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

NCT Number: NCT04418232

Date of Consent Form Approval: 10/6/2022

Feasibility of a Novel Systems Approach for Improving Utilization of Alzheimer's Disease Services Among Latinos Attending Primary Care Practices

SPECIFIC AIMS

Alzheimer's disease and related dementias (ADRD) are a major cause of mortality and disability in later life and cost the US healthcare system more than cancer or heart disease.[1,2] The National Alzheimer's Plan Act and the National Institutes of Health have identified ADRD disparities among ethnic minorities as a public health priority.[3-5] Latinos with ADRD experience substantial disparities with reduced rates of early diagnosis and lower quality care compared to their non-Latino white peers, which put them at an increased risk for steeper cognitive decline, morbidity, mortality and higher caregiver burden.[6-9] A number of barriers conspire to create these disparities including a lack of an evidence-based strategy to address ADRD in clinics, patient and primary care provider (PCP) reduced ADRD knowledge, negative attitudes regarding ADRD, PCP's lack of time, cultural and language barriers and health insurance status.[10-19] To improve healthcare delivery to Latinos with ADRD, we need to redesign current ADRD detection and care systems to follow evidence-based recommendations for early detection and culturally appropriate chronic care.

The **overall aim** of this proposal is to enhance the delivery of ADRD services to Latinos in primary care through a scalable systems approach that includes evidence-based recommendations.[20] Primary care clinics are the ideal setting to provide ADRD services, as 93% of older Latinos have a usual source of healthcare. The novel systems approach (*Alianza Latina*/Latino Alliance) will enhance timely ADRD diagnosis and optimal care to minimize behavioral symptoms and cognitive decline among Latinos in a linguistically and culturally-appropriate way. *Alianza Latina* will use the Collaborative Care Framework [21-24] that capitalizes on PCPs and Health Navigators. 1) PCPs will undergo evidence-based training to enhance timely and culturally appropriate diagnosis and implement it in their work routine. 2) PCPs will detect, treat and refer Latino ADRD patients to a bilingual Health Navigator to provide chronic care management, which will reduce PCP time burden.

This proposal is a natural progression of my work in the Latino community throughout my Diversity Supplement [25] and in line with my **long-term goal** to establish an independent research program to address disparities in ADRD experienced by Latinos. I have strong interdisciplinary expertise in epidemiology, aging and health disparities. During my Diversity Supplement, I gained relevant experience in ADRD assessment and community-engaged research with Latino community centers. This K01 will provide me with unique formal and hands-on training in 1) evidence-based ADRD care, 2) health systems research and 3) qualitative research. I will address these gaps guided by the mentorship of Drs. Burns, Greiner and Williams. This award will provide the necessary training to become an independent researcher via mentored research, formal coursework, directed readings, seminars, conferences and other career development activities.

> **Aim 1: Examine the current primary care models of ADRD care to identify what services are offered and how they are delivered across a variety of settings.** We will conduct semi-structured interviews among clinic staff, older Latinos with ADRD and their caregivers in primary care clinics from diverse regions. Our goal is to understand the barriers (and facilitators) that Latinos may encounter in primary care clinics regarding ADRD detection and care including: 1) currently offered ADRD services, 2) adherence to best practices, [20,26] 3) linguistic and cultural barriers to ADRD service access and 4) geographic differences in these services and barriers.
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> **Aim 2: Test the feasibility and acceptability of *Alianza Latina*.** <u>Aim 2.a:</u> We will train PCPs from 10 Kansas City clinics to enhance skills in cultural competence, ADRD detection, treatment and referral to a Health Navigator among Latinos 65 and older with ADRD. <u>Aim 2.b.</u> The Health Navigator will provide 100 patients/caregiver dyads referred by *Alianza Latina* PCPs or other sources (e.g., flyers, online advertising) with care management, psychosocial support and links to relevant community resources. We will assess the feasibility and acceptability [27,28] of 1) PCP training and 2) patient and caregiver ADRD care. Feasibility outcomes will provide the necessary information to further refine the intervention in preparation for a fully-powered R01 RCT comparing the efficacy and cost-effectiveness of *Alianza Latina* vs Standard Care in the state of Kansas, a state where 11% of the population identifies as Latino and 13 counties have a Latino population of more than 20%.[29]

This proposal is innovative, as there is a lack of healthcare systems developed to address disparities in ADRD diagnosis and care among Latinos. *Alianza Latina* may reduce costs by reducing the need for highly specialized memory clinics, emergency room visits and other avoidable healthcare use and by prioritizing crisis-prevention rather than reaction. [30-37] This proposal will have a significant impact given its potential high cost-effectiveness and the fact that it focuses on Latinos, the largest ethnic minority and fastest growing older group in the USA.[38]

SIGNIFICANCE

The impact of Alzheimer's disease

Alzheimer's disease and related disorders (ADRD) pose a serious public health threat in the USA. The share of American older adults is increasing and the risk of ADRD increases with age.[39,40] ADRD is the fifth leading cause of mortality and its associated disability has increased substantially in the past two decades.[41-43] Individuals with ADRD have more chronic conditions, polypharmacy use and hospitalizations than older adults without ADRD.[41] Caregivers of people with ADRD often experience disproportionate depression (~34%) and anxiety (~44%).[44] ADRD costs exceed those of cancer and heart disease. [2,41]

A timely detection and optimal care can optimize the prognosis for patients with ADRD and is a priority for National Alzheimer's Project Act (NAPA).[3] Though there are no treatments that prevent or stop the progression of ADRD, there is evidence that pharmacologic and behavioral interventions can stabilize and delay the progression of cognitive, functional and behavioral outcomes, improving the lives of individuals with ADRD and their families.[45,46] Given the progressive nature of ADRD, early diagnosis may allow both the patient and family to participate in their care plan and begin more efficacious interventions.[47] Early detection and care also has economic benefits at the individual, familial and societal levels.[48-50]

Why focus on improving ADRD diagnosis and care among Latinos?

