



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

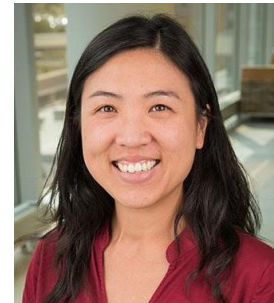
Cultural adaptation of ADRD clinical trials for Latino participants



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Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **Q&A/chat box** and send to All Panelists and Attendees
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Associated podcast released about 2 weeks after Grand Rounds
- Visit impactcollaboratory.org
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Learning Objectives

Upon completion of this presentation, you should be able to:

- Review barriers to ADRD research for diverse populations
- Learn best practices for engaging Latino ADRD caregiver advisors in research
- Understand the process of cultural adaptation of ADRD research protocols

ADRD research gaps for diverse populations

By 2050, people who identify as Hispanic / Latino will become the largest minority population in the US

- For people aged 65+ ADRD prevalence is higher for minority populations
 - Hispanic / Latino older adults are 1.5x as likely to develop ADRD
 - Lifetime prevalence is 32%
- ADRD clinical trials fail to represent the affected population
 - Clinical trial enrollment is disproportionately White
 - ADRD care / behavioral interventions are rarely linguistically or culturally adapted

Inclusivity Clinical Trials 2000-2020

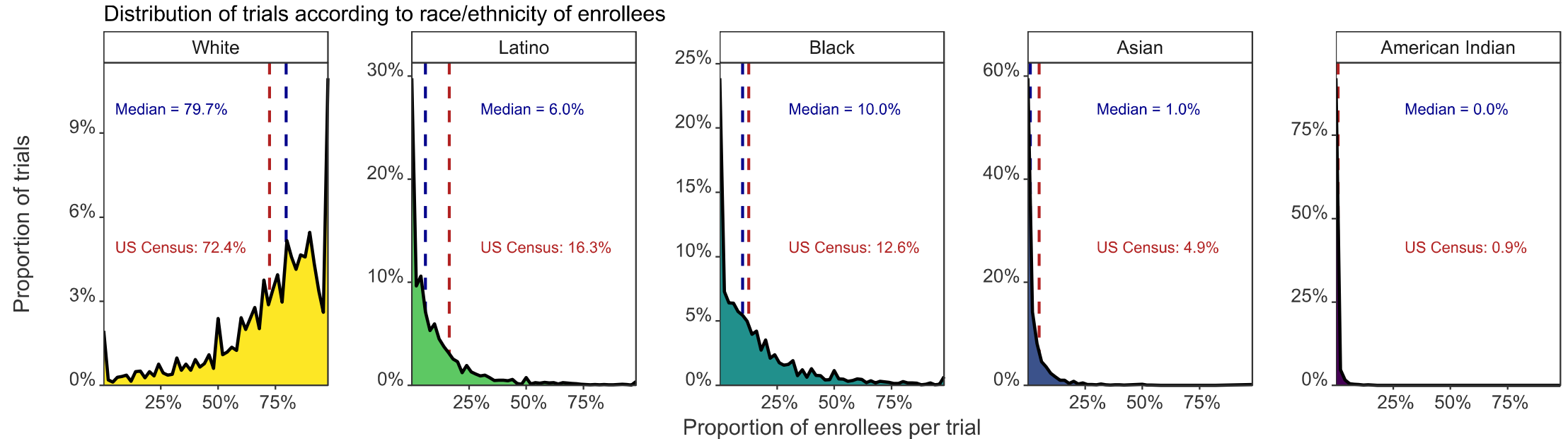


Figure 3. Race/ethnicity representation among all United States-based clinical trials with race/ethnicity enrollment data in Clinical-trials.gov.

The graph shows the distribution of trials and the representation of each racial/ethnic group organized by racial/ethnic category. Distribution only includes trials that reported data for all five racial/ethnic groups. Census calculations reflect 2010 US Census data.

