Clinical Interventional Study Protocol Template

PREFACE

The Clinical Intervention Study Protocol Template is a suggested format for clinical trials sponsored by the National Institute on Aging (NIA). Investigators are encouraged to use this format, as appropriate, when developing protocols for their studies. Large multi-site observational studies will also benefit from this protocol template.

Note that instructions and explanatory text are indicated by italics and should be replaced in your protocol with appropriate text. Section headings and template text formatted in regular type should be included in your protocol document as provided in the template.

The goal of this template is to provide a general format applicable to all single- and multicenter clinical intervention trials (e.g., drug, surgery, behavioral, nutritional, device, etc).

As you can see the version number and date are on the bottom of each page. When making changes to an approved and "final" protocol, please provide a summary of the changes, with the date, at the front of the protocol.

VIRTUAL TRAINING FOR LATINO CAREGIVERS TO MANAGE SYMPTOMS OF DEMENTIA

Study Chairman or Principal Investigator: Magaly Ramirez, PhD, MS, MS, Assistant Professor, University of Washington School of Public Health, Department of Health Services

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TABLE OF CONTENTS **PAGE**

PRÉCIS

Study Title

Virtual Training for Latino Caregivers to Manage Symptoms of Dementia

Objectives

The objectives of this study are to: (1) culturally and linguistically adapt the STAR-VTF online training modules for Latino caregivers of people living with dementia (PLWD), (2) pilot test Latino caregivers' responses to the adapted online training modules, and (3) develop a REDCap survey to pragmatically collected caregiver outcomes in a future study.

Design and Outcomes

The study will use a single-arm pilot trial design with Latino caregivers of PLWD. We will assess self-reported outcomes at baseline and 6-8 weeks post-enrollment using a REDCap survey. Outcome measures will include the Revised Memory and Problem Behavior Checklist and Preparedness for Caregiving Scale. In addition, we will assess caregivers' perceived usability of the online training modules, and we will conduct

qualitative interviews 6-8 weeks post-enrollment. The interviews will assess caregiver satisfaction with and acceptability of the adapted online training modules.

Interventions and Duration

For 6-8 weeks, caregivers will complete online training modules asynchronously. They will access the modules via email or text message. There are 7 online training modules. Caregivers will be instructed to complete one module per week. The content of the modules is as follows: Module 1 provides an understanding and overview of dementia; Module 2 introduces caregivers to the behavioral treatment of dementia, realistic expectations, and effective communication; Module 3 covers the ABC (antecedents, behaviors, consequences) approach to problem-solving, including rationale and development of an ABC plan; Module 4 instructs caregivers to review the ABC plan and revise as needed; Module 5 covers pleasant events and managing negative thinking; Module 6 instructs caregivers to review the ABC plan, pleasant activities schedule, and to revise as needed; Module 7 covers coping with caregiving and maintaining gains. Each module takes about 15 minutes to complete. The modules use text, pictures, and illustrations with a voiceover presentation. Caregivers will receive the online training modules in their preferred language (English or Spanish). They will also receive a workbook to accompany the lesssons. The total length of time each caregiver will be in the study is approximately 8 weeks.

Sample Size and Population

Participants will: be aged 18 years or older, live with PLWD or within 5 miles, provide at least 8 hours of care per week, provide care to PLWD who lives at home, and self-identify as Hispanic/Latino. We expect to enroll up to 20 participants. The primary objective of this study is to pilot test the adapted online training modules. Therefore, it is not powered to detect an effect of the intervention.

STUDY TEAM ROSTER

Principal Investigator: **Magaly Ramirez, PhD, MS, MS**

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Dr. Ramirez will provide overall direction and oversight of the research study. Responsibilities will include culturally and linguistically adapting the online training modules, reviewing Spanish translations of materials, designing the interview guide, managing recruitment and data collection, conducting analysis and interpretation of results, and refining online training modules based on the results. In addition to overall project responsibility, Dr. Ramirez will supervise the research coordinator working on the project.

Co-Investigator: **Robert Penfold, PhD**

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Dr. Penfold will consult on the project, provide access to all existing STAR-VTF intervention materials, and provide input and guidance on the adaptation of the STAR-VTF online training modules. Dr. Penfold will also collaborate on planned analyses and the preparation of presentations and manuscripts. To accomplish these tasks, Dr. Penfold will participate in regular team meetings.

Research Coordinator: **Celeste Garcia, CHES**

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Celeste Garcia will assist with the human subjects application, adaptations of the online training modules, programming of REDCap survey, recruitment of study participants, providing study participants with access to online training modules and REDCap survey, helping to address any technical issues encountered by study participants, data collection and analysis, and management of participant incentives. In addition, Ms. Garcia will coordinate with a translation company for Spanish translations of all materials.

Research Assistant: **Lily Zavala**

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Lily Zavala will assist with the programming of REDCap surveys, recruitment of study participants, providing study participants with access to online training modules and REDCap survey's, data collection and analysis, and management of participant incentives.

PARTICIPATING STUDY SITES

All human subjects activities will be conducted at the University of Washington.

Study Site Investigator: **Magaly Ramirez, PhD, MS, MS**

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1 STUDY OBJECTIVES

1.1 Primary Objective

This pilot study is not testing hypotheses.

1.2 Secondary Objectives

The objectives of this study are to: (1) culturally and linguistically adapt the STAR-VTF online training modules for Latino caregivers of PLWD, (2) pilot test Latino caregivers' responses to the adapted online training modules, and (3) develop a REDCap survey to pragmatically collected caregiver outcomes in a future study.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Latinos are more likely to develop Alzheimer's disease and related dementias (ADRD). Driven by the growing population of older Latino adults in the U.S., the number of Latino PLWD is projected to increase more than nine fold from 379,000 in 2012 to 3.5 million by 2060.[1] Older Latino adults have a higher incidence and prevalence of ADRD compared to older White adults.[2] These differences are due in large part to the health conditions (e.g., diabetes) and socioeconomic factors (e.g., chronic exposure to economic and social adversity, lower levels and quality of education, and discrimination) that are more prevalent in Latino populations and that are associated with cognitive decline.[3,4] Despite Latinos being 1.5 times more likely to develop ADRD than White adults,[2] there is currently a lack of culturally-competent, accessible, and scalable interventions for Latino families.

