

Title: CuidaTXT: a Text Message Dementia-caregiver Intervention for Latinos

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CuidaTXT: a Text Message Dementia-Caregiver Intervention for Latinos

SPECIFIC AIMS

Family caregiving for individuals with dementia (IWD) has a serious emotional, physical and financial toll.¹⁻⁸ Most IWD live at home and are cared for by their relatives.⁹ Because the US healthcare system focuses mainly on acute care, relatives provide more than 80% of the long-term care to IWD.^{4,5} For these reasons, caregiver care is a key component of the National Alzheimer's Project Act.¹⁰

Most family caregiver interventions have been designed for non-Latino whites and results might not generalize to other groups.^{11,12} The number of Latino IWD is projected to increase from 379,000 in 2012 to 3.5 million by 2060, more than any other group.¹³ Latinos are more likely to become family caregivers than non-Latino whites.¹⁴ Latinos also provide more intense and longer caregiving and experience higher levels of caregiver depression and burden.^{8,14-20} However, Latino caregivers of IWD are less likely to attend caregiver support services partly due to the inconvenience of leaving the IWD and transportation, financial, language and cultural barriers.^{21,22} There is a need for targeted caregiver support interventions for Latinos. This need is in line with the NIA's call to address health disparities in aging research.²³

Text messaging is an ideal modality to deliver caregiver interventions to Latinos. Newer and more fashionable technologies for caregivers exist such as websites and apps.²⁴⁻²⁶ However, Latinos' low use of websites and apps would perpetuate their disparities in access to caregiving support.²⁷ Caregiver interventions for Latinos need to capitalize on text messaging as it is the technology of the people. Text message interventions 1) are effective in other health conditions, 2) can be used anywhere at any time, 3) are more cost-effective than other delivery systems and 4) can be personalized to caregivers' preferences and characteristics including language and culture.²⁸⁻³¹ Text message interventions are highly scalable among Latinos, as 92% of Latino adults own a cellphone and 87% use texting, 10% more than non-Latino whites.³² Text message interventions engage Latinos as 98% of them sent at least one text message, 66% more than 10 and 12% more than 100 in our 3-month smoking cessation trial.³³

The overall aim of this proposal is to develop and test the first text message intervention for caregiver support of IWD among Latinos. This intervention, *CuidaTXT* [Spanish for self-care and texting], will be available in English and Spanish, incorporate two-way messaging and will tailor text messages to the preferences of Latino caregivers. *CuidaTXT* will be multicomponent and based on the Stress Process Framework as supported by evidence.^{1,34-36} The intervention will include dementia education, problem-solving skills training, family communication, care management and referral to community resources.^{1,24,25} This research corresponds with Stage 1 of the NIH Stage Model for Behavioral Intervention Development.³⁷

Aim #1. Develop a culturally and linguistically-appropriate text message intervention for caregiver support among Latino family caregivers of IWD. We will use a variety of user-centered design methods and materials³⁸ to develop a text message library including: Advisory Board guidance, theory-based caregiving content, development of personas and prototyping, usability testing, establishment of the intervention's core vision and design specification, and collaboration with a text message vendor.³⁹ The result will be a text message library indicating the type of message, content, character count, delivery date and time, tailoring branching and theoretical construct corresponding to each text message.

Aim #2. Test the feasibility and acceptability of CuidaTXT. We will allocate 20 Latino caregivers to six months of *CuidaTXT* in a one-arm trial. We will use standard criteria^{40,41} to assess feasibility (direct observation of text message enrollment, interaction and unsuspension metrics and self-reports of technical problems and proportion of read messages) and acceptability (satisfaction with the intervention, its logistics, content and refinement suggestions). Secondary outcomes will include caregivers' dementia knowledge, burden and depression.

At the end of this project, we will have a defined and refined culturally and linguistically-appropriate text message library ready to be tested in a fully-powered R01 RCT. This study is innovative as, to our knowledge it is the first text message intervention for caregivers of IWD of any ethnicity and will deliver a caregiver

intervention via the most widely used mobile health technology among Latinos. Even if the efficacy of the text message intervention is modest, its high scalability has the potential to make it more impactful than most strong-efficacy in-person interventions.¹²

SIGNIFICANCE

The impact of Alzheimer's disease

Alzheimer's disease and related disorders (ADRD) pose a serious public health threat in the US. The number of American older adults is increasing, and the risk of ADRD increases with age.^{42,43} Most individuals with ADRD live in the community and are cared for by their relatives.^{1,2,4,5,7,44} As a result, family caregiving for IWD has a serious emotional, physical and financial toll.¹⁻⁸ For example, caregivers have substantially higher depression⁴⁵ and stress biomarkers⁴⁶ than other caregivers and non-caregivers. The strong impact of ADRD on family caregivers has led to the US national ADRD plan to include caregiver care as a key component.¹⁰

Why focus on improving caregiver support among Latino family caregivers of IWD?

There is a need for targeted caregiver support interventions for Latino caregivers of IWD. Nearly 200 caregiver interventions for older adults have been tested in randomized designs.^{1,12,47} However, most interventions were designed for non-Latino whites and results might not generalize to other groups.^{11,12} Ethnic ADRD disparities are core targets of major US agencies including National Alzheimer's Project Act and the NIA.^{10,23} Latinos are the largest ethnoracial US minority (18%)⁴⁸ and the fastest growing elder group.^{13,43} Correspondingly, the number of Latino IWD is projected to increase from 379,000 in 2012 to 3.5 million by 2060.¹³ Latinos are more likely to become family caregivers than non-Latino whites.¹⁴ Latinos also provide more intense and longer caregiving and experience higher levels of caregiver depression and burden.^{8,14-20}

Despite the existence of caregiver support programs, these have inherent limitations for broader deployment in the general population. Current interventions are conducted at facilities, require group trainings and involve costly investment of professional assistance.²⁶ Latino caregivers of IWD are even less likely to use these services.^{21,22} Latinos' low use of caregiver support might be related to several barriers:

- Many Latinos report time constraints and see attending caregiver interventions as burdensome.^{49,50}
- Latinos experience more unreliable transportation and difficulty finding a caregiving substitute.^{49,51}
- Latinos have one of the lowest average incomes and might find caregiver support costs high.^{49,52}
- Spanish language is the preferred and usually the only communication language for many Latinos.^{49,53}
- The frequent lack of patient-provider cultural concordance may affect Latinos' engagement.^{49,54,55}
- Certain frequent cultural values among Latinos require specific approaches. For example, caregiving tasks and decision-making are more likely to be shared by multiple relatives of the IWD.^{49,56}

Why is text messaging the ideal modality to deliver caregiver interventions to Latinos?