ADRD-PC Clinical Trial

Palliative Care for Persons with Late-stage Alzheimer's and Related Dementias and Their Caregivers

- Multi-site RCT of ADRD-PC intervention vs educational materials
- N=424 dyads of hospitalized patients with late-stage ADRD and family caregivers

Aim 1: Can ADRD-PC reduce 60-day hospital transfers?

Aim 2: Can ADRD-PC improve a) symptom treatment, b) symptom control, c) post-acute use of PC / hospice, and d) reduce new NH placements?

Aim 3: Can ADRD-PC improve a) communication about prognosis and GOC, b) shared decision-making, and c) caregiver distress?

ADRD-PC intervention

- 1) ADRD informed specialty palliative care consultation
 - Pain, neuropsychiatric, and other symptom management
 - Prognostic awareness and goals of care decisions
 - Caregiver support needs
- 2) Structured education for ADRD caregiver
- 3) Transitional care
 - Resource referrals
 - Follow-up calls

Barriers for inclusive enrollment

- Clinical interpreters not permitted to provide research protocol interpretation
- Study materials and interviews all conducted in English
 - Inclusion criterion: English-speaking ADRD caregiver
- Need for diverse study staff
- Lack of time and resources for linguistic and cultural adaptation

2-year NIA Administrative Supplement – essential to overcome barriers

Engaging Latino Caregiving Advisors

Why they
are
important?

How did the
group form?

How did
they
contribute?



Role of Caregivers in Dementia



- They provide needed and valuable service
- Most effective present intervention for dementia: supporting the caregivers
- Consistent risk factor for the institutionalization of persons living with AD or ADRD
- Psychological stress and depression of caregivers

Caregiving in the Latino Community



Latino caregivers are likely to be female (74%) and live with children or grandchildren



25% are caring for someone with dementia

Latino elders tend to live with relatives



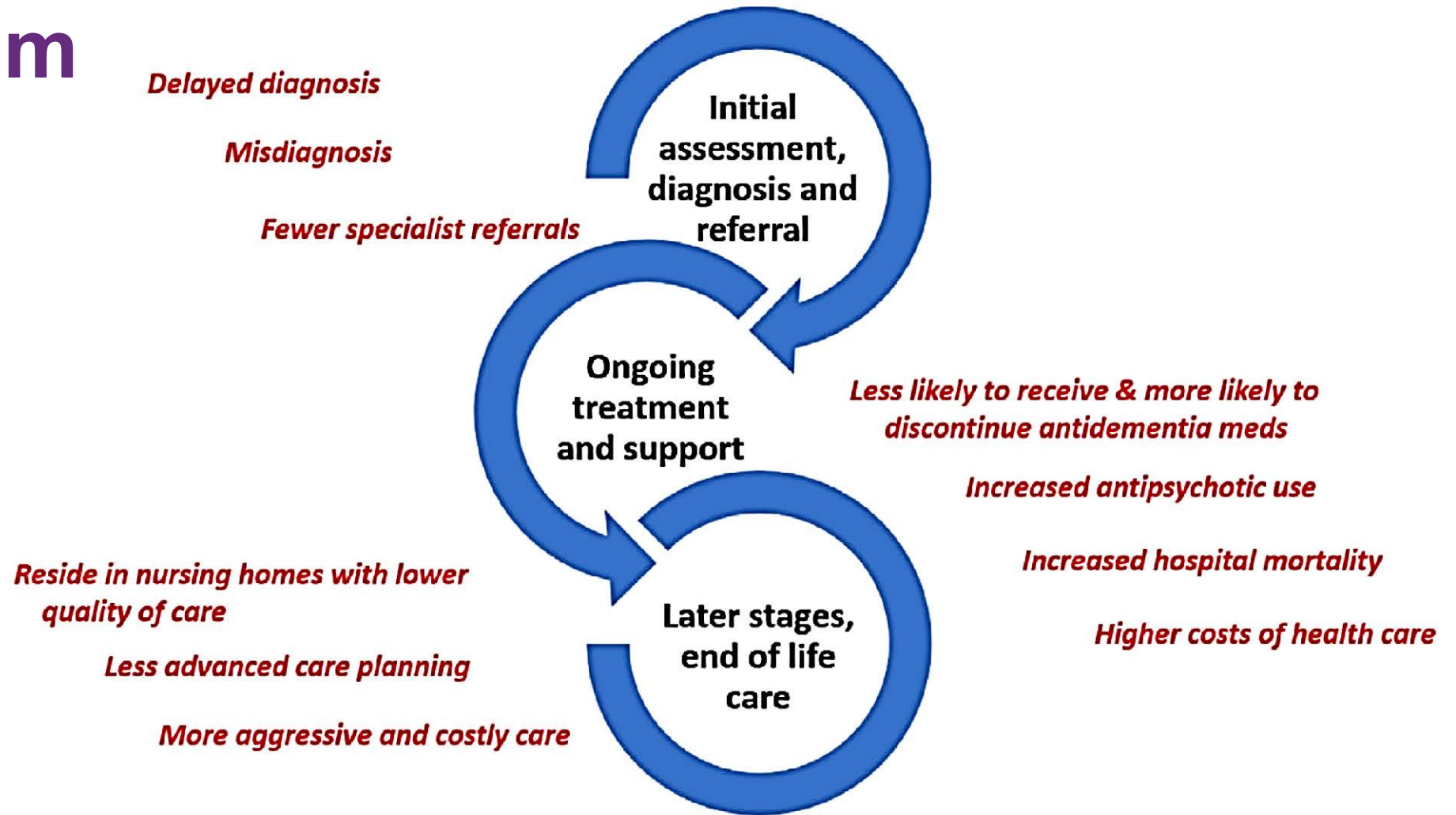
Almost 10% need help from another person for personal care