Latino PLWD have a higher prevalence of behavioral and psychological symptoms of dementia (BPSD) and their caregivers have a higher risk of depression, yet they remain underrepresented in research. Among community-dwelling PLWD, the prevalence of BPSD is higher among Latinos compared to White people, even after adjusting for age, gender, education, income, cognitive and functional status, and caregiver characteristics.[5] Prevalence of behavior problems in older adults is positively associated with caregiver burden and depression.[6] Furthermore, behavior problems play a larger role in predicting caregiver burden and depression than do the physical and cognitive impairments of older adults, hours per week providing care, number of care tasks, and duration in the caregiver role. Latino caregivers of PLWD are at higher risk for and have higher levels of depression compared to White caregivers.[7–11] Despite these disparities, Latinos are continually underrepresented in dementia research. Dozens of interventions for managing BPSD in PLWD and for improving the well-being of their caregivers have been developed and tested in the U.S.[12] However, these interventions have been tested predominantly with White caregivers. To address ethnic disparities in health and research, a pragmatic trial design must include the recruitment of Latino caregivers of PLWD.

Latinos experience worse quality of care and discrimination when accessing ADRD care. Compared to White people, Latinos are less satisfied in their communication with healthcare providers, are more likely to perceive that providers fail to provide needed information, and are more likely to report having a problem understanding healthcare providers.[13–15] Spanish-speaking Latinos report much worse experiences with healthcare than White people.[13,15–17] In a national survey, nearly 60% of Latino caregivers of PLWD report having faced discrimination when navigating healthcare settings for PLWD.[18] For 85% of Latino caregivers in the survey, it was important that healthcare providers treating ADRD understand their ethnic background, but less than 60% felt confident about having access to culturally-competent healthcare. Our preliminary work indicates that providers miss opportunities to identify Latino caregivers that need supportive services for managing BPSD. Barriers include caregiver-provider language discordance and differences in communication styles, particularly as it relates to the topic of BPSD. For this reason, culturally and linguistically adapting evidence-based interventions, like STAR-VTF, is a critical aspect in the design of pragmatic trials.

Latino caregivers face barriers in seeking ADRD healthcare. Like other minority caregivers of PLWD, Latinos tend to attribute memory loss to normal aging, normalize behavioral and psychological symptoms, and hide problems with symptoms to avoid stigmatization of their family member.[19] This stems from the lack of culturally- and linguistically-competent information about dementia that is available in these communities, rather than from culturally-influenced beliefs. The normalization of symptoms and the stigmatization of the disease is a major barrier to seeking ADRD healthcare. Other major barriers for Latino caregivers include clinicians' lack of knowledge about the differences between normal aging and early signs of dementia, lack of Spanish-speaking clinicians, and experience of discrimination in healthcare settings.[18–20] Our preliminary work indicates that Latino caregivers hesitate to raise concerns about BPSD with healthcare providers due to language discordance and health literacy factors. Interventions such as STAR-VTF embedded in healthcare systems can help to raise Latino caregivers' awareness about the availability of culturally-competent, nonpharmacological treatments for improving management of BPSD at home.

STAR-VTF is an evidence-based virtual intervention to support caregivers in managing BPSD. STAR-C Virtual Training and Follow-up (STAR-VTF) is a virtual adaptation of a systematic and standardized behavioral approach – known as the Seattle Protocols – to training caregivers to reduce BPSD in community-dwelling PLWD. The Seattle Protocols teach caregivers the ABCs of behavior change – a process that involves identifying specifics about the problem under consideration, identifying possible environmental or interpersonal factors that lead up to and sustain their occurrence, and systematically altering those factors to reduce problems.[21] The Seattle Protocols were consolidated into the STAR-C program wherein coaches (master's degree or equivalent in

psychology, social work, or a related field) visit caregivers at home to deliver the training.[22] The condensed 6-week program involves 4 in-home sessions and 2 telephone sessions.[23,24] A randomized controlled trial was conducted to compare STAR-C to routine medical care in English-speaking, predominantly White participants.[23] The study population included only 1 Latino caregiver (randomized to control arm). At 6 months, caregivers randomized to the intervention arm had significantly lower depression, subjective burden, and caregiver reaction scores.

To ease translation, STAR-VTF was developed and is now being tested in a pragmatic trial at Kaiser Permanente Washington (KPWA).[25,26] STAR-VTF delivers the same content as STAR-C but in an entirely virtual environment.[26] For 6-8 weeks, caregivers complete 6 online training modules asynchronously and have 6 30-minute weekly telephone check-ins with a coach (social worker or mental health counselor). The 6 modules cover the same content as STAR-C (Table 1). The modules are hosted on the Kaiser Permanente School of Allied Health Sciences learning management system. Currently, only caregivers participating in the ongoing pragmatic trial at KPWA have access to this website. Our preliminary data identified potential areas of misfit between STAR-VTF and Latino caregivers. The modules: do not sufficiently address dementia literacy, use language/semantics that could be insensitive, and do not reflect Latino cultural values that could influence family structures and views of caregiving.

Table 1. STAR-VTF Modules	
1	Introduction to behavioral treatment of dementia, realistic expectations, & effective communication
2	ABC approach to problem-solving, including rationale & development of an ABC plan
3	Review of ABC plan and revise if needed
4	Increasing pleasant events & managing negative thinking
5	Review of ABC plan, pleasant events schedule, & revise if needed
6	Coping with caregiving and maintaining gains

Table 2. Adapted STAR-VTF Modules	
1	Understanding and overview of dementia
2	Introduction to behavioral treatment of dementia, realistic expectations, & effective communication
3	ABC approach to problem-solving, including rationale & development of an ABC plan
4	Review of ABC plan and revise if needed
5	Increasing pleasant events & managing negative thinking
6	Review of ABC plan, pleasant events schedule, & revise if needed
7	Coping with caregiving and maintaining gains

2.2 Study Rationale

We conducted qualitative interviews with 44 stakeholders (e.g., Latino caregivers, frontline clinicians, and health educators). The stakeholders were not involved in the ongoing STAR-VTF pragmatic trial at KPWA and only viewed prototypes of the modules. Our analysis revealed that healthcare systems are not providing adequate education about dementia and support in managing BPSD. In fact, most Latino caregivers were unaware that healthcare providers could help with this matter. Stakeholders expressed interest in STAR-VTF, but there were concerns with particular aspects of the modules. Based on feedback from stakeholders, we have identified three adaptations to the STAR-VTF modules that would better serve Latino caregivers.