Addressing ADRD disparities among Latinos is a federal public health priority. Ethnic health and ADRD disparities are core targets of major USA agencies including Healthy People 2020,[51] the National Institute on Minority Health and Health Disparities,[5] National Institute on Aging [4] and NAPA.[3] Latinos are the largest ethnoracial US minority (18%) [52] and are the fastest growing elder group, projected to increase more than sevenfold by 2060.[38,40] Latinos have worse levels of ADRD risk factors than non-Latino Whites including education and cardiovascular health [53-66] and earlier ADRD onset.[38,67-74]

Latinos experience **substantial disparities in ADRD diagnosis and care.** Compared to non-Latino Whites, disparities in ADRD diagnosis and care among Latinos include:

- Lower detection of memory disorders by providers.[6]
- Higher severity and duration of ADRD symptoms at time of first diagnosis.[75-77]
- Higher risk of behavioral and psychological symptoms (BPSD)[78] and more BPSD unmet needs.[79]
- Higher risk of becoming an informal caregiver of a relative with ADRD and higher caregiver burden.[80]
- Lower probability to use caregiver support services and anti-dementia medication. [7-9,81,82]

What barriers to ADRD diagnosis and care do Latinos experience?

Data from 2011-2013 suggests that most older Latinos (93%) have a usual source of healthcare.[83] However, multiple factors contribute to the poor ADRD detection and care Latinos receive. Healthcare barriers include the lack of strategies to provide early ADRD diagnosis and care in primary care clinics.[84,85] For example, since its inception in 2011, no-cost fee-for-service Medicare Annual Wellness Visits require a cognitive screening among other relevant health assessments for older adults. However, these visits are under-implemented in minority-affluent clinics and do not require the use of validated tests for screening.[86] Some healthcare providers have poor attitudes towards addressing ADRD due to lack of ADRD knowledge on potential benefits of appropriate diagnosis and care.[11,12] Some health providers also lack the knowledge and skills to diagnose, provide care for or refer to frequently fragmented community resources.[11,12] Healthcare providers also experience time constraints.[11,12] These barriers are more prevalent among Latinos, as many providers lack cultural and linguistic proficiency and knowledge of validated tools for assessment and care.[12-15] At the individual level, Latinos are the group with the lowest ADRD knowledge and most misconceptions, which may hinder effective assessment and care-seeking behaviors on behalf of individuals with ADRD and their relatives.[12,17] For example, a lack of ADRD knowledge can lead to misconceptions such as thinking that ADRD is a normal part of aging.[17-19] At the socio-economic level, Latinos are the highest underinsured ethnic group leading to higher out-of-pocket costs that may result in a suboptimal ADRD assessment and care.[16] The current proposal will test the feasibility of a health systems approach to address ADRD healthcare, individual and socio-economic barriers experienced by Latinos. Reducing these barriers has the potential to reduce the disproportionate impact of ADRD among Latinos.

INNOVATION

ADRD research with culturally diverse populations is critical; however, most ADRD research among Latinos is observational.[69,73,87,88] Research on health systems interventions to address barriers leading to disparities in ADRD diagnosis and care among Latinos is lacking. This proposal will implement a health systems intervention (*Alianza Latina*-Latino Alliance) based on the Collaborative Care Framework [21-24] to address healthcare, individual and socio-economic level barriers. The Collaborative Care Framework offers a guide for higher-quality chronic illness management within primary care in which informed, activated patients interact with prepared, proactive practice teams. Interventions based on this framework have shown to be effective in improving patient outcomes.[89] The intervention capitalizes on the potential of primary care providers (PCPs) to be the point of access to healthcare for Latino older adults, as most of them are insured (96%) and have a usual source of healthcare (93%).[10,83] Focusing on PCPs may reduce the cost and saturation of expensive and highly specialized memory clinics. The intervention also capitalizes on Health Navigators. While interventions have used Health Navigators to address health disparities among minorities,[90] to our knowledge, no intervention has implemented these models to address disparities in ADRD care. Health Navigators may reduce costs by addressing complications that lead to avoidable healthcare use such as emergency room visits and institutionalization and prioritizing crisis-prevention rather than reaction. [30-37] Table 1 shows how *Alianza Latina* will address barriers to ADRD diagnosis and care among Latinos using the Collaborative Care Framework. Health Navigators will provide chronic care relieving PCP time burden and ensuring central Latino values and barriers are taken into account in the care process (i.e. educating the family on ADRD, promoting warm communication and tailoring messages in line with participants' literacy levels).[91]

Table 1. Barriers among Latinos in ADRD services addressed by the Collaborative Care Framework

Barriers in ADRD services	**Collaborative Care Framework components**
Healthcare barriers: Lack of clinics' strategies to provide ADRD detection & care Lack of PCP knowledge and nihilistic attitudes Linguistic & cultural barriers Fragmented community resources Time constraints	Use of evidence-based recommendations for timely ADRD detection and optimal care; PCP education in cultural proficiency and ADRD knowledge, detection and care skills and attitudes; linguistically and culturally proficient Health Navigators who manage ADRD chronic care and refer to culturally appropriate community resources
Individual barriers: Lack of patient and family ADRD knowledge	PCPs and Health Navigators provide culturally appropriate patient and family ADRD education
Insurance barriers: Underinsurance	Health Navigators refer patients to existing financial assistance programs for ADRD expenses if needed

SUSTAINABILITY PLAN

Alianza Latina will be built to be sustainable. Aim 1 will examine what ADRD care services are currently being offered to Latinos in primary care clinics to accommodate evidence-based recommendations to their workflow. *Alianza Latina* will capitalize on Medicare billing. First, PCPs will be encouraged to use Medicare Annual Wellness visits to screen Latinos 65+. The Medicare Annual Wellness Visit is important as most Latinos 65+ have Medicare. These visits bring more revenue to clinics than the typical problem-based visit, and both the Annual Wellness Visit and problem-based visits can be billed concurrently.[86] Second, *Alianza Latina* will provide chronic care coordination services built around Medicare's Chronic Care Management system, which will allow billing services through Medicare.[92,93] These services include establishing a plan for monthly in-person and telephone case management.

PRELIMINARY STUDIES

I have the necessary experience, training and environment to achieve my **overall research aim** of enhancing the delivery of ADRD services to Latinos in primary care through a scalable systems approach that includes evidence-based recommendations. During my first postdoctoral position, I developed interventions for Latinos using the Collaborative Care Framework.[94-96] The efficacy of these interventions has informed the use of the same framework in the development of *Alianza Latina*. During my fellowship training at the KU ADC, I have developed, tested and implemented an intervention to increase ADRD knowledge in the Latino community.[25] In this study, the Latino community identified use of ADRD services as a top need in the Latino community informing the development of *Alianza Latina*. Because our ADRD educational presentation was effective in increasing knowledge among Latinos,[25,97] PCPs and Health Navigators in *Alianza Latina* will use it to educate patients and families. The KU ADC has a growing PCP collaborative care network program led by social work navigators to handle the complex needs of ADRD in the community. This program is directed by my primary mentor and Michelle Niedens (LSCSW) both appointed to the Kansas Governor's Work Group to establish a statewide plan to address ADRD. The goal of this program is to extend across Kansas. I will leverage this program's connections, materials and staff to implement *Alianza Latina*.