Caregiver interventions for Latinos need to capitalize on text messaging as it is the technology of the people. Newer and more fashionable technologies for caregivers exist such as websites and apps.²⁴⁻²⁶ However, Latinos' low use of websites and apps would perpetuate their access disparities.²⁷ Affordability and widespread use of cellphones across all socioeconomic and age levels create new opportunities for broad deployment of health interventions.^{27,57} About 92% of Latino adults own a cellphone and 87% use texting, 10% more than non-Latino whites.³² Text message interventions engage Latinos; in our three-month smoking cessation trial, 98% sent at least one text message, 66% sent more than 10 and 12% sent more than 100.³³ Text messaging may address most barriers to caregiver support-use among Latinos as these interventions:

- Are effective in treating several health conditions including diabetes self-management and smoking cessation.²⁹
- Can be used anywhere at any time addressing time constraints, unreliable transportation and the difficulty to find a caregiver substitute to attend caregiver support programs.²⁸
- Are more cost-effective than standard care.^{30,31} Lower implementation costs might translate into a lower cost for Latinos or the institutions serving them (i.e. insurance companies, ADRD associations).

- Can be personalized to caregivers' preferences and characteristics,²⁸ which can address barriers related to language, cultural values and cultural concordance.

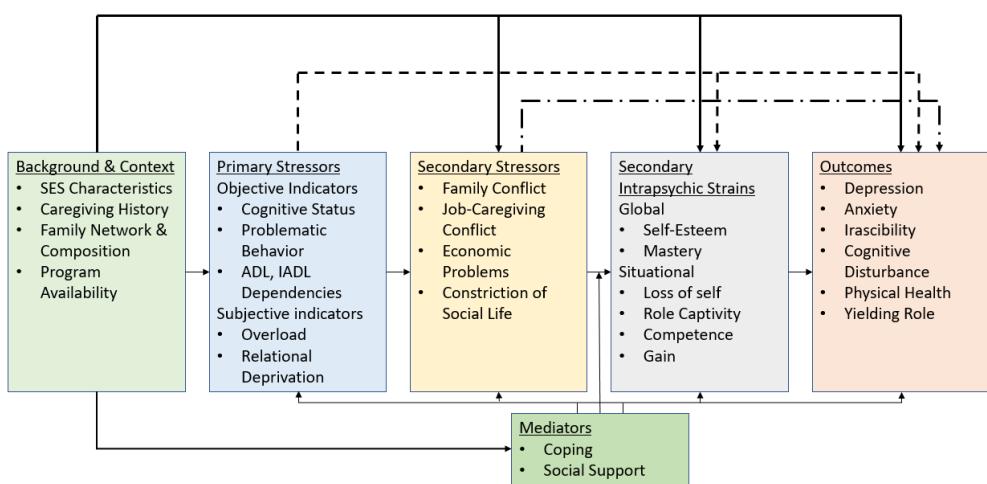
Which theoretical framework will the intervention be based on?

This project will develop and test the first text message caregiver support intervention for Latino caregivers of IWD (*CuidaTXT* [Spanish for self-care and texting]). Optimizing caregiver support among Latinos will help achieve better levels of emotional and physical health and reduce its associated costs.¹⁻⁸ *CuidaTXT* will be based on the Stress Process Framework.³⁴ Most of the existing psychoeducational caregiver interventions to date are based on this framework (i.e. Savvy Caregiver).¹ This framework highlights the importance of caregivers' coping and social support mechanisms while facing multiple stressors, taking into account their background and context (see Figure 1).

IMPACT

There are more than 400k Latinos with ADRD in the United States;¹³ few of whom are currently receiving support via caregiver interventions.⁵⁸ A text message intervention for caregivers of IWD could dramatically increase the reach of these interventions in this underserved community. Indeed, the reach of a text messaging intervention among Latinos could far exceed in-person, phone call, computer or app-based interventions.²⁷ Moreover, we expect that a text message intervention that is culturally and linguistically-appropriate for the target community could increase its efficacy compared to interventions designed for the general public. An evidence-based and clinically tested text message intervention for caregivers of IWD that is proven to better engage Latino caregivers could be of significant interest to health care purchasers, providers, ADRD associations and community organizations particularly those who cover and/or treat a disproportionate share of the Latino population.

Figure 1. Stress Process Framework



INNOVATION

The key innovation will be a new model to deliver wider reaching and more impactful interventions for Latino caregivers of IWD. The proposed study will be the first to test a text message caregiver support intervention in general and among Latinos in particular. *CuidaTXT* will be one of few interventions that tailor the delivery and content to Latinos. *CuidaTXT* will deliver an intervention immediately available to 92% of Latinos via cellphone. Since Latinos tend to share caregiving decision-making,^{49,56} *CuidaTXT* will be one of few interventions that includes multiple caregivers of a same IWD.^{26,59-62} Text message content will be informed by formative research via literature and qualitative work and will be culturally-appropriate avoiding the terms "dementia" and "caregiver burden, frequently considered taboo among Latinos.^{16,62} In line with new technologies, we will use several user-centered design methods^{38,63} to develop *CuidaTXT*: Advisory Board guidance, theory-based caregiving content, development of personas and prototyping, usability testing, design specification, and collaboration with a text message application vendor. User-centered design highlights the importance of tailoring the intervention to users rather than forcing them to change their behavior to use the intervention.

PRELIMINARY STUDIES

We have the necessary experience and environment to develop and test *CuidaTXT*. Dr. Perales has built a strong network in the Latino community in the last four years comprised of community centers, faith-based institutions and the media. Kansas City Latinos identify ADRD caregiver services as a top ADRD need.⁶⁴ We

developed a culturally-appropriate educational intervention that increases ADRD knowledge and research participation among Latinos, which will be integrated in *CuidaTXT* (P30 AG035982-06). ^{64,65} Dr. Perales has tailored, developed, tested and copyrighted several mHealth interventions for smoking cessation among Latinos, including text messaging (R41 MD010318, P30CA 168524). ^{33,66-69} Dr. Vidoni and Ms. Niedens have implemented caregiver support interventions in Kansas City that will inform *CuidaTXT*'s recruitment and delivery (90ALGG0009; #UL1RR033179; T32NR013456). ^{70,71} The KU Alzheimer's Disease Center (KU ADC) has a growing primary care provider collaborative care network program (MyAlliance) led by social work navigators to handle the complex needs of ADRD in the community. This program is directed Dr. Burns (neurologist) and Ms. Niedens (LSCSW) both appointed to the Kansas Governor's Work Group to establish a statewide plan for addressing ADRD. We will leverage MyAlliance for recruitment as 96% of older Latinos are insured and 93% have a usual source of healthcare.^{72,73} Dr. Hinton found that cognitively impaired older Latinos had elevated levels of neuropsychiatric symptoms, which were associated with higher levels of non-spousal caregiver depressive symptoms.¹⁹ Latino caregivers report high levels of unmet needs for ADRD counseling and education.²⁰ Dr. Hinton developed a culturally-appropriate psychoeducational intervention, which was found to be more effective than usual care in reducing depressive symptoms among Latino caregivers.^{60,74} These findings and experience will inform the development and testing of *CuidaTXT*.