Increase knowledge about dementia to reduce normalization of symptoms and stigmatization of PLWD. Similar to other studies of racial and ethnic minority caregivers, our preliminary data reveal that Latinos tend to: believe dementia is a normal part of aging; attribute behavioral and psychological symptoms to normal aging or to their family member's personality; attribute the development of dementia to emotions; believe that dementia is a mental health disorder, and therefore, perceive PLWD as being *loco* (crazy); view pharmacological treatment of BPSD as accepting that their family member is *loco* (crazy); and believe that dementia can be healed or its symptoms managed through herbal remedies, praying, and therapy.

Module 1 includes a 7-minute section titled "Overview of Dementia." It covers the links between dementia and behavior, common causes of dementia, how dementia affects a person's ability to do daily tasks, and how changes in behavior are progressive and not intentional. The first adaptation of our proposed study will be to expand the content in this section. The goal is to reduce normalization of BPSD and the stigma associated with ADRD. For example, when discussing common causes of dementia, we will add content about the differences between normal age-related forgetfulness and serious memory problems. We will also explain that dementia is a physical (not mental) illness.

Eliminate stigmatizing, offensive, and culturally irrelevant language. We found that Latinos tend to prefer the term *pérdida de la memoria* (memory loss) instead of "Alzheimer's disease" or "dementia." Furthermore, stakeholders were concerned with program materials describing behavior symptoms as "challenging," "problematic," and "bothersome." It could be misinterpreted as describing PLWD (as opposed to their symptoms). In addition, stakeholders explained that Latinos tend to place the needs of the person they are caring for over their own needs. It is a way of expressing the Latino cultural value of *familismo* (familism). Thus, stakeholders strongly advised against program materials describing caregiving as burdensome. Finally, Latinos rarely identified with the label "caregiver." The translated word (*cuidador*) does not appear to be commonly-used. It is sometimes misinterpreted to refer to a formal caregiver or to an informal/family caregiver who gets paid to provide care. Latino caregivers we interviewed preferred to simply use kinship terms (e.g., daughter, daughter-in-law, wife of person with memory loss) to describe their role.

Based on these findings, the second adaptation of our proposed study will be to revise the language used across all modules. The goal is to eliminate any language that could be stigmatizing, offensive, and culturally irrelevant. For example, we will replace "dementia" with "memory loss," eliminate negative descriptions of BPSD, avoid the term "caregiver burden," and replace the label "caregiver" with kinship terms.

Incorporate Latino family structure and the nature of caregiving in Latino families. Stakeholders stressed the importance of targeting the family unit, as opposed to a primary caregiver, in ADRD healthcare for Latinos. A bilingual and bicultural social worker said, "It's not necessarily just one person [caring for PLWD]. Because our families come in packs… I think being able to be flexible in some of the norms that an education program will have, whether that means two people or more -- because usually, it's a family." In the vast majority of cases, Latino caregivers we interviewed described receiving extensive support from family members (including small children). They lived in multigenerational households or within close proximity of relatives, facilitating frequent help with care responsibilities and emotional support. In addition, there was a strong aversion to using formal respite services, driven by cultural, language, and economic factors.

In module 7, caregivers learn that enlisting the help of family members and formal respite care providers could help them better cope with caregiving. It assumes most caregivers live alone with PLWD and that other family members provide minimal support. The third adaptation of our proposed study is to incorporate content that reflects the structure of Latino families (i.e., multigenerational households, living near family) and how caregiving is often a shared responsibility within the family unit. Furthermore, when suggesting use of formal respite care services, we will be sensitive to culturally-influenced preferences. We will also address concerns about the lack of bilingual, bicultural, and affordable services.

Intervention Regimen: For 6-8 weeks, caregivers will complete the 7 online training modules asynchronously. They will access the video modules sent to them through text message or email. As described in Table 2, the content of the modules includes an overview of dementia, realistic expectations, effective communication, using the ABC approach to problem-solve BPSD, and planning pleasant events. Each module takes about 15 minutes to complete. The modules use text, pictures, and illustrations with a voiceover presentation. They will also receive a printed workbook to go along with the lessons. ***While the STAR-VTF intervention incorporates a coaching component, the present study will only pilot test the adapted online training modules.*** The full STAR-VTF intervention – adapted modules coupled with coaching – will be tested in a future study with Latino caregivers.

3 STUDY DESIGN

Objective 1: Culturally and linguistically adapt the STAR-VTF online training modules for Latino caregivers of PLWD

Findings from our stakeholder interviews indicate that no major changes to the intervention's core components are required. Instead, we need to improve the content and

language used in the online training modules. The first adaptation will be to expand the content in the "Overview of Dementia" section of module 1. The content will address common beliefs and attitudes about dementia that result in families normalizing dementia symptoms and stigmatizing PLWD. The second adaptation will be to revise the language across all modules. We will eliminate any language that stakeholders suggested could be stigmatizing, offensive, and culturally irrelevant. We will rewrite the content to a 6th grade or lower reading level – a suggestion made by frontline clinician and health educator stakeholders. The content of the modules will be translated and the voiceover presentations recorded in Spanish. The third adaptation will be to incorporate content into module 7 that reflects the structure of Latino families (e.g., tendency to live multigenerational households) and how caregiving can often be a shared responsibility within the family unit.

The PI will lead this adaptation work with support from the study's staff member. Feedback on draft adaptations will be obtained from stakeholders, including Latino caregivers of PLWD and Spanish-English bilingual and bicultural health educators. These individuals are members of a community advisory board. We will refine adaptations based on stakeholder feedback.

Objective 2: Pilot test Latino caregivers' responses to the adapted online training modules

The study will use a single-arm pilot trial design. Participants will be up to 20 caregivers of PLWD. We will target individuals who are: aged 18 years or older, live with PLWD or within 5 miles, provide at least 8 hours of care per week, provide care to PLWD who lives at home, and self-identify as Hispanic/Latino.

Caregivers will complete a baseline survey using a REDCap link that will be delivered to caregivers via email or text message. The survey will include sociodemographic characteristics and the outcome measures (i.e., Revised Memory and Problem Behavior Checklist and Preparedness for Caregiving Scale). We will collect outcome measures from caregivers again 6-8 weeks post-enrollment using the same data collection method. Sociodemographic characteristics will include: caregiver age, occupational status, whether caregiver works outside of the home, number of people living in caregiver's home, educational attainment, English fluency, preferred language, languages spoken at home, race, gender, annual household income, device ownership, Internet access at home, health insurance status of caregiver and PLWD, relationship to PLWD, age of PLWD, gender of PLWD, number of years in caregiving role, whether caregiver lives in same household as PLWD, and hours per week providing care.