APPROACH

The research proposal comprises two inter-related studies that aim to identify novel methods for improving diagnosis and care services among Latinos in primary care (See Figure 1). This project builds upon my connections with the Latino community and my mentors' PCP connections, infrastructure, and experiences in transforming healthcare systems. The project will be implemented over five years and will use mixed-methods spanning formative and intervention research. Results from Aim 1 will inform the logistics of the intervention proposed on Aim 2. Results from Aim 2 will help refine *Alianza Latina* and will inform the subsequent R01 study design proposal of a randomized clinical trial to assess its efficacy.

Recruitment Sites. Aim 1 will be conducted in primary care clinics in the Kansas City region and other regions. Including clinics in different regions will increase generalizability of results as they vary in readiness to serve Latinos and patient ancestry (i.e. Mexican/Caribbean). Most clinics have already established a partnership with my mentors and are committed to participate (see letters of support). Aim 2 will include clinics (urban and rural) in the Kansas City region. I will establish partnerships with additional clinics meeting with administrators and highlighting the potential benefits of *Alianza Latina* to their clinic (i.e. PCP training and lower time burden in ADRD care) and their patients and relatives (i.e. improved care at no additional cost). I will send clinics bi-weekly newsletters with information on key issues in ADRD management and program elements to keep them engaged in our partnership. It is important to note that the role of all clinics -including those at the KU Medical Hospital- is purely as recruitment sites (of clinic staff and individuals with ADRD and their caregivers). No clinic will consent or interview participants or analyze data of any type for aims 1 or 2 of this study. These tasks will be conducted solely by Dr. Perales and his Research Assistant (RA).

Figure 1. Research strategy

Year 1 (Preparation).
- Train RA in research
- CAB meetings 1-3 (guideline adaptation)
- Develop clinic partnerships
- Prepare Aim 1 bilingual materials

Year 2 (Aim 1).
- CAB meeting 4 (recruitment)
- Recruit PCPs and participants
- Plan and implement interviews
- Analyze data

Year 3 (Aims 1 & 2).
- CAB meeting 5 (refinement)
- Develop materials
- Train RA in Health Navigation
- Implement *Alianza Latina*
- Start data collection

Year 4 (Aim 2).
- CAB meeting 6 (recruitment)
- Continue to implement *Alianza Latina*
- Continue data collection
- Start data analysis

Year 5 (R01 preparation).
- CAB meeting 7 (refinement)
- Conclude data analysis
- Disseminate results
- Apply for R01 and related grants

Aim 1. Examine the current primary care models of ADRD care to identify what services are offered and how they are delivered across a variety of settings.

Overview. This study will use mixed-methods, a methodology increasingly used by health systems researchers. Mixed-methods refers to collecting, analyzing and mixing quantitative and qualitative methodologies in a project.[26] This approach is required given the scarce literature on ADRD services among Latinos in primary care and has been used to understand barriers to guideline adherence in other conditions resulting in descriptions that helped develop important recommendations for improvement.[98] Aim 1 is tightly linked to my training goals, as I will assess the implementation of evidence-based ADRD care and will use methods from health systems and qualitative research. We will conduct:

1. Focus groups with a Community Advisory Board (CAB) to incorporate Latino, PCP and ADRD care perspectives into existing ADRD care evidence-based recommendations.
2. Semi-structured interviews with Latino ADRD patients and clinic staff to understand ADRD services currently used in clinics and how they could be tailored to address the needs of ADRD Latino patients.

Community Advisory Board (CAB). During my Diversity Supplement, I convened a CAB to incorporate their perspectives in our research. The CAB will include national and local leaders of the Latino community: Jason Resendez (Director of the national advocacy group LatinosAgainstAlzheimer's), Diane Rojas (Director of the Guadalupe Senior Center), Cielo Fernández (Director of Latino outreach at the Swope Clinic) and Erica Andrade (Chief Program Officer of El Centro Community Center). The CAB will also include leaders in primary and ADRD care: Dr. Burns (Primary Mentor), Dr. Greiner (Secondary Mentor) and Natalia Loskutova, the Director of Evaluation at American Academy of Family Physicians, who has a special interest in the implementation of ADRD care in primary care clinics. CAB members will receive $100 per meeting.

CAB members will be asked to participate in three focus groups in Year 1 and one annually in the following years. In Year 1, as representatives of the Latino community and ADRD care, the CAB will examine the ACT on Alzheimer's evidence-based ADRD detection and care recommendations that will be implemented in Aim 2 and identify gaps in the needs of Latino patients.[20] The goal of the focus groups is to discuss the recommendations in hopes of understanding of the unique needs representative of Latino patients and modify the recommendations to include the CAB's suggestions. The CAB will discuss copies of the evidence-based recommendations syllabus, interactive course materials and themes. Semi-structured discussion will include, but will not be limited to, the following questions: What materials/content seems essential? What materials are missing to address the Latino patient situation? What materials are useful but need to be changed to better address these needs? After this focus group, the RA and I (PI) will revise the materials and curriculum and present them to the CAB who will evaluate revisions via semi-structured discussion and Likert scales. Year 2 and 4 will address how to optimize recruitment and retention. Years 3 and 5 will address how to refine *Alianza Latina* considering the study's findings. I will facilitate all focus groups by asking clear, open-ended questions, balancing the participation of all participants avoiding few people to dominate the discussion, redirecting the discussion if it strays far off topic and checking with participants to ensure their message is understood. I will audiotape all focus groups.

PCP and patient interviews. These 60-minute semi-structured interviews will gather information about the ADRD care services currently in place and how they could be tailored to address the needs of ADRD Latino patients. We will recruit a purposive sample of PCPs and Latino ADRD patients from clinics in Kansas City Metro, San Antonio, TX and Ft Meyers, FL. The RA and I will develop open-ended discussion guides and conduct the interviews. A HIPAA-compliant company will transcribe the audiotaped interviews. We will complete a checklist in all clinics to assess adherence to ADRD evidence-based recommendations.[20] Participants will give signed consent. ADRD patients will receive a $40 pre-paid card and PCPs will receive $40 for their time.