APPROACH

The research proposal comprises two inter-related studies that aim to develop and test a text message caregiver support intervention for Latino caregivers of IWD. This research corresponds with Stages 1a (development) and 1b (feasibility testing) of the NIH Stage Model for Behavioral Intervention Development.³⁷ This project builds upon our experience tailoring, developing and implementing text message, caregiver support and Latino-targeted interventions and capitalizes on our strong connections with the Latino community. Aim 1 will result in a text message library ready to be tested on Aim 2. At the end of this project, we will have defined and refined a culturally and linguistically-appropriate text message library for Latino caregivers ready to be tested in a fully-powered R01 RCT.

Table 1. project timeline	Year 1												Year 2												
	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	
Aim 1. Development																									
Stage 1: Advisory Board		x	x	x	x	x																	x		
Stage 2: Evidence-based content	x	x	x																						
Stage 3: Sketching & prototyping				x	x	x																			
Stage 4: Usability testing					x	x	x																		
Stage 5: Vision & specifications						x																			
Stage 6: Vendor collaboration							x	x	x																
Manuscript submission of development								x	x	x															
Aim 2. Feasibility testing																									
Recruitment										x	x	x	x												
Data collection									x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Analysis and incorporation into R01 application																		x	x	x	x				
Manuscript submission of feasibility testing																				x	x	x	x	x	x

Aim 1. Develop a culturally and linguistically-appropriate text message intervention for caregiver support among Latino family caregivers of IWD.

Overview. Aim 1 corresponds to Year 1 and will use mixed-methods guided by user-centered design principles.³⁸ Mixed-methods are required given the lack of literature on text message interventions for Latino family caregivers of IWD.⁷⁵ Aim 1's six stages are based on previous research used to develop successful behavioral intervention software (see Table 1).³⁹ Aim 1 will result in a text message library indicating the type of message, content, character count, delivery date and time, tailoring branching and theoretical construct corresponding to each text message. This text message library will be ready to be implemented on Aim 2's feasibility testing.

Stage 1. Advisory Board guidance aims to understand the needs of Latino caregivers directly related to a text messaging intervention. We and other researchers have used Advisory Boards previously to inform similar interventions.^{39,68,69,76} The Advisory Board will include ADRD social workers, Latino social and health professionals, neurologists, geriatric psychiatrists, experts in text message interventions for Latinos and Latino communication specialists (see letters of support). Parallel working groups with Latino caregivers of IWD will also be conducted.

The Advisory Board will meet five times on Aim 1 to develop and refine message content and logistics according to their area of expertise. We will take notes of all observations, identify agreements and focal points and organize them for qualitative review. The Advisory Board will also meet at the end of Aim 2 to provide feedback to refine the intervention and trial design.

Stage 2: Integration of evidence-based content aims to ensure the evidence-based foundation of *CuidaTXT*. We will select content information for text messages based on behavioral interventions supported by the literature.^{1,25,61,62,77} We will prioritize randomized controlled trial methodology and content tailored to Latino caregivers.

Stage 3: Ideation, sketching and prototyping aims to bridge the gap between the theoretical and practical use of the intervention. First, we will create personas, a technique that simulates motivations, context, and personal characteristics of potential users to increase the designer's emotional understanding of the users.⁷⁸⁻⁸⁰ Second, we will sketch the intervention in a prototype using BOTMOCK⁸¹ to quickly iterate on variations of text message structure, interactions and the layout of content.^{78,82}

Stage 4: Usability testing aims to test the sketched text message intervention among actual Latino caregivers. We will use BOTMOCK to preview the behavior of diverse Latino caregivers in a variety of key scenarios (i.e. setting a notification or asking for specific instructions). The prototype testing will last one hour.

Assessment. We will use three usability assessment modalities. First, direct observation of task completion with the text message intervention prototype. Second, open-ended interviews regarding their user experience with the different tasks and suggested changes to improve it. Third, the completion of the System Usability Scale,⁸³ a valid and reliable 10-item 5-point Likert scale. Scores above 68 out of 100 indicate higher levels of usability. Given the iterative nature of this testing phase, we will modify the design features after each participant and provide the new version to the following participant. This iterative process is standard in formative evaluations.⁸⁴

Data analysis. We will write down observed behaviors during the observation and integrate them into the text with the interviews. Interviews will be recorded, transcribed, and analyzed employing content, domain, and taxonomic analysis.^{85,86} We will code and transcribe content using ATLAS-ti.⁸⁷ We will open-code transcripts by identifying keywords, themes, and descriptions of behavior within the text.⁸⁸ Later, we will group the themes into coding categories and develop a code map to categorize and retrieve comments on each theme. Two independent coders will code the transcripts and their agreement will be measured using kappa coefficient. Central tendency estimates, frequencies and percentages will describe quantitative data on R Software.⁸⁹

Sample size. We will recruit five individuals as suggested by software development cost-benefit analyses.⁹⁰ The first participant discovers most flaws, and after the fifth user, findings tend to repeat without learning much new. Inclusion criteria for this stage include Spanish and English-speaking individuals who are over the age of 18, identify as Latino, report providing hands-on care for a relative who has been given a clinical or research ADRD diagnosis and whose AD-8 cognitive screening score is ≥ 2 , indicating cognitive impairment.^{91,92} Participants will receive \$20 prepaid cards for completing assessments.

Stage 5: Vision & specifications aims to optimize our communication with the text message application vendor. The vendor will assist with programming the text message intervention. We will develop a design specifications file laying out the overall vision of the text-message intervention, its basic components and features.⁹³ This file will optimize communications with the text message application vendor.

