete and all information will be kept confidential. Assessment will be done before and after completing the Cuidando Juntos program. Participation in these online questionnaires is completely voluntary and you can choose to withdraw from the study at any time.
- The **second** part entails attending the educational workshop program. It consists of 6 sessions led by a trained facilitator and held over consecutive weeks, via the HIPPA compliant Zoom teleconferencing platform for 120 minutes per session. Trained facilitators will contact you via the email provided with links to each program module and invitations to the weekly Zoom sessions. Participation in each of these sessions is voluntary and you can choose to withdraw from the program at any time. These sessions will be recorded (audio and visual). Only members of the research team will have access to these recordings. The content will address the following topics:
    a. Stress & Frustration (Session 1)
    b. Asking for Help (Session 2)
    c. Challenging Behaviors (Session 3)
    d. Handling Challenging Behaviors with Less Distress (Session 4)
    e. Doing things together (Session 5)
    f. Putting New Skills into Action (Session 6).

- The **third** part entails responding to semi structured interview questions after completing the 6-week Cuidando Juntos. These questions will assess the cultural appropriateness of the program, barriers Latino caregivers face, satisfaction, and difficulties with the program.

What benefits might I experience?

Caregivers may experience a reduction in their level of stress, gain better mastery and skills in providing care for family members with dementia, and increase instrumental and emotional social support. These gains are not guaranteed.

What risks might I experience?

The questions we will ask you are personal and sensitive. For example, we will ask you about the types of stressful caregiving experiences you've had questions about your relationship with your care recipient. You might experience some mild emotional discomfort when answering these questions. We do not expect this risk to be common and you may choose to skip questions you do not want to answer. We will keep all your answers and information confidential. Only members of the research team will be able to connect your name to your answers.

How will my information be protected?

- You are asked to provide your name and email address as part of this study. You can also choose to provide your phone number if this is your preferred method of contact regarding questions for members of the research team. We will use your email address to contact you with instructions and links to the surveys, Cuidando Juntos program modules, and Zoom meeting invites. We will use your name to link your questionnaires from the pre and post surveys.
- To protect your privacy (identity), we will assign a study ID code to your questionnaires responses. Once we do this, we will delete your name from the questionnaire responses so the

responses will only have the study ID code. Finally, once your participation in the study has concluded we will delete your email address unless you agree to be contacted for future research studies or to receive information regarding the results of the present study. While the study is active, all data will be stored in a password-protected database that can be accessed by the primary researcher and project coordinator.

- Video recordings of the sessions will be stored in a secure password-protected database that can be accessed by the primary researcher and project coordinator.
- Only the research team will have routine access to the study data. Other people with approval from the Primary Investigator may need to see the information we collect about you. Including people who work for UNC Charlotte and other agencies as required by law or allowed by federal regulations.

How will my information be used after the study is over?

After this study is complete, study data may be shared with other researchers for use in other studies without asking for your consent again or it may be needed as part of publishing our results. The data we share will NOT include information that could identify you.

Will I receive an incentive for taking part in this study?

You will not receive an incentive for taking part in this study.

What other choices do I have if I don't take part in this study?

Only participants who consent to complete the Cuidando Juntos program will have access to the Cuidando Juntos modules and facilitator support. Individuals who choose not to take part in this study will have access to a list of general resources for FCGs available on the project website.

What are my rights if I take part in this study?

It is up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

Who can answer my questions about this study and my rights as a participant?

For questions about this research, you may contact the Principal Investigator, Professor Julian Montoro-Rodriguez, Ph.D., jmontoro@charlotte.edu, 704-687-6166.

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the Office of Research Protections and Integrity at 704-687-1871 or uncc-irb@charlotte.edu.

Consent to Participate

You should have received a link to a survey containing this documents and will be asked to provide electronic consent that you agree to participate in this study. This document is for your records. If you have any questions about the study after reviewing this document, you can contact the study team using the information provided above.

Appendix 5

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Recruitment Materials
File Name: cuidando juntos flyer (1).docx

IRB: 24-0291-01

Cuidando Juntos

SUPPORTING FAMILY CAREGIVERS

Do you provide a broad range of assistance for an adult relative, partner, friend or neighbor with a chronic or disabling condition?