Semi-structured discussion with clinic staff will include, but will not be limited to, the following questions: 1) Can you describe the typical service a patient 65 and older would receive in a yearly visit? 2) How are people with ADRD usually detected in this clinic? 3) What care do people with ADRD usually receive in this clinic? 4) Are there any particularities about that service with Latino patients? 5) What are some of the challenges to ADRD detection and care experienced with Latino patients?

Semi-structured discussion with Latino ADRD patients and caregivers will include, but will not be limited to, the following questions: 1) Can you describe the ADRD services received in this clinic? 2) What went well with these services and what could be improved? 3) How relevant to your situation as a Latino patient were the services received? 4) What are some of the additional challenges that should be considered in these services?

Data Analysis and Dissemination. My mentor Dr. Williams has extensive expertise conducting mixed-methods research. She will assist me with analyses of findings on Aim 1. Focus groups and interviews will be transcribed by a HIPAA-compliant professional transcription company. Central tendency estimates, frequencies and percentages will describe quantitative data on R Software.[99] Qualitative analyses will employ content, domain and taxonomic analysis.[100,101] Transcribed content and notes will be coded and analyzed using ATLAS-ti software.[102] We will first open-code transcripts by identifying keywords, themes and descriptions of behavior within the text.[103] 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. Findings will be disseminated in peer-reviewed journals and results will inform the refinement of *Alianza Latina*.

Aim 2. Test the feasibility and acceptability of *Alianza Latina*.

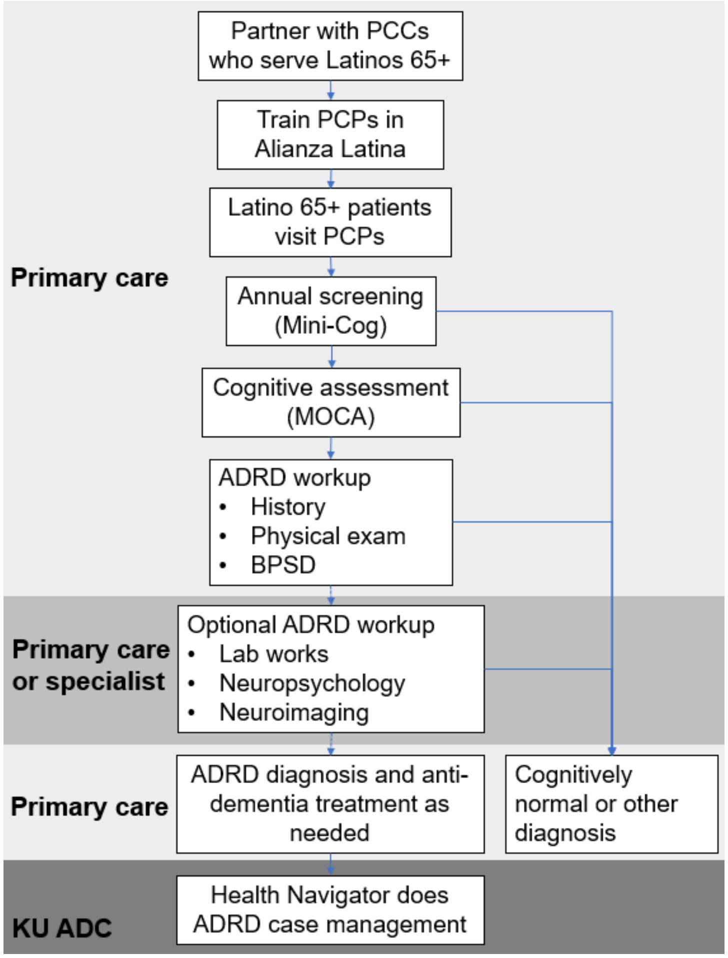
Overview. This study will be a one-arm clinical trial to examine the feasibility and acceptability of *Alianza Latina*, a health systems intervention to improve ADRD diagnosis and care among Latinos. The intervention will be conducted at the same 10 Kansas City clinics as Aim 1. *Alianza Latina* will use the Collaborative Care Framework (Table 1) and [21-24] will partner with primary care clinics to 1) provide PCPs with training and tools for timely ADRD diagnosis, optimal treatment and cultural competence and 2) incorporate Health Navigators to enhance ADRD care and reduce PCP burden (See Figure 2). Feasibility and acceptability outcomes will be obtained from metrics and surveys with PCPs, Latino patients with MCI and ADRD and their caregivers. Aim 2 is tightly linked to my training goals, as PCPs and Health Navigators will implement evidence-based ADRD care in primary care and measure outcomes using semi-structured interviews. The one-arm design will allow testing most types of study feasibility while focusing on the newly designed intervention.

Intervention. The main components of *Alianza Latina* are 1) providing PCPs with education, training and tools for timely ADRD diagnosis and optimal treatment and 2) providing Latino ADRD patients with enhanced chronic care through bilingual Health Navigators. These two components will be assessed in two separate sub-aims.

Aim 2.a. Providing PCPs with education, training and tools for timely ADRD diagnosis and optimal treatment.

Alianza Latina will partner with 10 primary care clinics who serve Latino older adults. We will train PCPs in cultural competence and ADRD knowledge, skills and attitudes.[104] For Cultural Competence Care, PCPs will complete an online course by the US Department of Health & Human Services.[105] For ADRD knowledge, skills and attitudes, PCPs will receive a standardized online or in-person training modeled after Minnesota's "ACT on Alzheimer's" ADRD Curriculum and a specific training developed by our research team.[20] The online ACT on Alzheimer's ADRD Curriculum is free, self-directed and consists of 10 modules (understanding dementia; demographics; societal impact; early detection; screening; assessment and diagnosis; interventions; caregiver support; behavior as communication and philosophy of care). The in-person training will take one day, will be delivered by Dr. Burns' ADRD collaborative care team and me and will cover the same topics as the online training. Both trainings will include specifics about ADRD detection and care among Latinos, including validated tools for Spanish speakers. All three courses provide Continuing Medical Education credits upon completion, which may incentivize PCP participation in *Alianza Latina*. In April, the KU ADC delivered a similar training event to 13 rural providers, all of which have started implementing the evidence-based recommendations among their patients.

