Official Title: Feasibility of a Systems Approach for Alzheimer's Services Among Latinos Attending Primary Care Practices

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RESEARCH CONSENT FORM: Stage 2; Pilot
Alianza Latina

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You are being asked to participate in this study because you are either a person with memory and thinking issues or an individual who is making decisions on behalf of a person with memory and thinking issues and providing care or support.

You do not have to participate in this research study. The main purpose of research is to test a dementia care program for Latinos with memory and thinking problems and their caregivers.

To participate in this study, you will need your family caregiver as study partner. This is someone who has frequent contact with you, provides hands on care for you in any way (e.g., physical, emotional) and has an adequate understanding and awareness of your health.

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. One hundred people will be in the second stage of the study at KUMC.

BACKGROUND
Mild cognitive impairment and dementia have an enormous health and financial impact on individuals, families and the society as a whole. A timely detection and optimal care can optimize the prognosis for patients and improve their families' lives. Latinos experience substantial disparities in dementia diagnosis and care compared to their non-Latino white peers, putting them at an increased risk for steeper cognitive decline, morbidity, mortality and caregiver burden.

This project will address this research gap by 1) Examining the current primary care models of dementia care to identify what services are offered and how they are delivered across a variety of settings and 2) Testing the feasibility and acceptability of Alianza Latina, a dementia care program to reduce disparities in dementia diagnosis and care experienced by Latinos.

Why would Alianza Latina be a better way to help Latino caregivers of people with memory and thinking problems and their caregivers?

- Alianza Latina will enhance timely dementia diagnosis and optimal care to minimize behavioral symptoms and cognitive decline among Latinos in a linguistically and culturally-appropriate way.

PURPOSE
The specific objectives of this proposal is to test whether you are satisfied with Alianza Latina and understand how to best implement it.

PROCEDURES FOR THE PILOT
If you are eligible and decide to participate in this study, your participation in this pilot study will last six months and you will be asked to do monthly visits with Health Navigators. All visits will be conducted at either the KU Alzheimer's Disease Center, at an easily accessible community-based site, over the phone or via videocall. You will be given feedback following your Health Navigator visits and allowed to ask questions. A summary of your visit will be sent to your personal primary care provider. The purpose of this disclosure is to update your primary care provider about your health. We will assess the following:

- Demographics such as the age and gender of both the person with memory problems and their caregiver.
- You will be asked to complete 2 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 Alianza Latina on Latino care recipients and caregivers.
- The program and the assessment will be in your preferred language (Spanish or English). Your participation will be key in improving Alianza Latina.

Your caregiver will be enrolled in CuidaTEXT, a program that sends messages to caregivers via cellphones to improve caregiver support.

RISKS
Risks to participants will be minimal. You might find the questions or Health Navigator information 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. A written summary of your visits with Health Navigators will be released to your personal primary care provider. Because of this information or if your primary care provider writes in your medical record any information you have given him/her regarding your research participation, your information could be seen by person's obtaining your medical record.

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.

DISCLOSURE OF RESEARCH RESULTS
Dr. Perales of his team will tell you about any study results that directly affect your personal medical care during the study. They will do so unless you prefer them not to.

BENEFITS
By participating in this study, you will be able to speak with a Health Navigator with experience in implementing guidelines to address problems associated with memory and thinking issues.

Clinical Intake Assessments will include behavioral symptoms, safety at home, driving, legal issues and others. Alianza Latina also has the potential to detect dementia timely for early provision of care, which may improve your quality of life. In addition, you will be given the opportunity to contribute to finding better ways of improving the quality of life among people with memory and thinking issues and their caregivers by participating in this study. You will be compensated for assessments, but incentives are not contingent on any outcome.

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.

COSTS
There is no cost for being in the study.

PAYMENT TO SUBJECTS
You will receive a $20 gift card 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, 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 harm 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.

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.

Your health information is protected by a federal privacy law called HIPAA. If you sign this consent form, you give permission for KUMC to use and share your health information. You can decide not to sign this form and not be part of the study.

Dr. Perales and members of the research team will only use and share information that is needed for the study. They will collect health information from the study activities and from your medical record. Your medical records may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

If you sign this form, you give the study team permission to share your medical and research information with people outside KUMC. These groups or agencies may make copies of study records for audit purposes. Some of these groups might not have to comply with the HIPAA law,

but they have agreed to protect your information. These groups may include:

- National Institutes of Health
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- Other federal agencies that oversee human research (if a study audit is performed)
- Ethics committees that review the study for other locations
- Your primary care provider

Your study information will be labeled with your research ID number. The KUMC study team will keep a separate list that matches your name to the research ID number. By taking these steps, there is less risk that your personal identity and information will be seen by others who shouldn't have it.

Researchers plan to use your information indefinitely unless you cancel your permission. Any research information that is put in your medical record will be kept indefinitely. You have the right to see and copy any study information that is included in your medical record.

You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Perales using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your cancellation.

FUTURE USE OF YOUR RESEARCH INFORMATION

In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

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 on your behalf and on the behalf of the person you provide care for (if not able to consent for themselves). By

signing, you also authorize Dr. Jaime Perales Puchalt or members of the study team to release information about my health to my primary care provider _____ (insert healthcare provider name), who works at _____(insert name of clinic). 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 Explaining Consent

_____ _____ _____

Signature of Person Explaining Consent Time Date

CONSENT BY A SURROGATE DECISION-MAKER

As legal guardian or representative, I,_____,
Type/Print Name of Guardian/Representative
authorize the participation of _____ in this study.
Type/Print Name of Participant

I understand that I may not authorize participation in this study if the individual has previously expressed wishes to the contrary, either orally or in writing.

I understand that I and the person for whom I make decisions are under no obligation to participate in any future research studies.

I am (please initial one of the following categories):
A) Legal guardian or Durable Power of Attorney for Healthcare Decisions
B) Adult or emancipated minor's spouse (unless legally separated)
C) Adult child
D) Parent
E) Adult relative by blood or marriage

_____ _____ _____
Signature of Legal Guardian/ Representative Time Date

_____
Print Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Time Date

ASSENT

I am being asked to be in a research study because I have memory problems. The investigator and/or his assistants have explained the study to me and my caregiver.

If I decide to be part of this study, I will attend study visits over six months in person, over the phone or via teleconference. I will answer questions about my physical and mental health for assessment and care purposes.

My caregiver has read the consent form and has agreed for me to do this research study. If I sign my name, I am saying that I want to be in the study. I know that I don't have to do it even if my caregiver has given their permission. I know that I can stop being in this study even if I signed my name. If I want to stop at any time, all I have to do is tell my caregiver, the primary investigator, or his assistants.

_____
Print Subject's Name

_____ _____
Signature of Subject Date