What is Caregiver Cuidando Juntos?

The Cuidando Juntos Research Program will develop a FREE ONLINE support to caregivers providing care to people with dementia. Caregivers will complete six weekly virtual Zoom sessions led by trained facilitators. This workshop will teach caregivers coping skills to deal with stress, depression, burden and other well-being strategies.

Is Cuidando Juntos For Me?

- Do you provide care to a person with memory loss? For example, Do you help your family member:
  - To remember appointments?
  - Get bathed or dressed in the morning?
  - To remember take medications on time
- Could you attend six weekly 2-hour virtual sessions?
- Would you like to connect with other caregivers near you?
- Do you have a personal email address?

* Technical support will be available to assist you with Zoom access and usage

How Do I Learn More and Register?

- To register: Visit the Caregiver TLC Website at: To Be added
- Questions: contact us at JMONTORO@Charlotte.EDU or call at 704-687-6166

Appendix 6

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Other Approval/Agreements
File Name: IRB Cuidando Juntos CAB MOU.docx

Cuidando Juntos: Memorandum of Understanding for Community Advisory Board Members (CAB)

Between

(CAB Member Name)

and

(Julian Montoro-Rodriguez, Ph.D.

UNC Charlotte)

This Memorandum of Understanding (MOU) sets for the terms and understanding between (CAB member name) and the PI of the Project, Julian Montoro-Rodriguez, Ph.D., UNC Charlotte to serve on the Community Advisory Board for the Cuidando Juntos Program.

The above goal will be accomplished by undertaking the following activities:

I. CAB Meetings: Attendance and Responsibilities

1) Attendance

CAB members are required to attend up to 10 virtual meetings at the scheduled dates and times below. Meetings will be recorded (audio and visual). Only members of the research team will have access to these recordings.

Meeting	Date	Time
Introductory Meeting	10/25/2023	4-5pm (ET)/1-2pm(PST)
Session 1 Meeting	11/1/2023	4-5pm (ET)/1-2pm(PST)
Session 2 Meeting	11/8/2023	4-5pm (ET)/1-2pm(PST)
Session 3 Meeting	11/15/2023	4-5pm (ET)/1-2pm(PST)
Session 4 Meeting	11/29/2023	4-5pm (ET)/1-2pm(PST)
Session 5 Meeting	12/6/2023	4-5pm (ET)/1-2pm(PST)
Session 6 Meeting	12/13/2023	4-5pm (ET)/1-2pm(PST)
First Draft	Jan. or Feb. 2024	TBD
Second Draft	March or April 2024	TBD
Final Draft	May or June 2024	TBD

2) **Meeting Responsibilities/Tasks**

CAB members will engage in and complete the following tasks prior to and during the scheduled virtual meetings:

a) One-week prior to each scheduled virtual CAB meeting, CAB members will be emailed the materials in English (and/or Spanish depending on the stage of the Program) to be reviewed during the scheduled meeting for that week. Members are expected to read the materials and prepare notes to be discussed during the meeting. CAB members should focus on the cultural appropriateness of the materials.

b) During each weekly meeting, CAB members will be guided through the materials they reviewed and asked to provide written feedback in response to a series of questions regarding the cultural appropriateness of the materials and culturally appropriate and available resources for caregivers.

c) After each meeting, CAB members are expected to email their written feedback to a member of the research team (email address to be provided) no later than 48 hours after the meeting has ended.

II. Compensation

Each CAB member will be compensated for the time spent attending each meeting, reviewing materials, and providing feedback. Each CAB member will be compensated $200 per meeting attended, provided all required tasks are successfully completed for that meeting.

This MOU is at-will and may be modified by mutual consent of authorized officials.

Signature:

Name (First and Last) _____ Date:_____
(CAB Member)

Signature:_____ Date:_____
(CAB Member)

PI Name: Julian Montoro-Rodriguez Date:_____

PI Signature: _____ Date: _____

Please email a signed copy of this MOU to Julian Montoro-Rodriguez, Ph.D. at Jmontoro@charlotte.edu. This signed copy will serve as the acknowledgement of the duties and understanding of responsibilities as outlined in this MOU.