Figure 2. Flow chart of *Alianza Latina* feasibility study design



PCPs will be trained to follow culturally and linguistically appropriate diagnostic and treatment algorithms using an evidence-based approach to timely screening, diagnosis and management of dementia intended to decrease the need for sub-specialty care.[20] PCPs will be trained to administer an evidence-based ADRD screener to all Latinos 65+. We will suggest using the Mini-Cog, as it is freely available, takes only three minutes to administer and has shown excellent psychometric properties in a multilingual US sample.[106] PCPs will be trained to follow-up with a more comprehensive cognitive test for those who screen positive. We will suggest using the Montreal Cognitive Assessment (MoCA), as it is also freely available, short and has been shown to detect ADRD and MCI among US English and Spanish speaking individuals.[107,108] Those screened positive will undergo a dementia work-up (i.e. family and medical history, physical exams, behavioral symptoms) which will use Latino-validated tools when possible. This information will inform ADRD diagnosis and prescription of anti-dementia medication as needed. PCPs will be trained to refer ADRD patients to our bilingual Health Navigator following diagnosis. Verbal consent to share PHI with the Health Navigator is acquired by the PCP and explicitly stated in the referral.

Assessment Procedures and Measures. Feasibility and acceptability assessments will include metrics and survey information from PCPs following standard criteria for feasibility studies (Table 3).[27,28] Metrics will assess PCP completion of training, assessments and referrals. PCPs will complete a baseline (BL) survey before training and a follow-up (FU) survey after they have detected and referred enough Latino ADRD patients to fill Aim 2.b's enrollment in approximately seven months (100 Latino MCI/ADRD patients receiving chronic care services from the Health Navigators though *Alianza Latina*). FU surveys will assess implementation of screening in PCPs' regular workflow and their satisfaction with the *Alianza Latina* training.

Aim 2.b. Providing Latino ADRD patients with enhanced ADRD chronic care through Health Navigators. The Health Navigator will be the single-point-of-contact between the patient and the PCP. The Health Navigator will be a Bachelor's degree-level individual with experience working with the Latino community in health-related projects and will be trained and supervised closely by Dr. Burns' Social Worker team. The training will include the ACT on Alzheimer's online course for care managers, a Dementia Intensive one-day course from the KU ADC and progressive shadowing to achieve independence supervised weekly by Dr. Burns' team. The KU ADC recently had a highly successful Dementia Intensive training for Social Workers drawing nearly 100 social work students from 7 colleges in the region and significantly increasing their levels of objectively assessed ADRD knowledge. The first Health Navigator visit will be in-person and will coincide with the BL assessment. The Health Navigator will perform a Clinical Intake Assessment using validated instruments when possible including the Brief Neuropsychiatry Inventory Questionnaire, Geriatric Depression Scale or the Functional Assessment Questionnaire.[109] The initial Clinical Intake Assessment will result in a written "Chronic Care Plan" that will be provided to the dyad and encouraged to be shared with their PCP. The Health Navigator will enroll the co-participant in *CuidaTEXT* a culturally tailored text message program to educate Latino caregivers on ADRD care.[110] Educating families is important among Latinos as decision-making is more likely to be shared by multiple relatives.[111] Given that Latinos are among the groups with the lowest income in the USA,[112] Health Navigators will inform participants about available financial assistance applications for ADRD expenses. Further visits will continue the Chronic Care Plan, which will address the most pressing needs reported by the patient and caregiver. Table 2 includes potential patient and caregiver needs depending on ADRD stage.[113] The Chronic Care Plan will use evidence- and consensus-based recommendations to address those needs,[20] including Gitlin's non-pharmacologic management of behavioral symptoms protocol,[46] the Reducing Disability in Alzheimer's Disease community program to promote functioning and caregiver support,[114] the At the Crossroads kit for driving safety for individuals with ADRD [115] and other resources. Community resources referred to by the Health Navigator will either provide bilingual services or include interpreters. If there is no other option, the Health Navigator will assist with interpretation.

Table 2. ADRD needs addressed by the Chronic Care Plan

MCI Patient	Prevent behaviors, slow cognitive decline, engagement, legal planning
Caregiver	Caregiver support, legal planning & training
Early & moderate ADRD Patient	Safety, security, engagement, functioning, behavioral management, pain, sleep co-morbidities, legal planning
Caregiver	Caregiver support and training, respite, stress reduction, legal planning
Severe ADRD Patient	Stress, anxiety, agitation, pain
Caregiver	Caregiver support, end of life care, counseling, role resumption

Recruitment and retention. We will provide *Alianza Latina* Health Navigator-services to all Latinos diagnosed with ADRD by *Alianza Latina* PCPs, other clinicians, or the research team. Outreach will include multiple in-person (i.e., clinic referrals and health events) and remote methods (i.e., calls from research registries, online advertising and flyers). We will enroll 100 Latino ADRD patients. The Health Navigator will contact participants to schedule a consent and BL appointment during their first visit. Participants who sign the informed consent will be enrolled. To reduce attrition, we will collect contact information from an alternate contact person and staff will keep flexible hours and allow home visits. Participants will receive $40 pre-paid cards for completing assessments at BL and FU. All materials developed by the research team will be bilingual and follow World Health Organization translation and back translation guidelines.[116]

Eligibility Criteria: 1) identify as Latino, 2) community dwelling, 3) diagnosed with MCI or ADRD by *Alianza Latina* PCPs, other clinicians, or the research team, 5) have a caregiver 18 years old or older and 6) access to a privately-owned cell phone with a flat rate fee for text messages.

Recruitment Estimates. Based on the primary care population of our clinics, each serves an average of 12 Latino individuals/day. We expect 12% to be 65 and older based on the Census.[117] In 261 working days, they will serve 376 Latinos 65+. Because ADRD prevalence among Mexican-Americans is 10%, we expect 38 Latinos 65+ with ADRD per year per clinic.[72] In a conservative scenario, 66% of those with ADRD have never been diagnosed (28 per clinic). Research shows that 74% of ADRD patients are willing to participate in Health Navigator services,[30] which reduces the number to 18 per clinic. Because there will be approximately 10 clinics, the time needed to recruit 100 participants will be approximately seven months.