After completing the baseline survey, caregivers will begin participation in the intervention. ***The intervention tested in this study will only involve the self-directed training component of the STAR-VTF intervention***. We will provide caregivers with the video modules via text messgae or email. We will also mail each participant a copy of the adapted version of the STAR-VTF workbook in their preferred language. There are handouts and resources to along with each lesson. Caregivers will be instructed to complete 1 module per week for 7 weeks (Table 2).

After 6-8 weeks, we will schedule an exit interview with caregivers. The interview will happen virtually (phone or videoconferencing) and will be under 1 hour. We will ask participants semi-structured questions to understand their experience with the online training modules and with completing the survey via REDCap.

Objective 3: Develop a REDCap survey to pragmatically collected caregiver outcomes. We will create a REDCap survey that will facilitate collection of caregiver outcomes pragmatically in a larger pilot study and full-scale embedded pragmatic clinical trial that we plan to conduct in the future. The REDCap instrument will include the English and Spanish versions of the Revised Memory and Problem Behavior Checklist and the Preparedness for Caregiving Scale. In the future, this functionality will allow remote collection of caregiver outcomes that can be securely linked back to the patient electronic medical record – solving the issue with health information management laws that make it difficult or impossible to collect caregiver outcomes as part of a patient's electronic medical record. In the present study, we will pilot the REDCap survey by asking caregivers to complete it at baseline and 6-8 weeks post-enrollment.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

Participants will be eligible if the meet the following criteria:

- Age 18 years or older
- Live with PLWD or within 5 miles
- Provide at least 8 hours of care per week
- Self-identify as Hispanic/Latino
- Caregiver self-report of PLWD having ≥ 3 BPSD occurring ≥ 3 in past week

4.2 Exclusion Criteria

Participants will be excluded if:

- PLWD lives in assisted living or skilled nursing facilities

4.3 Study Enrollment Procedures

We will identify potential study participants using a variety of strategies. First, we will contact Latino caregivers of PLWD who receive care at UW Medicine. These individuals participated in a previous study led by Dr. Ramirez and agreed to be contacted again for participation in future studies. Second, we will distribute recruitment flyers in federally qualified health centers and across primary care clinics that are part of the WWAMI (Washington, Wyoming, Alaska, Montana and Idaho) region Practice and Research Network. Next, we will advertise the study in Spanish language media (e.g., radio

stations and newspapers). Finally, we will recruit via the Alzheimer's Prevention Registry.

For caregivers who are interested in study participation, the study staff members, Celeste Garcia and Lily Zavala, will schedule a phone call to answer any questions they may have and screen for eligibility. We will email or mail the consent form to caregivers who are eligible. After mailing these materials, study staff will contact caregivers by phone to review the consent form and answer any questions. Caregivers will sign the consent form electronically or by paper and mail it to staff members. After receiving the signed consent form, caregivers will receive an email or text message asking them to complete the online baseline survey. Participants who do not sign the consent form will not be allowed to participate in the study. We will use a screening log to document reasons for ineligibility and for non-participation of eligible candidates.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

For 6-8 weeks, caregivers will complete the 7 online training modules asynchronously. As described in Table 2, the content of the modules includes an overview of dementia, realistic expectations, effective communication, using the ABC approach to problem-solve BPSD, and planning pleasant events. Each module takes about 15 minutes to complete. We will instruct caregivers to complete one module per week. The modules use text, pictures, and illustrations with a voiceover presentation. The modules also include an adapted workbook with for participants to complete. ***While the STAR-VTF intervention incorporates a coaching component, the present study will only pilot test the adapted online training modules.*** The full STAR-VTF intervention – adapted modules coupled with coaching – will be tested in a future study with Latino caregivers.

We believe there is minimal risk associated with participating in the study. The intervention is an education and training program to give caregivers more tools and better knowledge for minimizing and responding to BPSD. The primary risk with the intervention is discomfort with the intervention content. The intervention's recommendations based on the best available clinical evidence and has already been extensively tested in prior research. Core elements of the intervention have been proven in previous research to significantly improve average clinical outcomes. Nevertheless, treatment recommendations that improve care on average may have adverse consequences for any individual patient. Participants will be fully informed of the risks and their right to decline or withdraw from the study or specific activities.

5.2 Handling of Study Interventions

From home, caregivers will access the asynchronous, self-directed modules via a website hosted on the Kaiser Permanente School of Allied Health Sciences learning management system. Caregivers will log in to the website from their preferred web browser using an email address and user-generated password.

5.3 Concomitant Interventions

The intervention is an adjunct to usual care. No services that are usually available to PLWD or their family caregivers will be withheld.

5.4 Adherence Assessment

Caregiver adherence data will be captured automatically via the Kaiser Permanente School of Allied Health Sciences learning management system. There are built-in metrics that track how users interact with the website, which we will utilize to determine caregiver completion rates for each module. We will use descriptive statistics to characterize caregiver adherence to completing the modules.

6 STUDY PROCEDURES

6.1 Schedule of Evaluations

Assessment	Screening Assessment (Week 0)	Baseline Assessment (Week 0)	Module Assessments (Weeks 1-6)	Final Assessment (Weeks 7-8)
Inclusion/Exclusion Criteria	X			
Informed Consent Form	X			
Enrollment	X			
Sociodemographic characteristics		X		
Revised Memory and Problem Behavior Checklist		X		X
Preparedness for Caregiving Scale		X		X
Perceived Usability of Modules			X	
Qualitative Assessment of Intervention Acceptance				X

6.2 Description of Evaluations

6.2.1 Screening Assessment

For caregivers who are interested in study participation, the study staff members will schedule a phone call to answer any questions they may have and screen for eligibility. Study staff will use a structured screening survey to ask potential participants their age, whether they live with PLWD or within 5 miles, the number of hours of care they provide each week, their race/ethnicity, and whether PLWD lives in assisted living or skilled nursing facilities.

We will email an e-consent form to caregivers who are eligible. After emailing these materials, study staff will contact caregivers by phone again to review the e-consent form and answer any questions. Caregivers will be instructed to sign the e-consent form. Enrollment will begin when the study staff members receive the e-consent forms signed by caregivers.