Appendix 7

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Other Approval/Agreements
File Name: Individual-Investigator-Agreement Ramsey (1).docx

UNIVERSITY OF NORTH CAROLINA CHARLOTTE | DIVISION OF RESEARCH

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): UNC Charlotte

Applicable FWA #:

Individual Investigator's Name: Jennifer Ramsey

Specify Research Covered by this Agreement: Caring Together: A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date _10.21.2023_____

Name: Ramsey_____Jennifer_____L. _____ Degree(s): __Ph.D.___
(*Last*) (*First*) *(Middle Initial)*

Address: _1430 Lonan Drive_____phone #: 330-360-3842_____

__Waxhaw_____NC_____28173_____
(*City*) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee):

_____ Date: _____

John L. Daniels, D.Eng., P.E.
Interim Vice Chancellor for Research, UNC Charlotte 9201 University City Blvd., Charlotte, NC 28223-0001; PH: 704-687-8428

Appendix 8

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Other Approval/Agreements
File Name: MQ Individual-Investigator-Agreement (1) (1).docx

UNIVERSITY OF NORTH CAROLINA CHARLOTTE | DIVISION OF RESEARCH

Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): UNC Charlotte

Applicable FWA #: NA

Individual Investigator's Name: Maria M. Quiñones

Specify Research Covered by this Agreement: Caring Together: A Cultural Adaptation of the Caregiver TLC Psychoeducational Program to Support Latino Caregivers

(1) The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.

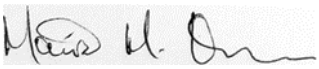
(9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.

(11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature:  Date 10/30/2023

Name: _Quiñones_____Maria_____M._____ Degree(s): PhD
(*Last*) (*First*) (*Middle Initial*)

Address: __225 Crittenden Blvd_____ phone #: 585-276-3903

_____Rochester_____NY_____14642_____
(*City*) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee):

_____ Date: _____

John L. Daniels, D.Eng., P.E.
Interim Vice Chancellor for Research, UNC Charlotte 9201 University City Blvd., Charlotte, NC 28223-0001; PH: 704-687-8428

Appendix 9

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Training and Other Materials
File Name: Ramsey citiCompletionReport3321039.pdf

CITI PROGRAM

Completion Date 11-Dec-2020
Expiration Date 11-Dec-2023
Record ID 36483476

This is to certify that:

Jennifer Ramsey

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 2: Social-Behavioral-Educational Researchers - HSR Basic
(Course Learner Group)
3 - Refresher Course
(Stage)

Under requirements set by:

North Carolina State University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w9819d353-fc8c-48df-9a11-0a222d716f18-36483476

Appendix 10

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Training and Other Materials
File Name: CITI JMR.pdf

CITI PROGRAM

Completion Date 11-Jan-2021
Expiration Date 10-Jan-2025
Record ID 25388603

This is to certify that:

Julian Montoro-Rodriguez

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Social & Behavioral Research - Basic/Refresher
(Curriculum Group)
Social & Behavioral Research (IRB) - Basic/Refresher
(Course Learner Group)
3 - Refresher Course
(Stage)

Under requirements set by:

University of North Carolina at Charlotte

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?wbce3e21e-20bf-4321-9794-ab3482ef58e0-25388603

Appendix 11

EForm Name: Initial Application
Page: **Study Attachments**
Section: Attachments
Question: Upload Training and Other Materials
File Name: MQ citiCompletionCertificate_1399471_50532615 (1).pdf

CITI PROGRAM

Completion Date 07-Oct-2022
Expiration Date 06-Oct-2025
Record ID 50532615

This is to certify that:

Maria Quiñones

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

GCP – Social and Behavioral Research Best Practices for Clinical Research
(Curriculum Group)
GCP – Social and Behavioral Research Best Practices for Clinical Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

University of Rochester

CITI
Collaborative Institutional Training Initiative

101 NE 3rd Avenue, Suite 320
Fort Lauderdale, FL 33301 US
www.citiprogram.org

This GCP training contains all of the attested CITI Program modules from the **GCP SBR Advanced Refresher Version 2**. This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Verify at www.citiprogram.org/verify/?w737af809-ee31-4886-8f73-8f5148cf5117-50532615