Assessment Procedures and Measures. Assessments will include metrics and survey information to Latino ADRD patients and their caregivers based on standard criteria for outcomes in feasibility studies (Table 3).[27,28] BL surveys will include sociodemographic data: age, gender, marital status, educational level, insurance type, household income, Latino origin and caregiver relationship [118] and acculturation: English preference, place of birth and years in the USA.[119] Metrics will assess enrollment in Health Navigator services, six-month retention, completion of BL and FU assessments (i.e. BPSD and quality of life scales) and adherence to Health Navigator visits. FU surveys will assess satisfaction with the *Alianza Latina* Health Navigator services.

Data analysis and sample Size Justification. Drs. Burns and Mahnken will guide me in the analysis of Aim 2. We will use R software to upload and analyze quantitative data.[99] 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. *Alianza Latina's* primary outcomes will be assessed using simple descriptive statistics. The primary quantitative feasibility/process 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. With an anticipated 50/100 PCPs integrating *Alianza Latina* screenings to their regular workflow and 100/135 newly referred Latino ADRD dyads who enroll in Health Navigator services, our confidence intervals will be within approximately ±11.0% and ±7.4%, respectively, of their estimated proportions. These proportions have been chosen based on clinically significant levels estimated in consensus between my mentors and I and from the literature.[30] 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 processes measures to inform the subsequent R01 application. At the end of the study, my mentors, consultants and I will meet and review all results to make modifications to the intervention and study design and calculate the appropriate sample.

Table 3. Feasibility and acceptability outcomes in Aim 2

Outcome	Data source	Operationalization
PCP training Feasibility	Metrics (recruitment)	Number of PCPs who agree to be trained per month
	Metrics (retention)	% of PCPs followed up
	PCP FU survey & metrics (fidelity)	% able to implement screenings in regular workflow; Number of referrals to Health Navigator per month
	Metrics (assessment process)	% of PCPs who complete BL and FU surveys about ADRD knowledge, attitudes and skills
	Metrics (treatment adherence)	% of PCPs who complete training
Acceptability	PCP FU survey	5-item Likert scales on satisfaction with training
ADRD care Feasibility	Metrics (recruitment)	% of referred Latino ADRD dyads who enroll in Health Navigator services
	Metrics (retention)	% of referred Latino ADRD dyads followed up at 6m
	Metrics (assessment process)	% of planned BL and FU survey ratings completed including BPSD [109] and quality of life [120,121]
	Metrics (treatment adherence)	% of referred Latino ADRD dyads who attends at least 50% of Health Navigator visits
Acceptability	Dyad FU survey (6m)	5-item Likert scales on satisfaction with clinic and Health Navigator services

CONSIDERATIONS, POTENTIAL PITFALLS, AND LIMITATIONS

This study aims to assess the feasibility of Alianza Latina to inform the design and implementation of future, larger scale efficacy randomized controlled trials.[28] Because feasibility studies are not hypothesis testing studies, we have not planned to include a control group to evaluate efficacy. In this study we will administer pre- and post-intervention measures that will serve as efficacy outcomes in future randomized control trials (i.e. BPSD, quality of life). However, the main objective of those measurements in the current study is to evaluate assessment feasibility. If feasibility findings are favorable, we will conduct a fully-powered R01 RCT to assess efficacy and cost-effectiveness. 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. We have estimated that 10 clinics will recruit 100 ADRD participants in seven months. If recruitment is slow, we will identify Latino older adults in the community through our center's recurrent ADRD educational events, the Latino community network and the participant pool I developed during my Diversity Supplement and attempt to train their PCPs in the *Alianza Latina* services to speed up the process. A previous study trained and used abstracters to assess adherence to ADRD services recommendations at the clinics at all times.[122] This approach is not financially feasible for this project but will be considered for a future study. Because this intervention is multicomponent, it will not allow disentangling effects of specific components. We will attempt to deconstruct the intervention in future studies if results are favorable. Most information gathered is focused on the person with ADRD. Though we plan to gather more information from caregivers in the future, this is secondary. We acknowledge that the involvement of caregivers in the aid of people with MCI or mild ADRD might be much lower than that of moderate and late stages, which may affect feasibility and acceptability outcomes.

PROTECTION OF HUMAN SUBJECTS

Aim 1: Examine the current primary care models of ADRD care to identify what services are offered and how they are delivered across a variety of settings

1. Risks to Human Subjects

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

Aim 1 will assess the implementation of evidence-based ADRD care and will use methods from health systems and qualitative research. None of the studies will require protected health information. Dr. Perales will lead all interviews and focus groups with PCPs, patients and the CAB. The Research Team will conduct:

1. Focus groups with a Community Advisory Board (CAB) to incorporate Latino and ADRD care perspectives into existing ADRD care guidelines.
2. Semi-structured interviews with Latino ADRD patients and PCPs to understand ADRD protocols currently used in clinics and how they could be tailored to address the needs of ADRD Latino patients.

Eligibility criteria:

- Patients:
  1) Self-identify as Latino,
  2) Proficient in English or Spanish,
  3) Willing to participate in study.

- PCPs:
  1) 18 years old and older,
  2) working as PCP in a primary care clinic.

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

Treatment: None.
Assessment.

- CAB Focus groups. CAB members will be asked to participate in three focus groups in Year 1 and one annually in the following years. In Year 1, as representatives of the Latino community and ADRD care, the CAB will examine the ACT on Alzheimer's evidence-based ADRD detection and care recommendations that will be implemented in Aim 2 and identify gaps in the needs of Latino patients.[20] The goal of the focus groups is to discuss the recommendations in hopes of understanding of the unique needs representative of Latino patients and modify the recommendations to include the CAB's suggestions. The CAB will discuss copies of the evidence-based recommendations syllabus, interactive course materials and themes. Semi-structured discussion will include, but will not be limited to, the following questions: What materials/content seems essential? What materials are missing to address the Latino patient situation? What materials are useful but need to be changed to better address these needs? After this focus group, the RA and the PI will revise the materials and curriculum and present them to the CAB who will evaluate revisions via semi-structured discussion and Likert scales. Year 2 and 4 will address how to optimize recruitment and retention. Years 3 and 5 will address how to refine *Alianza Latina* considering the study's findings. The PI will facilitate all focus groups by asking clear, open-ended questions, balancing the participation of all participants avoiding few people to dominate the discussion, redirecting the discussion if it strays far off topic and checking with participants to ensure their message is understood. The PI will audiotape all focus groups.
- PCP and patient interviews. These 60-minute semi-structured interviews will gather information about the ADRD care services currently in place and how they could be tailored to address the needs of