Stage 6: Vendor collaboration aims to materialize the vision and design specifications resulting from our formative work. We will select the text message application vendor using a Comparison Matrix recommended in the literature to assist the decision-making process.²⁸ The Comparison Matrix will include information on whether the vendor provides message personalization, scheduling, conditional branching logic, ability to track information and cost per message. Examples of vendors include Mosio, SUMOTEXT or Callpointe.⁹⁴⁻⁹⁶

Aim 2. Test the feasibility and acceptability of *CuidaTXT*.

Overview. We will conduct a one-arm trial to examine the feasibility, acceptability and preliminary effectiveness of *CuidaTXT*. We will allocate 20 Latino caregivers to six months of *CuidaTXT*. We will use standard criteria ^{40,41} to assess feasibility, acceptability and preliminary efficacy outcomes.

Recruitment. We will recruit through multiple modalities capitalizing on the KU ADC's strong networks (see support letters). Our network includes 1) clinic referrals within our collaborative care network in Kansas City, 2) partners from Latino-affluent community centers, 3) the Hispanic Ministry of the Kansas City Catholic Dioceses, 4) our Spanish and English language Facebook page and 5) local Latino media (radio, newspaper and TV). There are >24,000 Latinos 50 or older in Kansas City Metro, many of them served by our community partners (i.e. EL Centro serves >10,000 Latino families/year). ⁹⁷ Our previous research suggests that approximately one in every four adult Latinos we reach through our ADRD educational presentations provide or have provided care to a relative with ADRD. ⁷⁶ Out of those caregivers, ~75% reported needing caregiver support. Therefore, we will need to reach 107 Latinos to enroll 20, which should take no more than 2-3 months.

Eligibility, consent, enrollment and baseline assessment. We will provide participants with study information in their preferred language adapted for individuals with low literacy levels either in person, at the recruitment site or via phone. After providing study information, we will assess participants' eligibility. Inclusion criteria for this stage include Spanish and English-speaking individuals who are over the age of 18, identify as Latino and who report providing hands-on care for a relative who has been given a clinical or research ADRD diagnosis and has an AD-8 screening score ≥ 2 , indicating cognitive impairment. ^{91,92} Participants will need to self-report being able to read and write, own a cell phone with a flat fee and use it at least weekly for texting. The Research Assistant (RA) will schedule an appointment with eligible participants to complete the informed consent and baseline assessment. We will consent participants via Zoom, phone, at the ADC, community centers or their homes to address potential participation barriers commonly experienced by Latinos. ⁴⁹ The RA will review consent forms, which will describe study goals, procedures and confidentiality while emphasizing that study participation is voluntary and participants may withdraw at any time. The RA will respond to questions, obtain verbal and written informed consent and provide a copy of the consent form to the participant. Participants who sign the informed consent will be considered enrolled and will proceed to complete the baseline assessment.

Retention and reimbursement. To reduce attrition, we will collect contact information from an alternate contact person. We will keep flexible hours and conduct home visits or remote calls via zoom or phone as needed. Participants will receive \$20 prepaid cards for completing assessments at baseline and follow-up. All materials developed by the research team will be bilingual and follow translation and back translation procedures following the guidelines of the World Health Organization. ⁹⁸

Intervention. *CuidaTXT* will be a text message intervention designed to engage Latino caregivers of IWD in a personal and intensive process of caregiver support. The intervention will send Latino caregivers a series of structured and interactive text messages on their cell phones over six months. *CuidaTXT* will be available in English and Spanish, incorporate two-way messaging and tailor the content and delivery of text messages to the preferences and characteristics of Latino caregivers. Text messages will be 140 characters long maximum ²⁸ and include three modalities: 1) Scheduled messages: Structured automatic messages delivered recurrently. For example, sending participants a text message on ADRD education every day. 2) Keyword-driven messages: Automatic responses or new scheduled messages sent to participants as a response to a specific keyword they typed in. For example, if the participant texts the keyword RELAX, they automatically receive instructions on how to relax. 3) Open-ended text responses: manual responses to participants as a response to a non-specified text. For example, if participants text they need troubleshooting, the team may help via text. The RA will monitor open-ended responses during business hours and report to the social worker as needed.

CuidaTXT will be multicomponent and based on the Stress Process Framework as supported by evidence. ^{1,34-36} Text messages will belong to components deemed important by the literature and our formative work on Aim 1 including the following examples: ^{1,24,25}

- Logistics: “We will send you daily messages to learn more about memory loss. You can also text us keywords to learn more about a specific topic”.
- ADRD education: “A common symptom of Alzheimer’s is memory loss. Early signs of Alzheimer’s include misplacing your keys more often than before”.
- Problem-solving skills training: “Please rate your level of stress from 1 to 5, 1 being none and 5 being very high” “You have indicated that you have very high stress. Which of the methods we learned would you like to use? Type RELAX, CBT or NONE”.
- Social support: “Want your family to receive texts like the ones we send you? Ask them to text us by typing CUIDATXT at [number]”.
- Care management: “You want me to notify you when [IWD] needs meds. Would you like this to be punctual or recurrent?” “You selected punctual notification. Please indicate the date typing Month/Day/Year. For example: 04/20/2019”.
- Referral to community resources: “Your Area Agency on Aging offers home-delivered meals to frail and elderly homebound residents and spouses. Call 913-573-5000 for more info”.

Measures. Assessments will include observation, metrics and survey information from Latino caregivers of IWD. Baseline surveys for caregivers will include sociodemographic data (age, gender, marital status, educational level, insurance type, household income, Latino origin and characteristics of the IWD) and acculturation (English preference, place of birth, years in USA).⁹⁹ Table 3 shows the feasibility, acceptability and preliminary efficacy assessments based on standard criteria.^{40,41,100} Preliminary efficacy outcomes are based on Stress Process Framework dimensions and include adapted Spanish-language scales.^{34,101}

Sample Size Justification. *CuidaTXT*’s primary outcomes will be assessed using simple descriptive statistics. The primary quantitative feasibility endpoints are dichotomous measures, so the proportions will be estimated as the main statistical results. Results will include 95% confidence intervals based on an exact binomial distribution. We hypothesize that 20/21 Latino caregivers will be able to opt into *CuidaTXT* without carrier restrictions, 16/20 Latino caregivers will not opt out of the intervention within six months and 18/20 will send at least one text message other than to opt in or to opt out. Taking these proportions into account, our confidence intervals will be within approximately $\pm 11.9\%$, $\pm 19.0\%$ and $\pm 15.2\%$, respectively, of their estimated proportions. These feasibility proportions have been chosen based on consensus between the investigators on clinically significant levels and the literature including our findings in previous text message intervention development.^{33,66-69,100,102,103} Because this is a feasibility study, the sample size was not fully-powered to test a hypothesis but allow a sufficiently accurate estimation of these important process measures to inform the subsequent R01 application. At the end of the study, all investigators, the ADC’s statistician, the RA and the Advisory Board will meet and review all results to make modifications to the intervention and study design and calculate the appropriate sample.