40% of working Latino caregivers reported they needed to take a leave of absence, change jobs, cut back hours or stop work entirely to take care of their loved one.



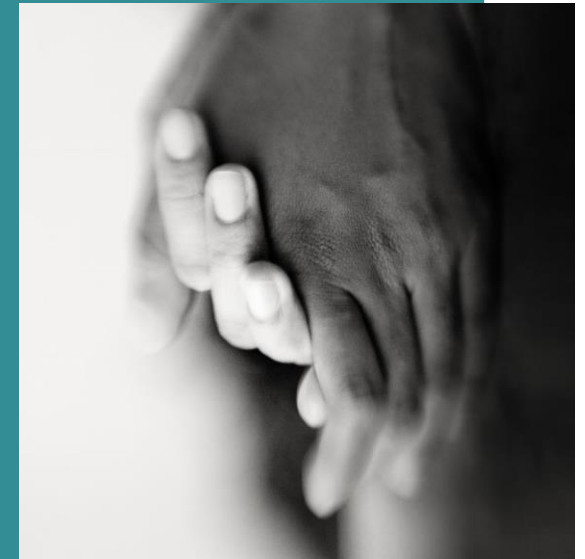
Latinos live longer than non-Latino whites, but their health tends to be worse.

Disparities in dementia care exist across the continuum

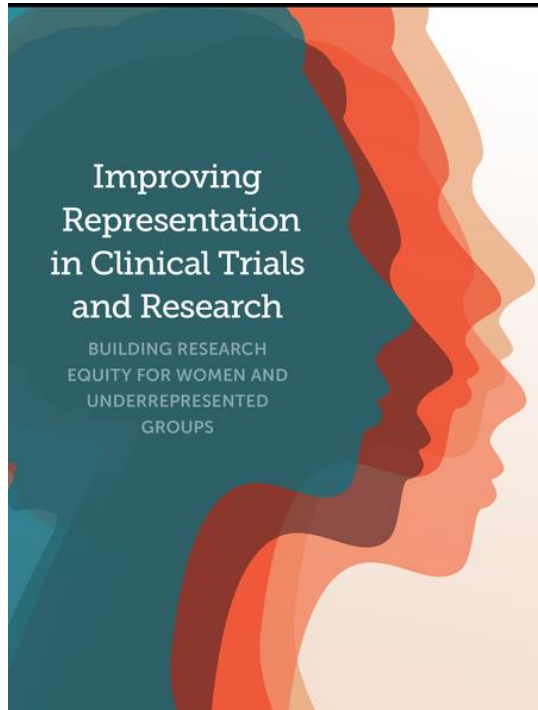


Disparities in caregiving of persons living with dementia

- Limited availability of support services
- Limited culturally tailored interventions regarding ADRD diagnosis and treatment.
- Limited resources available in different languages
- Increased time spent on caregiving
- Cultural perceptions of the burden of caregiving
- Psychological well-being of the caregiver



Key facilitators to inclusion

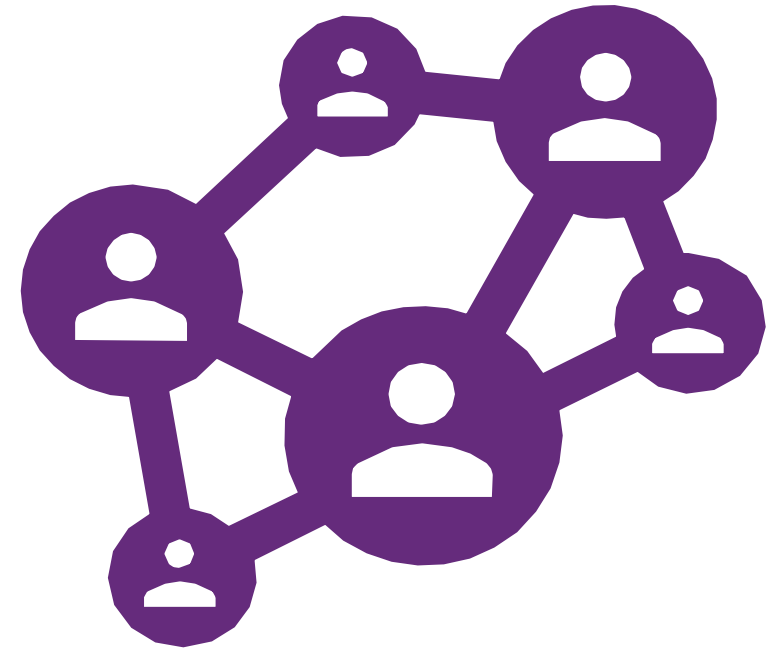


- (1) starting with intention and agency to achieve representativeness;
- (2) establishing a foundation of trust with study participants and community;
- (3) anticipating and removing barriers to study participation;
- (4) adopting a flexible approach to recruitment and data collection;
- (5) building a robust network by identifying all relevant stakeholders;
- (6) navigating scientific, professional peer, and social expectations;
- (7) optimizing the study team to ensure alignment with research goals,
- (8) attaining resources and support to achieve representativeness

National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Bibbins-Domingo K, Helman A, editors. Washington (DC): National Academies Press (US); 2022 May 17. PMID: 36137057.