ADRD Latino patients. The Research team will recruit a purposive sample of PCP and Latino ADRD patients from clinics in Kansas City Metro, San Antonio, TX and Ft Meyers, FL. The RA and the PI will develop open-ended discussion guides and conduct the interviews. A HIPAA-compliant company will transcribe the audiotaped interviews The Research Team will complete a checklist in all clinics to assess adherence to ADRD evidence-based recommendations.[20]

- Semi-structured discussion with PCP will include, but will not be limited to, the following questions: 1) Can you describe the typical service a patient 65 and older would receive in a yearly visit? 2) How are people with ADRD usually detected in this clinic? 3) What care do people with ADRD usually receive in this clinic? 4) Are there any particularities about that service with Latino patients? 5) What are some of the challenges to ADRD detection and care experienced with Latino patients?
- Semi-structured discussion with Latino ADRD patients and caregivers will include, but will not be limited to, the following questions: 1) Can you describe the ADRD services received in this clinic? 2) What went well with these services and what could be improved? 3) How relevant to your situation as a Latino patient were the services received? 4) What are some of the additional challenges that should be considered in these services?

Data analysis. Interviews and focus groups will be recorded and analyzed employing content, domain, and taxonomic analysis. The Research Team will code content using ATLAS-ti. They will open-code transcripts by identifying keywords, themes, and descriptions of behavior within the text. Later, they 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, Burns, Greiner, and Williams. 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 patients with ADRD, talking about their condition 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

The Research Team will translate the informed consents from English to Spanish using translation-back translation guidelines from the World Health Organization. Signed 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. Informed consent will be obtained either through a paper signature or via REDCap.

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 obtaining consent. The information collected cannot put participants at legal or physical risk of any kind. 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 shared with the transcription company via encrypted email to be transcribed and all word processing files will be labeled with participant 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. The Research Team 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 refinement of Alianza Latina which might improve the lives of many people with ADRD, their relatives and the 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 improve the delivery of ADRD services among Latinos in primary care clinics.

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. The PI and Dr. Williams will monitor Data quality weekly. They will resolve any issues related to data and modify data collection procedures 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 Alianza Latina

Risks to Human Subjects

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

Aim 2 will be a one-arm clinical trial to examine the feasibility and acceptability of Alianza Latina, a health systems intervention to improve ADRD diagnosis and care among Latinos. The intervention will be conducted in the same 10 Kansas City Latino-affluent primary care clinics as Aim 1. Alianza Latina will enhance timely ADRD diagnosis and optimal care to minimize behavioral symptoms and cognitive decline among Latinos in a linguistically and culturally-appropriate way. Alianza Latina will use the Collaborative Care Framework that capitalizes on PCPs and Health Navigators. 1) PCPs will undergo training in evidence-based recommendations to enhance timely and culturally appropriate diagnosis and implement it in their work routine. 2) PCPs will detect, treat and refer Latino ADRD patients to a bilingual Health Navigator to perform a Clinical Intake Assessment and subsequent ADRD Chronic Care Plan, which will reduce PCP time burden. The PI will lead all interviews with PCPs, patients and Latino older adults.

Eligibility criteria:

- Latino patients: Eligible participants will
    - Identify as Latino,
    - Community dwelling,
    - Diagnosed with MCI or ADRD by Alianza Latina PCPs, other clinicians, or the research team
    - Have a caregiver 18 or older,
    - Have access to a privately-owned cell phone.

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

Treatment. The main components of *Alianza Latina* are 1) providing PCPs with education, training and tools for timely ADRD diagnosis and optimal treatment and 2) providing Latino ADRD patients with enhanced chronic care through bilingual Health Navigators. These two components will be assessed in two separate sub-aims.

- Providing PCPs with education, training and tools for timely ADRD diagnosis and optimal treatment. *Alianza Latina* will partner with 10 primary care clinics who serve Latino older adults. The Research team will train PCPs in cultural competence and ADRD knowledge, skills and attitudes.[104] For Cultural Competence Care, PCPs will complete an online course by the US Department of Health & Human Services.[105] For ADRD knowledge, skills and attitudes, PCPs will receive a standardized online or in-person training modeled after Minnesota's "ACT on Alzheimer's" ADRD Curriculum and a specific training developed by the research team.[20] The online ACT on Alzheimer's ADRD Curriculum is free, self-directed and consists of 10 modules (understanding dementia; demographics; societal impact; early detection; screening; assessment and diagnosis; interventions; caregiver support; behavior as communication and philosophy of care). The in-person training will take one day, will be delivered by Dr. Burns' ADRD collaborative care team and me and will cover the same topics as the online training. Both trainings will include specifics about ADRD detection and care among Latinos, including validated tools for Spanish speakers. All three courses provide Continuing Medical Education credits upon completion, which may incentivize PCP participation in *Alianza Latina*. In April, the KU ADC delivered a similar training event to 13 rural providers, all of which have started implementing the evidence-based recommendations among their patients. PCPs will be trained to follow culturally and linguistically appropriate diagnostic and treatment algorithms using an evidence-based approach to timely screening, diagnosis and management of dementia intended to decrease the need for sub-specialty care.[20] PCPs will be trained to administer an evidence-based ADRD screener to all Latinos 65+. The Research team will suggest using the Mini-Cog, as it is freely available, takes only three minutes to administer and has shown excellent psychometric properties in a multilingual US sample.[106] PCPs will be trained to follow-up with a more comprehensive cognitive test for those who screen positive. The Research Team will suggest using the Montreal Cognitive Assessment (MoCA), as it is also freely available, short and has been shown to detect ADRD and MCI among US English and Spanish speaking individuals.[107,108] Those screened positive will undergo a dementia work-up (i.e. family and medical history, physical exams, behavioral symptoms) which will use Latino-validated tools when possible. This information will inform ADRD diagnosis and prescription of anti-dementia medication as needed. PCPs will be trained to refer ADRD patients to the bilingual Health Navigator following diagnosis. Verbal consent to share PHI with the Health Navigator is acquired by the PCP and explicitly stated in the referral.