Data Analysis and Dissemination. We will use R software to upload and analyze quantitative data.⁸⁹ All electronic data will be stripped of identifiers and stored in password-protected files at the KU ADC and will be accessible only to research staff. We will use univariate statistics to describe feasibility, acceptability and preliminary efficacy. As the primary feasibility measures for Aim 2 are proportions, we will estimate proportions and exact 95% confidence intervals based on the binomial distribution (i.e. Clopper-Pearson confidence intervals).

Table 3. Feasibility, acceptability and preliminary efficacy outcomes in Aim 2

Outcome	Data source	Operationalization
Feasibility Enrollment	Direct observation	% of participants able to opt into <i>CuidaTXT</i>
Opting out of intervention	Metrics	% participants who texted STOP keyword
Technical problems	Follow-up survey (6m)	Open-ended reports of technical problems
Engagement	Metrics	% who sent at least one text message
	Follow-up survey (6m)	% of participants who report reading most or all texts
Acceptability Satisfaction with intervention	Follow-up survey (6m)	5-item Likert scale on satisfaction with intervention, text message logistics and content

Suggestions for refinement	Follow-up survey (6m)	Open-ended reports of suggestions
Preliminary efficacy Objective stressors	Follow-up survey (BL vs 6m)	IWD's cognitive status (MOCA), ^{104,105} physical function (FAQ) and behavior problems (NPI-Q) ¹⁰⁶
Subjective stressors	Follow-up survey (BL vs 6m)	Caregiver self-rated health (HEPESE), ¹⁰⁷ income inadequacy ¹⁰¹ and burden (ZBI) ¹⁰⁸
Resources	Follow-up survey (BL vs 6m)	Alzheimer's Disease Knowledge Instrument, ^{109,110} caregiver social support (ISEL-12), ¹¹¹ religiosity, ¹¹² self-efficacy (RSCSE) ^{113,114} and coping (COPE) ¹¹⁵
Outcome	Follow-up survey (BL vs 6m)	Depression (BDI-II) ¹¹⁶

CONSIDERATIONS, POTENTIAL PITFALLS, AND LIMITATIONS

Aim 1. We will use a comprehensive recruitment strategy (senior centers, media, clinic referrals and others in Kansas City). If needed, we will connect with clinics in rural Kansas where Latinos comprise a sizable portion of the population (i.e. 30-61% in 10 counties). The sample size used in the usability testing stage might seem small. However, five individuals is the optimal number of users needed to test a software program suggested by cost-benefit analyses.⁹⁰ The first participant discovers most flaws, and after the fifth user, we would observe the same findings repeatedly without learning much new.

Aim 2. Including a control group and powering the trial to assess efficacy in clinical outcomes would require too large a sample and is beyond the resources provided by this grant mechanism. The priority of this study is to develop and test the feasibility of the *CuidaTXT* following standard criteria (Stages 1a and 1b of the NIH Stage Model for Behavioral Intervention Development).^{40,41,100,117} If feasibility findings are favorable, we will conduct a fully-powered R01 RCT to assess efficacy (Stage 2).¹¹⁷ If not favorable, we will use the qualitative information gathered in the study and new research to refine the intervention and test its new feasibility before conducting an efficacy trial. Most information gathered is focused on the caregiver. Even though in the future we plan to gather more information from IWD, this is secondary. We acknowledge that the involvement of caregivers in the help of people with MCI or mild ADRD might be much lower than that of moderate and late stages, which may affect efficacy outcomes. Newer technologies such as Apps and chatbots might be more popular among Latinos in the future. The experience and materials used in this project will help develop future interventions using App and chatbot modalities if needed. Eligibility criteria requires participants to provide hands-on care for a relative with ADRD. This criterion excludes long-distance caregivers, who comprise 15% of caregivers, usually secondary.¹¹⁸ *CuidaTXT* will address this long-distance caregiving by including an option for secondary caregivers to request joining *CuidaTXT*. However, we will not include secondary caregivers in our data analyses. Future versions might interact with Facebook and WhatsApp, as they are the most common means of communication between Mexican Americans and their relatives living in Mexico.¹¹⁹ *CuidaTXT* will allow open-ended text responses. While it is important to reduce the need to use these messages to reduce human resources, open-ended text responses will help automatize new messages in the future.

PROTECTION OF HUMAN SUBJECTS

Aim 1. Develop a culturally and linguistically-appropriate text message intervention for caregiver support among Latino family caregivers of IWD

1. Risks to Human Subjects

1.a. Human Subjects Involvement, Characteristics, and Design.

Aim 1 corresponds to Year 1 and will use mixed-methods guided by user-centered design principles. Mixed-methods are required given the lack of literature on text message interventions for Latino family caregivers of IWD. Aim 1's six stages are based on previous research used to develop successful behavioral intervention software. Aim 1 will result in a text message library indicating the type of message, content, character count, delivery date and time, tailoring branching and theoretical construct corresponding to each text message. This text message library will be ready to be implemented on Aim 2's feasibility testing.

The only stage of Aim 1 that will require the recruitment of human subjects is Stage 4 (Usability testing). This stage aims to test the sketched text message intervention among actual Latino caregivers. We will use BOTMOCK to preview the behavior of diverse Latino caregivers in a variety of key scenarios (i.e. setting a notification or asking for specific instructions). The prototype testing will last one hour. The study will not require protected health information. The PI and Research Assistant will lead all observations and interviews.

Eligibility criteria:

- Spanish and English-speaking individuals
- Over the age of 18
- Identify as Latino
- Report providing hands-on care for a relative who has been given a clinical or research ADRD diagnosis
- Care recipient has an AD-8 cognitive screening score is greater than or equal to 2, indicating cognitive impairment

1.b. Study Procedures, Materials, and Potential Risks

Treatment: None.

Assessment. We will use three usability assessment modalities. First, direct observation of task completion with the simulated text message intervention. Second, open-ended interviews regarding their user experience with the different tasks and suggested changes to improve it. Third, the completion of the System Usability Scale, a valid and reliable 10-item 5-point Likert scale. Scores above 68 out of 100 indicate higher levels of usability. Given the iterative nature of this testing phase, we will modify the design features after each participant and provide the new version to the following participant. This iterative process is standard in formative evaluations. The PI and Research Assistant will lead all observations and interviews.