6.2.2 Baseline Assessment

After receiving the signed e-consent form, caregivers will receive an email or text message asking them to complete the REDCap baseline survey that contains:

- Sociodemographic questionnaire
- Revised Memory and Problem Behavior Checklist
- Preparedness for Caregiving Scale

6.2.3 Module Assessment

At the end of each online training module, there is a short survey that caregivers are asked to complete. The survey contains:

- System Usability Scale

6.2.4 Final Assessment

After 6-8 weeks post-enrollment, caregivers will receive an email or text message asking them to complete the REDCap baseline survey that contains:

- Revised Memory and Problem Behavior Checklist
- Preparedness for Caregiving Scale

In addition, study staff members will schedule an exit interview with participants. The interview will happen virtually (phone or videoconferencing) and will be under 1 hour. We will ask participants semi-structured questions to gauge their acceptance of the online learning modules and their experience completing the REDCap survey.

7 SAFETY ASSESSMENTS

7.1 Potential Risks and Benefits for Participation

Potential Risks: We believe there is minimal risk associated with participating in the study. The primary risks to participation are:

- Breach of confidentiality
- Discomfort in answering survey or interview questions
- Discomfort with the intervention content

Potential Benefits: We anticipate that this research will yield important new information regarding the delivery of culturally competent support to Latino caregivers of PLWD. The results of the study will help to improve future care for Latino caregivers.

7.2 Adverse Event (AE) and Serious Adverse Event (SAE) Collection and Reporting

7.2.1 AE/SAE Definitions

The study will adhere to the definitions for AEs and SAEs stipulated in the *NIA Adverse Event and Serious Adverse Event Guidelines* as outlined below.

AE Definition: AE is any untoward or unfavorable medical occurrence in a human study participant, including increased stressed, inability to cope, or other emotional discomfort, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.

AEs for this study include:
This study is designed to pilot test a behavioral intervention with caregivers. As such, we believe it will pose minimal risk to participants because the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The risks of participating in this study may include feeling discomfort discussing personal matters during the intervention, survey, or exit interview, as well as frustration as caregivers attempt to implement the suggestions of the STAR-VTF online learning modules.

SAE Definition: SAEs consist of any adverse event that results in death; is life threatening or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects; is another condition which investigators judge to represent significant hazards

SAEs for this study include:
Research activities may identify immediate risk of harm or other urgent need. While we would not conclude that any such emergencies are consequences of study participation or

intervention content, there is still a clear obligation to report and respond appropriately to these urgent needs.

7.2.2 Classification of Severity and Study Relatedness

All data and safety monitoring reporting will classify SAEs and AEs as to their severity, expectedness, and potential relatedness to the study intervention as per the definitions below:

Severity

- **Mild:** Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.
- **Moderate**: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning
- **Severe**: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating

Expectedness

- **Unexpected** - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol, consent form, product brochure, or investigator brochure.
- **Expected** - event is known to be associated with the intervention or condition under study.

  Unexpected events will be subject to expedited reporting requirements as described in the NIA Guidance on Clinical Trials and in Section 1.2.3, below.

Relatedness

- **Definitely Related**: The adverse event is clearly related to the investigational agent/procedure – i.e. an event that follows a reasonable temporal sequence from administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement on stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.
- **Possibly Related**: An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.
- **Not Related**: The adverse event is clearly not related to the investigational agent/procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event

and the study intervention and/or a causal relationship is considered biologically implausible.

7.2.3 AE/SAE Reporting

The study will adhere to the reporting requirements for AEs and SAEs stipulated in the NIA Adverse Event and Serious Adverse Event Guidelines as outlined below.

Process for identifying AEs and SAEs: The study staff members, Celeste Garcia and JP Lopez Garcia, will be in contact with participants while carrying out research activities and will be able to identify any AEs and SAEs that occur. When an adverse event is identified, Dr. Ramirez and study staff will follow NIA's AE/SAE process flow. They will meet on a weekly basis throughout the project period and will review study progress and adverse events. NIA's template for AEs and template for SAEs will be used to collect information about adverse events.

Adverse event reporting schedule:

- All **adverse events that are both serious** (SAE) **and unexpected** (i.e., have not been previously reported for the study's intervention) will be reported to the IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) within 48 hours of the study's knowledge of SAE.
- The summary of all other SAEs will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) quarterly, unless otherwise requested by the DSMB Chair or a Safety Officer.
- All deaths will be reported to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) and to the DSMB Chair (or project's Safety Officer) within 24 hours of study's knowledge of death.
- AEs will be reported per IRB policies and also to IMPACT Collaboratory Regulatory and Data Team Leader (Julie Lima PhD), Advarra IRB, NIA IMPACT Collaboratory PO (Dr. Partha Bhattacharya), and the IMPACT Collaboratory DSMB Chair (or the project's Safety Officer) and to the DSMB Chair (or project's Safety Officer) at minimum every 6 months, or at a frequency requested by NIA and/or by the DSMB.

8 INTERVENTION DISCONTINUATION

The intervention will be discontinued if they withdraw from participation in the study at any time and for any reason. We will document reason for discontinuation and, with their

permission, we will continue to follow-up with participants. We will replace participants who discontinue early (i.e., at enrollment).

9 STATISTICAL CONSIDERATIONS

9.1 General Design Issues

The overall objective of this pilot study is to prepare the culturally and linguistically adapted online training modules for Latino caregivers of PLWD and the REDCap survey that will be used to pragmatically collect caregiver outcomes in a future study. Thus, the study was not designed to test hypotheses. We have selected outcome measures that have already been translated and validated in Spanish: (1) Revised Memory and Behavior Problem Checklist[27,28] and (2) Preparedness for Caregiving Scale.[29]

9.2 Sample Size and Randomization

This study does not involve randomization. We have selected a sample size of up to 20 caregivers for study participation for pragmatic reasons (i.e., what can feasibly be accomplished given the study budget and timeline).

9.3 Interim analyses and Stopping Rules

We are not planning to conduct an interim analysis. Given the small sample of the pilot study, it is not possible to detect a significant positive or negative effect of the intervention to terminate recruitment early. Thus, we believe that a decision to prematurely terminate study recruitment or study intervention is not possible.

We have allocated 4 months of our 12-month study to recruiting study participants. If we are unable to recruit at least 5 study participants during that 4-month period, we will stop the study due to slow accrual.

9.4 Outcomes

9.4.1 Primary outcome

The primary outcomes are: (1) Revised Memory and Behavior Problem Checklist and (2) Preparedness for Caregiving Scale. We will collect these outcomes at baseline and 6-8 weeks post-enrollment via a REDCap survey.