- Providing Latino ADRD patients with enhanced ADRD chronic care through Health Navigators. The Health Navigator will be the single-point-of-contact between the patient and the PCP. The Health Navigator will be a Bachelor's degree-level individual with experience working with the Latino community in health-related projects and will be trained and supervised closely by Dr. Burns' Social Worker team. The training will include the ACT on Alzheimer's online course for care managers, a Dementia Intensive one-day course from the KU ADC and progressive shadowing to achieve independence supervised weekly by Dr. Burns' team. The KU ADC recently had a highly successful Dementia Intensive training for Social Workers drawing nearly 100 social work students from 7 colleges in the region and significantly increasing their levels of objectively assessed ADRD knowledge. The first Health Navigator visit will be in-person and will coincide with the BL assessment. The Health Navigator will perform a Clinical Intake Assessment using validated instruments when possible including the Brief Neuropsychiatry Inventory Questionnaire, Geriatric Depression Scale or the Functional Assessment Questionnaire.[109] The initial Clinical Intake Assessment will result in a written "Chronic Care Plan" that will be provided to the dyad and encouraged to be shared with their PCP. The Health Navigator will enroll the co-participant in *CuidaTEXT* a culturally tailored text message program to educate Latino caregivers on ADRD care.[110] Educating families is important among Latinos as decision-making is more likely to be shared by multiple relatives.[111] Given that Latinos are among the groups with the lowest income in the USA,[112] Health Navigators will inform participants about available financial assistance applications for ADRD expenses. Further visits will continue the Chronic Care Plan, which will address the most pressing needs reported by the patient and caregiver. Table 2 includes potential patient and caregiver needs depending on ADRD stage.[113] The Chronic Care Plan will use evidence- and consensus-based recommendations to address those needs,[20] including Gitlin's non-pharmacologic management of behavioral symptoms protocol,[46] the Reducing Disability in Alzheimer's Disease community program to promote functioning and caregiver support,[114] the At the Crossroads kit for driving safety for individuals with ADRD [115] and other resources. Community resources referred to by the Health Navigator will either provide bilingual services or include interpreters. If there is no other option, the Health Navigator will assist with interpretation.

Recruitment. The Research Team will provide *Alianza Latina* Health Navigator-services to all Latinos diagnosed with ADRD by *Alianza Latina* PCPs. The Research Team will enroll 100 Latino ADRD patients. The Health Navigator will contact participants to schedule a consent and BL appointment during their first visit. Participants who sign the informed consent will be enrolled. Contacts can be either via KUMC-contracted Zoom videocalls, phone calls or in-person, depending on the participants' preferences.

Eligibility, consent, enrollment and baseline assessment. Eligibility criteria includes 1) identify as Latino, 2) community dwelling, 3) diagnosed with MCI or ADRD by *Alianza Latina* PCPs, other clinicians, or the research team, 4) have a caregiver 18 years old or older and 5) access to a privately-owned cell phone. Based on the primary care population of our clinics, each serves an average of 12 Latino individuals/day. We expect 12% to be 65 and older based on the Census.[117] In 261 working days, they will serve 376 Latinos 65+. Because ADRD prevalence among Mexican-Americans is 10%, we expect 38 Latinos 65+ with ADRD per year per clinic.[72] In a conservative scenario, 66% of those with ADRD have never been diagnosed (28 per clinic). Research shows that 74% of ADRD patients are willing to participate in Health Navigator services,[30] which reduces the number to 18 per clinic. Because there will be 10 clinics, the time needed to recruit 100 participants will be approximately seven months.

Assessments will include metrics and survey information to Latino ADRD patients and their caregivers based on standard criteria for outcomes in feasibility studies (Table 3).[27,28] BL surveys will include sociodemographic data: age, gender, marital status, educational level, insurance type, household income, Latino origin and caregiver relationship [118] and acculturation: English preference, place of birth and years in the USA.[119] Metrics will assess enrollment in Health Navigator services, six-month retention, completion of BL and FU assessments (i.e. BPSD and quality of life scales) and adherence to Health Navigator visits. FU surveys will assess satisfaction with the *Alianza Latina* Health Navigator services.

Retention and reimbursement. To reduce attrition, the Research Team will collect contact information from an alternate contact person and staff will keep flexible hours and allow home visits. Participants will receive $20 pre-paid cards for completing assessments at BL and FU. All materials developed by the research team will be bilingual and follow World Health Organization translation and back translation guidelines.[116]

Investigators/Institutions. The team of investigators include Drs. Perales, Burns, Greiner, and Williams. 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 patients with ADRD or their relatives, talking about their condition 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. Health Navigators may provide education and advice that can affect patients negatively.

2. Adequacy of Protection Against Risks

2.a. Informed Consent and Assent

The Research Team will translate the informed consents from English to Spanish using translation-back translation guidelines from the World Health Organization. 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. 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. 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. The Health Navigator will be comprehensively trained by taking the courses specified in the candidate section and shadowing Dr. Burns' experienced Health Navigators. The Health Navigator will follow specific guidelines for the management of ADRD and will be directly supervised by Dr. Burns' team.

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. The Research Team 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

ADRD Participants will be able to speak with a Health Navigator with experience in implementing evidence and consensus-based guidelines to address problems associated with ADRD. Clinical Intake Assessments will include behavioral symptoms, safety at home, driving, legal issues and others. Alianza Latina also has the potential to detect ADRD timely for early provision of care, which may improve patients' and caregivers' quality of life. In addition, participants will be given the opportunity to contribute to finding better ways of improving the quality of life among people with ADRD and their caregivers 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 maintenance of cognitive and brain health through research that has adequate numbers of participants. This study will enhance our understanding on how to improve the delivery of ADRD services among Latinos in primary care clinics.

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. Me (PI) and Dr. Burns will monitor Data quality weekly. The Research Team will resolve any issues related to data and modify data collection procedures modified to improve data quality.

Safety Monitoring Plan: Health Navigators will continually monitor participants for unanticipated problems. The PI will review Satisfaction survey responses, texts received from participants, and any complaints submitted to the REDCap database on a monthly basis. Unanticipated problems will be reported to the IRB within 5 working days and to NIMHD within 48 hours of determining they meet reportability criteria. A report of any complaints that were assessed will be prepared by the study team and sent to the NIMHD program officer semi-annually. This report will also delineate those complaints that were reported as unanticipated problems to the IRB and the NIMHD within the expedited timeframes listed above.

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: A report of any complaints that were assessed will be prepared by the study team and sent to the NIMHD program officer semi-annually. This report will also delineate those complaints that were reported as unanticipated problems to the IRB and the NIMHD within the expedited timeframes listed above.