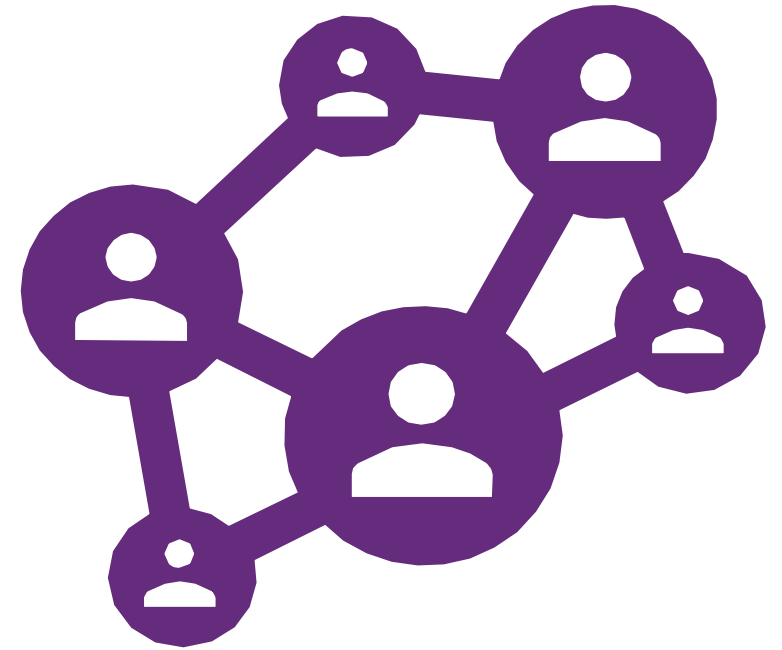
Engaging Latino Caregiving Advisors

- We recognized the need to better engage potential Latino participants.
- Work was led by bilingual co-investigators and research staff with substantive experience with Latino culture.
- Potential Advisors were invited to participate as research advisors (rather than study participants), where they would be asked to provide meaningful input based on their personal lived experiences.



Engaging Latino Caregiving Advisors

- The resulting group consisted of an advisory panel of eight caregivers
- The Latino Advisors participated in three two-hour evening virtual meetings (participants were from Colorado and Massachusetts).
- Advisors received a \$100 stipend per meeting for their time.
- These meetings were led by the neurologist (L.R.G.) and clinical research coordinator (I.M.), co-facilitating discussions with guiding questions.



Engaging Latino Caregiving Advisors

- We convened three meetings.
- The first two meetings informed linguistic and cultural adaptation of study materials and processes.
- After piloting the adapted materials with Latino patient-caregiver dyads in the ADRD-PC study, the third meeting focused on refining protocols for participant recruitment.



Engaging Latino Caregiving Advisors

Three key reflections emerged from the advisor meetings and guided the cultural adaptation of the ADRD-PC study:

- 1) personal perspectives on dementia caregiving,
- 2) patient, caregiver, and clinician interactions with the healthcare system, and
- 3) limited knowledge and misconceptions of palliative care.

Key Terminology from Latino Caregiver Advisor Perspectives

Term	Key Descriptor	Significance
Palliative Care	<p>Apoyo - support</p> <p>Cualquier etapa de una enfermedad – any stage of an illness</p> <p>Sin salir del hospital – without leaving the hospital</p>	<p>The word support evokes more meaning for caregivers when explaining the study</p> <p>Need to differentiate PC from hospice and its associations with end of life</p> <p>Need to address concerns that accepting a PC consult necessitates going to an external healthcare setting</p>
Hospice	<p>Hospicio - hospice</p> <p>al final de la vida - at end of life</p>	<p>To dispel misconceptions that PC is the same as hospice, hospice was defined with an emphasis on “at end of life”</p>
Caregiver	<p>Alguien que cuida de un ser querido - someone who cares for someone else</p>	<p>Recognizing cultural differences between Latino families, this descriptor was alternated with the term caregiver</p>
Research study	<p>Estudio - study</p> <p>Programa - program</p>	<p>Need to avoid using the word investigación, meaning both research and investigation; Advisors described that the latter could worry Latino caregivers</p>

Cultural Adaptation

What is
it?

What did
we do?

What did
we learn?

Cultural Adaptation

Systematic modification of an evidence-based treatment or intervention protocol to consider language, culture, and context in such a way that is compatible with the client's cultural patterns, meaning, and values.