1. **Revised Memory and Behavior Problem Checklist.**[27,28] Caregivers will rate memory, depression, and disruptive behavior problems in the PLWD. The instrument contains 24 items (7 memory-related, 8 depressive, and 9 disruptive) that assess problem behaviors and are rated for frequency of occurrence during the past week and caregiver reaction to the problem behaviors.

2. **Preparedness for Caregiving Scale.**[29] Caregivers will rate how prepared they are for various aspects of caregiving. The instrument contains 8 items that ask caregivers how well prepared they believe they are to provide physical care, emotional support, deal with the stress of caregiving, and set up in-home support services. Each item is rated on a 5-point scale ranging from 0 (not at all prepared) to 5 (very well prepared).

9.4.2 Secondary outcomes

The secondary outcomes the System Usability Scale. We will collect this outcome each time a caregiver completes an online training module. The instrument will be embedded within the modules.

- **System Usability Scale**.[30] Caregivers will rate how easy the online training modules are to use. The instrument contains 10 items. Each item is rated on a 5-point scale ranging from 0 (strongly disagree) to 7 (strongly agree).

Secondary outcomes will also include caregivers' acceptance of the online training modules, their experience completing the REDCap survey, and their adherence to the online training modules. We will develop a semi-structured interview guide to qualitatively assess, during exit interviews, caregiver acceptance and experience completing the REDCap survey. We will obtain caregiver completion rates of online training modules using built-in metrics from the Kaiser Permanente School of Allied Health Sciences learning management system.

9.5 Data Analyses

For analysis of quantitative outcomes, we will use descriptive statistics. For qualitative outcomes, we will use analytic procedures in qualitative research.[31] Given the small sample size and study objectives, we will not perform subgroup analyses.

10 DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

We will collect data on the Revised Memory and Behavior Problem Checklist and the Preparedness for Caregiving Scale via a REDCap survey. We will deliver a link to the survey via an email or text message. Caregivers will be instructed to follow the link and complete the survey.

We will collect data on the System Usability Scale via a REDCap survey. We will deliver a link to the survey via an email or text message. Caregivers will be instructed to follow the link and complete the survey.

We will collect qualitative data during exit interviews that will be conducted by Dr. Ramirez, Celeste Garcia, and/or JP Lopez Garcia. The interviews will be audio recorded, and we will also take notes during and after the interview.

10.2 Data Management

Data collection and management will be the responsibility of the University of Washington. All data collected from participants will be labeled with a unique study identification number and not the participant's name or any other information that could

identify the participant. Only the study identification number will appear on data records and computer files. The contact information of study participants will be kept in a password-protected file and computer. All data collected from participants will be kept confidential and accessible only by Dr. Ramirez, Celeste Garcia, and JP Lopez Garcia at the University of Washington. Dr. Penfold will view only summaries of aggregated data. We will not use participants names in reports of study findings, REDCap surveys, or audio recordings of interviews. Instead, we will label everything with the study identification number. We will destroy data that identifies participants when we have finished recruitment. We plan to keep de-identified data indefinitely.

10.3 Quality Assurance

10.3.1 Training

As is the case with all investigators, key personnel, and all those responsible for the design and conduct of research at the University of Washington, Dr. Ramirez, Celeste Garcia, and JP Lopez Garcia have received training on the protection of human subjects. Dr. Ramirez will be responsible for training study staff members on the study protocol.

10.3.2 Quality Control Committee

This study will not utilize a quality control committee.

10.3.3 Metrics

We will use a log to document whether and when caregivers enrolled in the study were prompted to complete outcome assessments via the REDCap survey. The log will also document whether and when an exit interview has been scheduled. We will review the log on a weekly basis.

10.3.4 Protocol Deviations

We will use a protocol deviation log. The log will enable us to capture a description of the protocol deviation, the deviation category (e.g., safety, informed consent, eligibility, protocol implementation), date the deviation occurred, and date the institutional review board was notified.

10.3.5 Monitoring

Dr. Ramirez will be responsible for regularly monitoring all aspects of the study to assure protocol compliance, data quality, etc.

11 PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB responsible for study oversight.

11.2 Informed Consent Form

Consent forms in English and Spanish will be IRB-approved and the participant will be asked to read and review the document. Using the language preferred by participants (English or Spanish), the study staff member will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice, and that the quality of their medical care will not be adversely affected if they decline to participate in this study. Participants will have the opportunity to carefully review the electronic consent form and ask questions prior to signing. The participants will be given a copy of the informed e-consent form so that they may discuss the study with their family or surrogates or think about it prior to agreeing to participate. The informed e-consent process will be conducted and documented in REDCap (including the date), and the form e-signed, before the participant undergoes any study-specific procedures. A copy of the signed informed e-consent document will be sent to the participants for their records.

11.3 Participant Confidentiality

Any data, forms, reports, audio recordings, and other records will be identified only by a participant identification number to maintain confidentiality. All records will be kept in a locked file cabinet. All computer entry and networking programs will be done using participant identification numbers only. Information will not be released without written permission of the participant, except as necessary for monitoring by IRB, the FDA, the NIA, and the OHRP.

11.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, the OHRP, the FDA, or other government agencies as part of their duties to ensure that research participants are protected.

12 ETHICAL CONSIDERATIONS

This study will follow the seven main principles that the NIH Clinical Center has described as guiding the conduct of ethical research:[32]

- Social and clinical value
- Scientific validity
- Fair subject selection
- Favorable risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

13 COMMITTEES

This study will not utilize committees.

14 PUBLICATION OF RESEARCH FINDINGS

We will adhere to the IMPACT publications, and resource and data sharing policies.

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16 SUPPLEMENTS/APPENDICES

I. Outcome Measures

Revised Memory and Behavior Checklist

Instructions: The following is a list of problems patients sometimes have. Please indicate if any of these problems have occurred during the past week. If so, how much has this bothered or upset you when it happened Use the following scale for your reaction. Please read the description of the ratings carefully.

Has it occurred in the past week:

0 = No
1 = Yes

Reaction Ratings:

0 = not at all
1 = a little
2 = moderately
3 = very much
4 = extremely

Please answer all the questions for both frequency and reaction.