Data analysis. We will write down observed behaviors during the observation and integrate them into the text with the interviews. Interviews will be recorded, transcribed, and analyzed employing content, domain, and taxonomic analysis. We will code and transcribe content using ATLAS-ti. We will open-code transcripts by identifying keywords, themes, and descriptions of behavior within the text. Later, we will group the themes into coding categories and develop a code map to categorize and retrieve comments on each theme. Two independent coders will code the transcripts and their agreement will be measured using kappa coefficient. Central tendency estimates, frequencies and percentages will describe quantitative data on R Software.

Investigators/Institutions. The team of investigators include Drs. Perales, Vidoni, Burns Ellerbeck and Niedens at the University of Kansas Medical Center (KUMC). The study will be conducted at KUMC and all source documents will be housed at KUMC. All investigators have completed the required human subjects training.

Potential Risks. Procedures in Aim 1 involve minimal risks. Participants may find the questions boring, embarrassing or uncomfortable. For example, when interviewing caregivers about their relatives' condition, questions might be perceived as sad or stressful. Providing and storing health information for future research participation comes with inherent privacy risks. These risks are mitigated using information security recommendations and data servers behind the University firewall. These risks are conveyed during the consent process. All staff interacting with participants are trained on HIPAA and privacy protections.

2. Adequacy of Protection Against Risks

2.a. Informed Consent and Assent

Dr. Perales, a bilingual researcher has developed the informed consents in both English to Spanish. Informed consent will be obtained by designated, trained staff, and the purposes of the study, its assessment procedures, and risks and benefits will be explained. The original signed consent form is kept with the participant's confidential file and a copy is given to the participant.

2.b. Protections Against Risk

Regarding potential perception of boring, embarrassing or uncomfortable of questions, interviewers are trained to be empathetic to minimize concerns, the consent will stress the volunteer nature of the study and of answering any questions as well as inform them of the risks of participating before signing the consent. The information collected cannot put participants at legal or physical risk of any kind. Although participant's identifying information will be collected in the informed consent and for incentive purposes this data will be kept separate from study data. All studies will undergo IRB approval. Identifiable information will be kept in secure file cabinets in a locked office and databases under password protection from the computer and the database. Digital audiotapes will be stored on secured university data servers. Audio files will be transcribed and all word processing files will be labeled with patient ID-codes only and stored in locked cabinets inside locked study offices. These databases will not be linked to interview information.

Additionally, the following policies will be adopted to assure the safety of the participants in this study:

1. Strict adherence to institutional regulations for conducting clinical research
2. The involved support staff will be adequately trained to conduct human research and will have completed the necessary institutional web-based training prior to the study
3. We will comply with HIPPA regulation and commit to maintaining the patient confidentiality.
4. Any research presentations or publications from the proposed studies will not disclose any personal identity information.

3. Potential Benefits of the Proposed Research to Research Participants and Others

Given the non-interventional nature of Aim 1, this aim will have no direct potential benefits for participants. Aim 1 however, has the potential to benefit the development of *CuidaTXT*, which might improve the lives of many caregivers of individuals with dementia, their relatives and society through reducing physical, emotional and financial costs. Research scientists and clinicians may be able to use the knowledge gained from this study as it will increase our ability to test dementia therapies.

4. Importance of the Knowledge to be Gained

Society benefits from research advances in aging and the improvement of life quality through research that has adequate numbers of participants. This study will enhance our understanding on how to develop a text message caregiver support intervention for Latinos who take care of individuals with dementia.

5. Data Safety Monitoring Plan

The purpose of the Data Safety Monitoring Plan is to ensure the safety of study participants and the validity of data, in compliance with NIH requirement for Data Safety Monitoring for Clinical Research.

Data Monitoring Plan: Data will be collected using laptop computers and directly entered into a password protected Microsoft Access Database that will be stored on study network folder at the University of Kansas

Medical Center that is only accessible to study staff. The codes sheet that links the study identification number with participant names will be stored separately from data in a password protected Microsoft Excel spreadsheet on a study network folder that is only accessible by study staff.

Outcome data will be investigated using thorough descriptive statistics and qualitative analysis. The PI and Research Assistant (RA) will monitor Data Quality weekly. They will resolve any issues related to data and modify data collection procedures modified to improve data quality.

Safety Monitoring Plan: Adverse events will not be monitored as there is no intervention. In the event of a data or privacy breach, the occurrence will be immediately reported to the PI, and the Human Participants Committee per KUMC Human Participant Committee reporting policies.

Conflict of Interest: The researchers involved in this study do not have any known conflict of interest issues in this Data and Safety Monitoring Plan.

Aim 2. Test the feasibility and acceptability of CuidaTXT.

Risks to Human Subjects

1.a. Human Subjects Involvement, Characteristics, and Design.

Aim 2 corresponds to Year 2 of the current project. We will conduct a one-arm trial to examine the feasibility, acceptability and preliminary efficacy of *CuidaTXT*. We will allocate 20 Latino caregivers to six months of *CuidaTXT*. We will use standard criteria to assess the outcomes. The PI and the RA will lead all interviews with Latino caregivers.

Eligibility criteria:

- Spanish and English-speaking individuals
- Over the age of 18
- Identify as Latino
- Report providing hands-on care for a relative who has been given a clinical or research ADRD diagnosis
- Care recipient has an AD-8 screening score greater than or equal to 2, indicating cognitive impairment
- Self-report being able to read and write
- Self-report owning a cell phone with a flat fee and use it at least weekly for texting

1.b. Study Procedures, Materials, and Potential Risks

Treatment. *CuidaTXT* will be a text message intervention designed to engage Latino caregivers of IWD in a personal and intensive process of caregiver support. The intervention will send Latino caregivers a series of structured and interactive text messages on their cell phones over six months. *CuidaTXT* will be available in English and Spanish, incorporate two-way messaging and tailor the content and delivery of text messages to the preferences and characteristics of Latino caregivers. Text messages will be 140 characters long maximum and include three modalities: 1) Scheduled messages: Structured automatic messages delivered recurrently. For example, sending participants a text message on ADRD education every day. 2) Keyword-driven messages: Automatic responses or new scheduled messages sent to participants as a response to a specific keyword they typed in. For example, if the participant texts the keyword RELAX, they automatically receive instructions on how to relax. 3) Open-ended text responses: manual responses to participants as a response to a non-specified text. For example, if participants text they need troubleshooting, the team may help via text. The RA will monitor open-ended responses during business hours and report to the social worker as needed.