Bernal, G., Jiménez-Chafey, M. I., & Domenech Rodríguez, M. M. (2009). Cultural adaptation of treatments: A resource for considering culture in evidence-based practice. *Professional Psychology*, 40(4), 361.

Cultural Adaptation Process Model: Three Phases



- 1) Researchers and participant collaboration to find a balance between participant needs and scientific integrity
- 2) Piloting of the intervention and study processes
- 3) Integrating observations into an adapted intervention

Domenech-Rodriguez, M., & Wieling, E. (2005). Developing culturally appropriate, evidence-based treatments for interventions with ethnic minority populations. *Voices of Color*, **313**, 313–334.

Cultural Adaptations to the ADRD-PC Study

- Cultural and linguistic adaption to study materials
 - Flyer
 - Consent form (as much as possible)
 - Local dementia caregiver resource guides
- Involvement and input from bilingual and bicultural research assistants
- Tailoring of the process and script for appropriate potential Latino patient/caregiver dyads
 - Engaging the caregiver in their preferred language
 - Choosing words to improve understanding of palliative care and trust related to the research process
 - Maintaining a bilingual or Spanish-only versions of the resource guide

Recruitment Considerations for Latino Participants

- Having another caregiver enroll participants
- Recruiting in-person rather than by phone
- Having a patient's trusted clinician (PCP or neurologist) recommend the study, including recruitment in outpatient clinics
- Ensuring recruitment happen in private and not in front of the patient
- Recognizing that the word research in Spanish (investigación) may cause fear

Lessons learned

- Engage diverse people with ADRD and caregivers in study planning & implementation
- Incorporate input into research that goes beyond translation
- Hire and involve bilingual and bicultural staff
- Recognize how cultural values need to be incorporated into recruitment and enrollment
- Plan for increased time for data collection

Specific to the ADRD-PC clinical trial:

- Recognize potential for different or limited awareness of palliative care
- Recognize that the nature of some interventions may not align with patient/caregiver preferences for clinical trial activities (i.e., in hospital, away from trusted outpatient clinicians)

Implications

- Given the multi-level barriers that exist for rigorous, culturally aligned clinical trial research how do we advocate for
 - Health care system involvement in this mission
 - NIH strategies, mandates are insufficient
- Investigator also need effective strategies to increase inclusivity in the context of limited time and resources



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Discussion and Questions?



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Additional Content



Phase 1 - Convening Latino ADRD caregiver advisors

Latino Advisors meeting #1 (December 2022)

- Introduction of members, group norms and purpose
- Discussion of the term palliative care (*cuidados paliativos*)
- Discussions of experiences in the healthcare system and roles as caregivers

Research team incorporation of input

- Certified translator translated materials into Spanish
- Bilingual team member back translated the Spanish materials
- Team discussion of different meanings of word

Phase 2 - Initial adaptation and preliminary testing

Latino advisors meeting #2 (February 2023)

- Presentation on the study (purpose, intervention, randomization, recruitment process, post-enrollment)
- Discussion of impressions of the study from Latino cultural perspective

Research team incorporation of input

- Terminology adaptations in both written documents and words used
- Adapted flyer to include Latino caregiver quotes
- IRB approval
- Piloting with Latino dyads approached and enrolled in the study

Phase 3 - Adaptation iterations

Latino advisors meeting #3 (November 2023)