(RC11)

Problem	Has it occurred? (in past week)		Reaction (how much it bothered you)
1. Asking the same question over and over	NO	YES	
2. Trouble remembering recent events (i.e. items in newspaper or TV)	NO	YES	
3. Trouble remembering significant past events	NO	YES	
4. Losing or misplacing things	NO	YES	
5. Forgetting what day it is	NO	YES	
6. Starting, but not finishing, things	NO	YES	
7. Difficulty concentrating on a task	NO	YES	
8. Destroying property	NO	YES	
9. Doing things that embarrass you	NO	YES	
10. Waking you or other family members up at night	NO	YES	
11. Talking loudly and rapidly	NO	YES	
12. Appears anxious or worried	NO	YES	
13. Engaging in behavior that is potentially dangerous to self or others	NO	YES	
14. Threats to hurt oneself	NO	YES	
15. Threats to hurt others	NO	YES	
16. Aggressive to others verbally	NO	YES	
17. Appears sad or depressed	NO	YES	
18. Expressing feelings of hopelessness or sadness about the future	NO	YES	
19. Crying and tearfulness	NO	YES	
20. Commenting about death of self or others	NO	YES	
21. Talking about feeling lonely	NO	YES	
22. Comments about feeling worthless or being a burden to others	NO	YES	
23. Comments about feeling like a failure, or about not having any worthwhile accomplishments in life	NO	YES	
24. Arguing, irritability, and/or complaining	NO	YES	

The Preparedness for Caregiving Scale

YOUR PREPARATION FOR CAREGIVING

We know that people may feel well prepared for some aspects of giving care to another person, and not as well prepared for other aspects. We would like to know how well prepared you think you are to do each of the following, even if you are not doing that type of care now.

	Not at all prepared	Not too well prepared	Somewhat well prepared	Pretty well prepared	Very well prepared
1. How well prepared do you think you are to take care of your family member's physical needs?	0	1	2	3	4
2. How well prepared do you think you are to take care of his or her emotional needs?	0	1	2	3	4
3. How well prepared do you think you are to find out about and set up services for him or her?	0	1	2	3	4
4. How well prepared do you think you are for the stress of caregiving?	0	1	2	3	4
5. How well prepared do you think you are to make caregiving activities pleasant for both you and your family member?	0	1	2	3	4
6. How well prepared do you think you are to respond to and handle emergencies that involve him or her?	0	1	2	3	4
7. How well prepared do you think you are to get the help and information you need from the health care system?	0	1	2	3	4
8. Overall, how well prepared do you think you are to care for your family member?	0	1	2	3	4

9. Is there anything specific you would like to be better prepared for? _____

_____

_____

_____

_____

MEAN SCORE of the number of items answered: _____

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Stewart & Archbold (1986, 1994)

System Usability Scale

Instructions: For each of the following statements, mark one box that best describes your reactions to the website *today*.

		Strongly Disagree				Strongly Agree
1.	I think that I would like to use this website frequently.	☐	☐	☐	☐	☐
2.	I found this website unnecessarily complex.	☐	☐	☐	☐	☐
3.	I thought this website was easy to use.	☐	☐	☐	☐	☐
4.	I think that I would need assistance to be able to use this website.	☐	☐	☐	☐	☐
5.	I found the various functions in this website were well integrated.	☐	☐	☐	☐	☐
6.	I thought there was too much inconsistency in this website.	☐	☐	☐	☐	☐
7.	I would imagine that most people would learn to use this website very quickly.	☐	☐	☐	☐	☐
8.	I found this website very cumbersome/awkward to use.	☐	☐	☐	☐	☐
9.	I felt very confident using this website.	☐	☐	☐	☐	☐
10.	I needed to learn a lot of things before I could get going with this website.	☐	☐	☐	☐	☐

Please provide any comments about this website:

II. Demographics Questionnaire

What is your age?
* must provide value

years old

What is your current occupational status?
* must provide value

- ○ Employed
- ○ Unemployed
- ○ Homemaker
- ○ Student
- ○ Retired
- ○ Disabled
- ○ Other

reset

Do you work outside your home?

- ○ Yes
- ○ No

reset

Who are the people living in your home?

- ☐ Partner or father of child
- ☐ Children, related or unrelated, such as newborn babies, grandchildren, or foster children
- ☐ Relatives, such as adult children, cousins, or in-laws
- ☐ Nonrelatives, such as roommates or live-in babysitters
- ☐ People staying here temporarily
- ☐ None of the above

Mark all that apply.

What is the highest grade or level of schooling you completed?
* must provide value

- ○ Less than 8 years
- ○ 8 through 11 years
- ○ 12 years or completed high school
- ○ Post high school training other than college (vocational or technical)
- ○ Some college
- ○ College graduate
- ○ Postgraduate

reset

How well do you speak English?

* must provide value

- ○ Very well
- ○ Well
- ○ Not well
- ○ Not at all

reset

What language do you prefer to speak?

* must provide value

- ☐ English
- ☐ Spanish
- ☐ Other

What language(s) do you speak at home?

* must provide value

- ☐ English
- ☐ Spanish
- ☐ Other

Are you of Hispanic, Latino/a, or Spanish origin?

* must provide value

- ○ No, not of Hispanic, Latino/a, or Spanish origin
- ○ Yes

reset

What is your race?

* must provide value

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Asian Indian
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Other Asian
- ☐ Native Hawaiian
- ☐ Guamanian or Chamorro
- ☐ Samoan
- ☐ Other Pacific Islander
- ☐ Other, specify

One or more categories may be selected.

What is your gender?

* must provide value

- ○ Female
- ○ Male
- ○ Other

reset

Thinking about members of your family that live in your household, what is the combined annual income, meaning the total pre-tax income from all sources earned in the past year?

* must provide value

- ○ $0 to $9,999
- ○ $10,000 to $14,999
- ○ $15,000 to $19,999
- ○ $20,000 to $34,999
- ○ $35,000 to $49,999
- ○ $50,000 to $74,999
- ○ $75,000 to $99,999
- ○ $100,000 to $199,999
- ○ $200,000 or more
- ○ don't want to disclose

reset

Do you own a smartphone, tablet, laptop or computer?

* must provide value

- ☐ Smartphone
- ☐ Tablet
- ☐ Laptop
- ☐ Computer
- ☐ None

Do you or any member of your household have access to the Internet using a:

- ☐ cellular data plan for a smartphone or other mobile device?
- ☐ broadband (high speed) Internet service such as cable, fiber optic, or DSL service installed in this household?
- ☐ satellite Internet service installed in this household?
- ☐ dial-up Internet service installed in this household?
- ☐ some other service?

Is the person with dementia currently covered by any of the following types of health insurance or health coverage plans?