CuidaTXT will be multicomponent and based on the Stress Process Framework as supported by evidence. Text messages will belong to components deemed important by the literature and our formative work on Aim 1 including the following examples:

- Logistics: “*We will send you daily messages to learn more about memory loss. You can also text us keywords to learn more about a specific topic*”.
- ADRD education: “A common symptom of Alzheimer’s is memory loss. Early signs of Alzheimer’s include misplacing your keys more often than before”.
- Problem-solving skills training: “Please rate your level of stress from 1 to 5, 1 being none and 5 being very high” “You have indicated that you have very high stress. Which of the methods we learned would you like to use? Type RELAX, CBT or NONE”.
- Social support: “Want your family to receive texts like the ones we send you? Ask them to text us by typing CUIDATXT at [number]”.
- Care management: “You want me to notify you when [IWD] needs meds. Would you like this to be punctual or recurrent?” “You selected punctual notification. Please indicate the date typing Month/Day/Year. For example: 04/20/2019”.

Referral to community resources: "Your Area Agency on Aging offers home-delivered meals to frail and elderly homebound residents and spouses. Call 913-573-5000 for more info".

Recruitment. We will recruit through multiple modalities capitalizing on the KU ADC's strong networks. Our network includes 1) clinic referrals within our collaborative care network in Kansas City, 2) partners from five Latino-affluent community centers, 3) the Hispanic Ministry of the Kansas City Catholic Dioceses, 4) our Spanish and English language Facebook page and 5) local Latino media (radio, newspaper and TV). There are >24,000 Latinos 50 or older in Kansas City Metro, many of them served by our community partners (i.e. El Centro serves >10,000 Latino families/year). Our previous research suggests that approximately one in every four adult Latinos we reach through our ADRD educational presentations provide or have provided care to a relative with ADRD. 70 Out of those caregivers, ~75% reported needing caregiver support. Therefore, we will need to reach 107 Latinos to enroll 20, which should take no more than 2-3 months.

Eligibility, consent, enrollment and baseline assessment. We will provide participants with study information in their preferred language adapted for individuals with low literacy levels either in person, at the recruitment site or via phone. After providing study information, we will assess participants' eligibility. Inclusion criteria for this stage include Spanish and English-speaking individuals who are over the age of 18, identify as Latino and who report providing hands-on care for a relative who has been given a clinical or research ADRD diagnosis and has an AD-8 screening score ≥ 2 , indicating cognitive impairment. Participants will need to self-report being able to read and write, own a cell phone with a flat fee and use it at least weekly for texting. The RA will schedule an appointment with eligible participants to complete the informed consent and baseline assessment. We will consent participants at the ADC, community centers or their homes to address potential participation barriers commonly experienced by Latinos. The RA will review consent forms, which will describe study goals, procedures and confidentiality while emphasizing that study participation is voluntary and participants may withdraw at any time. The RA will respond to questions, obtain verbal and written informed consent and provide a copy of the consent form to the participant. Participants who sign the informed consent will be considered enrolled and will proceed to complete the baseline assessment.

Retention and reimbursement. To reduce attrition, we will collect contact information from an alternate contact person. We will keep flexible hours and visit locations. Participants will receive \$20 prepaid cards for completing assessments at baseline and follow-up. All materials developed by the research team will be bilingual and follow translation and back translation procedures following the guidelines of the World Health Organization.

Investigators/Institutions. The team of investigators include Drs. Perales, Vidoni, Burns Ellerbeck and Niedens at the University of Kansas Medical Center (KUMC). The study will be conducted at KUMC and all source documents will be housed at KUMC. All investigators have completed the required human subjects training.

Potential Risks. Procedures in Aim 2 involve minimal risks. Participants may find the questions boring, embarrassing or uncomfortable. For example, when interviewing caregivers about their relatives' condition, questions might be perceived as sad or stressful. Providing and storing health information for future research participation comes with inherent privacy risks. These risks are mitigated using information security recommendations and data servers behind the University firewall. These risks are conveyed during the consent process. All staff interacting with participants are trained on HIPAA and privacy protections. *CuidaTXT* may provide education and advice that can affect caregivers negatively.

2. Adequacy of Protection Against Risks

2.a. Informed Consent and Assent

Dr. Perales (bilingual researcher) has developed the informed consents both in English to Spanish. Informed consent will be obtained by designated, trained staff. The informed consent will explain purposes of the study,

its assessment procedures, and risks and benefits. The original signed consent form is kept with the participant's confidential file and a copy is given to the participant.

2.b. Protections Against Risk

Regarding potential perception of boring, embarrassing or uncomfortable questions, interviewers are trained to be empathetic to minimize concerns, the consent will stress the voluntary nature of the study and of answering any questions as well as inform them of the risks of participating before signing the consent. The information collected cannot put participants at legal or physical risk of any kind. Although participants' identifying information will be collected in the informed consent and for incentive purposes, this data will be kept separate from study data. All studies will undergo IRB approval. Identifiable information will be kept in secure file cabinets in a locked office and databases under password protection from the computer and the database. Digital audiotapes will be stored on secured university data servers. These databases will not be linked to interview information. Text messages will not contain personal identity information. Study participants will be advised to protect their phone and turn off preview features that allow a preview of the message to be automatically displayed on the screen. Recipients will be told how to opt-out of receiving text messages in a timely manner. We will hire a text message vendor with built-in security features that will protect information.

Additionally, the following policies will be adopted to assure the safety of the participants in this study:

1. Strict adherence to institutional regulations for conducting clinical research
2. The involved support staff will be adequately trained to conduct human research and will have completed the necessary institutional web-based training prior to the study
3. We will comply with HIPPA regulation and commit to maintaining the patient confidentiality.
4. Any research presentations or publications from the proposed studies will not disclose any personal identity information.

3. Potential Benefits of the Proposed Research to Research Participants and Others

Caregivers will be able to receive a caregiver support intervention that aims to reduce depression and stress. Individuals with dementia can also benefit from the improved health of the caregiver and other support received via *Cuida TXT*. In addition, participants will be given the opportunity to contribute to finding better ways of improving their lives by participating in this study. Participants will be compensated for assessments and will be informed that incentives are not contingent on any outcome.

4. Importance of the Knowledge to be Gained

Society benefits from research advances in aging and the improvement of life quality through research that has adequate numbers of participants. This study will enhance our understanding on how to refine a text message caregiver support intervention for Latinos who take care of individuals with dementia.