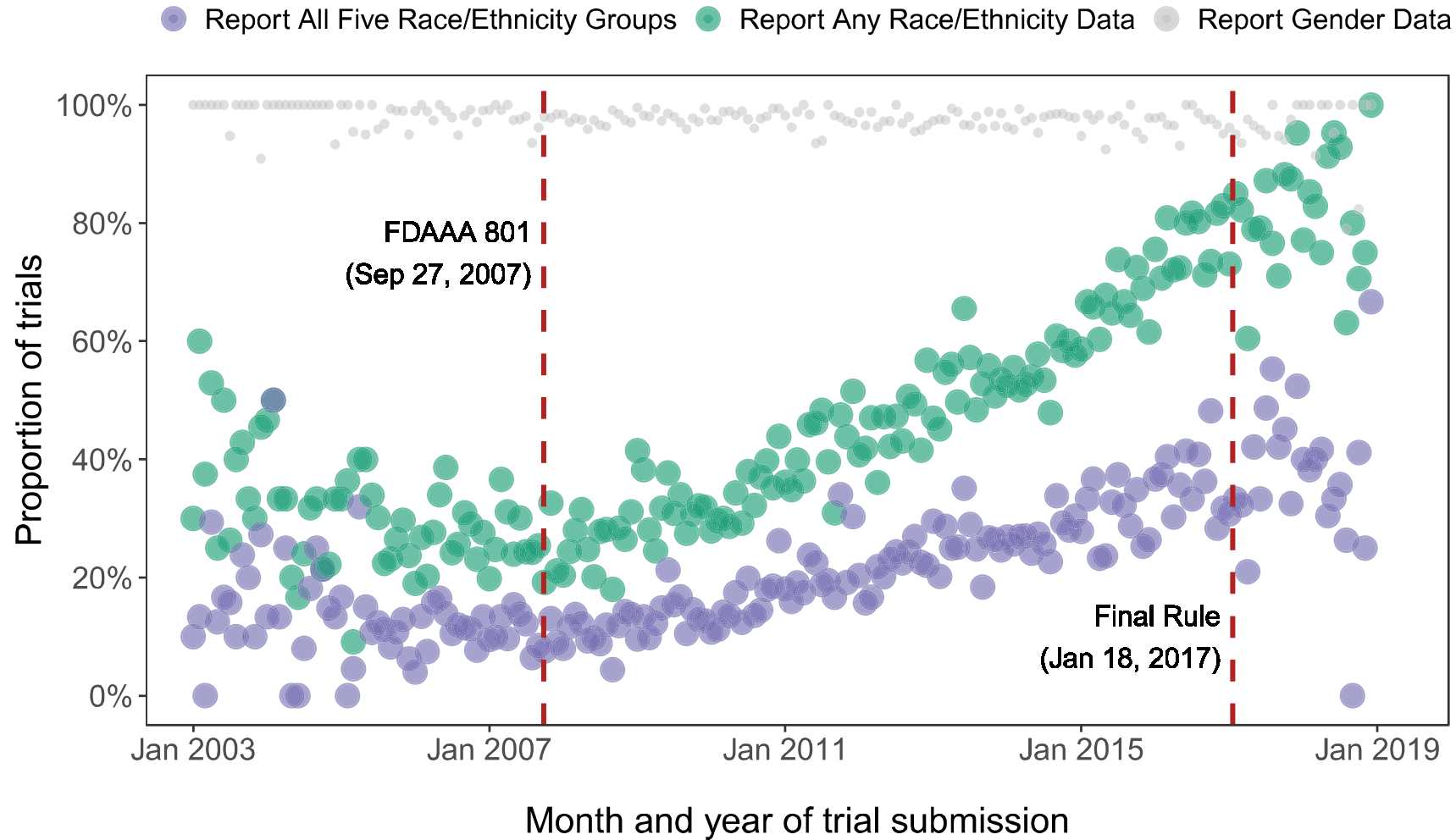
- Shared culturally adapted flyer and bilingual dementia caregiver resource guide
- Ongoing discussion of terms
- Ongoing discussion of study recruitment processes and challenges in pilot

Research team incorporation of input

- Use of recommended words and approaches to maximize trust
- Maintaining a bilingual or Spanish-only versions of the resource guides

Reporting Race/Ethnicity in Clinical Trials

A



Inclusivity in Clinical Trials

- 1993 NIH Revitalization Act
- Unrealized representation in clinical trials
- Multi-level barriers to realizing equity in enrollment