* must provide value

- ☐ Insurance through a current or former employer or union (you or another family member)
- ☐ Insurance purchased directly from an insurance company (by you or another family member)
- ☐ Medicare, for people 65 and older, or people with certain disabilities
- ☐ Medicaid, Medical Assistance or any kind of government-assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ VA (enrolled for VA health care)
- ☐ Indian Health Service
- ☐ Other

Are you currently covered by any of the following types of health insurance or health coverage plans?

* must provide value

- ☐ Insurance through a current or former employer or union (you or another family member)
- ☐ Insurance purchased directly from an insurance company (by you or another family member)
- ☐ Medicare, for people 65 and older, or people with certain disabilities
- ☐ Medicaid, Medical Assistance or any kind of government-assistance plan for those with low incomes or a disability
- ☐ TRICARE or other military health care
- ☐ VA (enrolled for VA health care)
- ☐ Indian Health Service
- ☐ Other

What is your relationship to the person with Alzheimer's disease or related dementia?

* must provide value

- ○ Spouse or partner
- ○ Parent
- ○ Close family member
- ○ Friend or other non-relative
- ○ Other

reset

How old is the person with Alzheimer's disease or related dementia? * must provide value	years old
What is the gender of the person with Alzheimer's disease or related dementia? * must provide value	○ Female ○ Male ○ Other reset
How long have you been in the caregiving role? * must provide value	years
Do you live in the same household as the person with Alzheimer's disease or related dementia? * must provide value	○ Yes ○ No reset
Thinking of all the kinds of help you provide for this person, about how many hours do you spend in an average week providing care? * must provide value	○ Less than 5 hours per week ○ 5-14 hours per week ○ 15-20 hours per week ○ 21-34 hours per week ○ 35 or more hours per week reset

III. Draft of Informed Consent Form

Virtual Training for Latino Caregivers to Manage Symptoms of Dementia Informed Consent Form

Researchers

University of Washington School of Public Health

Maggie Ramirez, MS, MS, PhD, Lead researcher
206-543-9773

Miriana Duran, MD, MPH, Research coordinator
206-221-6206

Key information about this study

We are asking you to be in a research study. This form explains the details of the study. Please read this entire form before agreeing to join the study. You do not have to be in this study. If you say yes, you can quit the study at any time.

The study, Virtual Training for Latino Caregivers to Manage Symptoms of Dementia, is about an online program we are designing to better support family caregivers of people living with dementia (PLWD). Our goal is to learn how we can design the online program to better meet the needs of family caregivers. We will do this by asking family caregivers to use the online program. We will also ask caregivers to answer survey questions and participate in an interview. This study is being conducted by the University of Washington (UW) and is funded by the NIA IMPACT Collaboratory.

This study may not help you personally, but we hope the results of this study will help improve care in the future. You might feel uncomfortable with the program materials or with answering some study questions. You may skip any part of the program you don't want participate in. You may also skip any questions you don't want to answer. In addition, the interview could last up to 60 minutes. We can schedule the interview on a date and time that is convenient for you. It's possible that someone other than the researchers could find out you were in the study or see your private information.

What will happen if I take part in this study?

If you are eligible and want to join the study, we will ask you to:

Use an online program for a period of 6 weeks. The online program consists of 6 videos. You would watch the videos at home from any device that you prefer to use. We will ask you to watch one video per week. The videos will provide information to help you better manage behavioral and psychological symptoms of dementia (e.g., agitation, sleep disturbance, aggression).

Complete online surveys. The surveys will ask you about the following:

- Sociodemographic characteristics (e.g., age, gender, race, ethnicity)
- Occurrence and frequency of dementia symptoms in the PLWD and your reactions to these symptoms
- How prepared you feel for various aspects of caregiving
- How easy or hard you think the online program is to use
- How useful you think the online program is to use

Take part in an in-person interview that will last up to 60 minutes. During the interview, a UW researcher will ask about your experience using the online program. They will also ask about your experience completing the online surveys. For example, what you liked about the program, what you did not like about the program, and how we can make the program better in the future. We will audio record the interview. Anything you say that could identify you will not be written down.

The interview recording and other information about you that we collect through the surveys will be labeled with a code number instead of your name.

We will provide you with $40 to thank you for taking part in the study.

Using Your Data in Future Research
The interview recording and other information about you that we collect through the surveys may be used or distributed for future research studies without your additional informed consent.

Will there be any costs to me?
There will not be any costs to you.

Will being in this study help me?

This study will not help you personally, but we hope the results of this study will help improve care in the future.

Can anything bad happen to me from being in this study?

You might feel uncomfortable with the program materials or with answering some survey or interview questions. You may skip any part of the program you don't want participate in. You may also skip any questions you don't want to answer.

It is possible that someone other than the researchers could find out you were in the study or see your private study information. The steps we take to keep this from happening are described below.

How will you protect my confidentiality?

This study is being done by researchers at the UW. They are listed above. These researchers sign a pledge at their institution that requires them to keep your information private.

Your study responses (data) will be kept confidential by the UW. The researchers listed on the first page will use your study information for research only. We won't use your name in study reports or write it on recordings of the interview. Instead, we will label everything with a code number only. We will store the interview recording and other information about you that we collect through the surveys in secure databases at the UW. We will destroy data that identifies you when we have finished recruitment. We plan to keep your de-identified study information as described in this form indefinitely.

Do I have to be in this study?

No, being in this study is up to you. You are free to say no now or to leave the study at any time later. Either way, there will be no penalty. Your decision won't affect the healthcare you receive or benefits that you are entitled to.

What happens if I say yes, but change my mind later?

You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:

Maggie Ramirez, MS, MS, PhD
Hans Rosling Center for Population Health
Department of Health Services
3980 15th Ave NE, Fourth Floor
Box 351621
Seattle, WA 98195
maggiera@uw.edu

If you take back your consent, it will not affect your healthcare or benefits. We may still use the study information we collected before we received the letter taking back your consent. But, we will destroy any record of your name or other information that could identify you.

Who do I call if I have questions?

- If you have questions about your rights as a research participant, please call [placeholder for IRB office] at [placeholder for phone number].
- If you have questions or concerns about the study, please call the research coordinator, Miriana Duran, at 206-221-6206.

Subject's Statement

This study has been explained to me. I volunteer to take part in this research. If I change my mind later, I may leave the study at any time. I've had a chance to ask questions, and they've been answered to my satisfaction. If I have more questions later, I may call the researchers listed in this form or their staff. I will get a copy of this form to keep.

_____ _____
Signature Date

_____
Please **PRINT** your name

_____ _____
Signature of study staff obtaining consent Date

_____
Printed name of study staff obtaining consent