5. Data Safety Monitoring Plan

This Human Subjects Research meets the National Institutes of Health (NIH) definition of a clinical trial. An appropriate Data Safety Monitoring Plan has been developed. The purpose of the Data Safety Monitoring Plan is to ensure the safety of study participants and the validity of data, in compliance with NIH requirement for Data Safety Monitoring for Clinical Research.

Data Monitoring Plan: Data will be collected using laptop computers and directly entered into a password protected Microsoft Access Database that will be stored on study network folder at the University of Kansas Medical Center that is only accessible to study staff. The codes sheet that links the study identification number with participant names will be stored separately from data in a password protected Microsoft Excel spreadsheet on a study network folder that is only accessible by study staff.

Outcome data will be investigated using thorough descriptive statistics. The PI and Research Assistant (RA) will monitor Data quality weekly. They will resolve any issues related to data and modify data collection procedures modified to improve data quality.

Safety Monitoring Plan: We have developed Standard Operating Procedures (SOPs) for participants that may report suicidality. Our RA will be trained in these SOPs and will notify the PI of any suspicious messaging. The PI will follow the SOP to ensure the safety of the participant and notify the IRB. The RA will continually monitor participants for these and other adverse events. Any adverse event will be immediately reported to the PI and the Human Subjects Committee per KUMC Human Subject Committee reporting policies. Should a study participant experience an adverse event in any category rated 3 or greater according to CTCAE v3.0 that is directly related to *CuidaTXT*, that individual will be removed from the study immediately. Should more than 10% of participants experience adverse events during the study period in any category rated 3 or greater according to CTCAE v3.0 directly related to the study, the study will be terminated immediately.

Conflict of Interest: The researchers involved in this study do not have any known conflict of interest issues in this Data and Safety Monitoring Plan.

Content of the Data Safety Monitoring Report: The PI will submit the Data Safety Monitoring report with the annual progress report. This report will include information organized into the following sections: study description, socio-demographic characteristics of the accumulated participants at baseline, data on the status of study participants, quality assurance issues, and regulatory issues, data on Adverse Events and Serious Adverse Events, and feasibility outcomes.

Title: CuidaTXT: a Text Message Dementia-caregiver Intervention for Latinos

NCT#: NCT04316104

Document date: 8/1/2022

File: Consent form

RESEARCH CONSENT FORM: Stage 2; CuidaTXT
CuidaTXT: A Text Message Dementia-Caregiver Intervention for Latinos

You are being asked to participate in this research study because you are a Latino caregiver of a person with memory and thinking problems.

You do not have to participate in this research study. The main purpose of research is to test the first text message caregiver intervention for Latinos who take care of someone with memory and thinking problems.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read the form carefully and ask as many questions as you need to, before deciding about participating. You can ask questions now or anytime during the study.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Jaime Perales Puchalt as the researcher. Twenty people will be in the first stage of the study at KUMC.

BACKGROUND

Taking care for an older adult with memory and thinking problems can be challenging for a person's mental and physical health and financially. While interventions exist to improve caregivers' lives, Latinos have a low access to them.

We are creating CuidaTXT, a program that will send messages to caregivers via cellphones to improve caregiver support through:

- Educating about memory and thinking problems
- Solving problems that are common among caregivers
- Sending reminders for things such as the time at which s/he needs to take the medications
- Improving communication with family, friends and other resources.

Why would text messages be a better way to help Latino caregivers of people with memory and thinking problems?

- The potential for cell phones and text message to deliver treatment messages is even greater among Latinos; because Latinos use cellphones or text messages more compared to other groups.

PURPOSE

The purpose of this study is to test the first text message intervention to support Latino caregivers of people with memory and thinking problems (CuidaTXT).

PROCEDURES FOR USABILITY TESTING PARTICIPANTS

If you are eligible and decide to participate in this study, your participation will last six months.

- You will be asked to complete 2 in person assessments to evaluate your wellbeing at the beginning (baseline), and at six months (follow up). These surveys will help us to understand the impact of providing care for an individual with memory and thinking problems and the benefits of using CuidaTXT.
- You will be asked to complete two calls during the first weeks to assess satisfaction with the first stages of the intervention and any technical problems you might have had.
- The text messages will be monitored, analyzed and summarized for this research project. Text messages will not include your name or any identifiable information.
- The program and the assessment will be in your preferred language (Spanish or English). Your participation will be key in improving CuidaTXT.

RISKS

There is minimal risk to participate in this study involved in receiving daily caregiving support text messages. You might find the questions boring, embarrassing or uncomfortable. The information collected cannot put you at any legal or physical risk. Although your identifying information will be collected in the informed consent and for incentive purposes, this data will be kept separate from study data. Identifiable information will be kept in secure file cabinets in a locked office and databases under password protection from the computer and the database.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

By participating in this study, you will receive free text messages to educate you about memory problems, help you solve problems related to caregiving, help you improve your communication with family and friends and links you to resources. These text messages may benefit you by ultimately reducing your levels of depression and stress. The improvement of CuidaTXT might benefit the lives of many caregivers, their relatives and society. These potential benefits may be physical, emotional and monetary. The knowledge gained from this study could potentially improve our ability to test dementia therapies.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you receive at the University of Kansas Medical Center. You can also enroll in caregiver support groups provided by the Alzheimer's Disease Center or the Alzheimer's Association, use respite care, psychotherapy or other caregiver support materials such as fotonovelas.

COSTS

There is no cost for being in the study.

PAYMENT TO SUBJECTS

You will receive a \$20 at the time of the first visit and \$20 at the second visit, up to a total of \$40. You will receive these payments in the form of gift cards and you will receive them regardless of whether the intervention works for you or not. The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to write checks for your study payments. Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if your payments are \$600 or more in a calendar year.

IN THE EVENT OF INJURY

If you experience side effects or other problems during this study, you should immediately contact Dr. Jaime Perales Puchalt at (913)-588-3716. A member of the research team will decide what type of treatment, if any, is best for you at that time.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study. Your permission to use and share your research information will not expire unless you cancel it.

QUESTIONS

Before you sign this form, Dr. Perales Puchalt or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. You can contact Dr. Jaime Perales Puchalt at (913)-588-3716. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

CONSENT

Dr. Jaime Perales Puchalt or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study. By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered. ***You will be given a signed copy of the consent form to keep for your records.***

Print Participant's Name

Signature of Participant

Time _____ Date _____

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date _____