RESEARCH ARTICLE

A service-oriented approach to clinical trial recruitment for dementia and brain health: Methods and case examples of MyAlliance for Brain Health

Eric D. Vidoni[1] | Emma Swinford[2] | Kelli Barton[2] | Jaime Perales-Puchalt[1] | C. Michelle Niedens[1] | Tina Lewandowski[1] | Tiffany Schwasinger-Schmidt[3] | Jill Peltzer[1] | JoEllen Wurth[1] | Jannette Berkley-Patton[4] | Ryan A. Townley[1] | W. Todd Moore[1] | Ashley R. Shaw[1] | Mickeal N. Key[1] | Erica Andrade[5] | Melissa Robinson[6] | Susan Sprague[7] | Aiden Bondurant[1] | Debra Brook[1] | Jennifer Freund[1] | Jeffrey M. Burns[1]

[1]University of Kansas Alzheimer's Disease Research Center, University of Kansas Medical Center, Fairway, Kansas, USA

[2]Institute for Human Development, University of Missouri Kansas City, Kansas City, Missouri, USA

[3]Department of Internal Medicine, University of Kansas School of Medicine–Wichita, Wichita, Kansas, USA

[4]Department of Biomedical and Health Informatics, University of Missouri Kansas City School of Medicine, Kansas City, Missouri, USA

[5]El Centro Inc., Kansas City, Kansas, USA

[6]Black Health Care Coalition, Kansas City, Missouri, USA

[7]OCCK Inc., Salina, Kansas, USA

Correspondence
Jeffrey M. Burns, MD, MS, Co-Director, University of Kansas Alzheimer's Disease Research Center; Director, University of Kansas Health System Memory Care Clinic; Edward H. Hashinger Professor of Medicine, Department of Neurology, University of Kansas Medical Center, Fairway, KS 66205, USA.
Email: jburns2@kumc.edu

Abstract

INTRODUCTION: Recruitment of sufficient and diverse participants into clinical research for Alzheimer's disease and related dementias remains a formidable challenge. The primary goal of this manuscript is to provide an overview of an approach to diversifying research recruitment and to provide case examples of several methods for achieving greater diversity in clinical research enrollment.

METHODS: The University of Kansas Alzheimer's Disease Research Center (KU ADRC) developed MyAlliance for Brain Health (MyAlliance), a service-oriented recruitment model. MyAlliance comprises a Primary Care Provider Network, a Patient and Family Network, and a Community Organization Network, each delivering tailored value to relevant parties while facilitating research referrals.

RESULTS: We review three methods for encouraging increased diversity in clinical research participation. Initial outcomes reveal an increase in underrepresented participants from 17% to 27% in a research registry. Enrollments into studies supported

Eric D. Vidoni and Emma Swinford contributed equally to this work.

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by the research registry experienced a 51% increase in proportion of participants from underrepresented communities.

DISCUSSION: MyAlliance shifts power, resources, and knowledge to community advocates, promoting brain health awareness and research participation, and demands substantial financial investment and administrative commitment. MyAlliance offers valuable lessons for building sustainable, community-centered research recruitment infrastructure, emphasizing the importance of localized engagement and cultural understanding.

KEYWORDS
clinical research, community engagement, diversity, enrollment, recruitment

Highlights

- MyAlliance led to a significant increase in the representation of underrepresented racial and ethnic groups and individuals from rural areas.
- The service-oriented approach facilitated long-term community engagement and trust-building, extending partnerships between an academic medical center and community organizations.
- While effective, MyAlliance required substantial financial investment, with costs including infrastructure development, staff support, partner organization compensation, and promotional activities, underscoring the resource-intensive nature of inclusive research recruitment efforts.

1 | BACKGROUND

Recruitment of participants into clinical research is among the biggest challenges slowing research efforts to treat and prevent Alzheimer's disease and related dementias (ADRD).[1] The speed of recruitment into studies directly impacts the cost and time to complete research projects.[2,3] In the effort to meet enrollment goals, study teams often fail to enroll populations that adequately represent the socioeconomic, cultural, contextual, ancestral, geographic, and genetic diversity critical for generalizing trial results. Although ADRD disproportionately impacts older adults from under-resourced, marginalized, and minoritized communities,[4–6] these communities continue to be underrepresented in research settings.[7,8] The absence of a diverse participant pool has resulted in ADRD research findings that are not generalizable to a minoritized population.[9] Barriers to the recruitment of underrepresented people include income and transportation inequity, lack of existing relationships, lack of access to resources and health information, bias on the part of research professionals, research entities failing to create trustworthy environments, lack of accessible information about research opportunities, and other manifestations of systems-based racism, place-ism, and sexism.[10,11] Especially relevant to the United States, many disparities in research engagement by people of color can be traced to structural racism explicitly and implicitly exercised in health care.[12,13] Likewise, place-based disparities, travel distances, and stereotypes of rural-dwelling individuals lead to center-

ing of urban and suburban health needs and infrastructure, which are reflected in research outcomes.[14,15]

In response to the challenge of effectively and inclusively recruiting participants for ADRD research, the University of Kansas Alzheimer's Disease Research Center (KU ADRC) created MyAlliance for Brain Health (MyAlliance). MyAlliance is a model for accelerating participation in ADRD research that emphasizes a "service first" approach by the research team. Historically, research recruitment relied on the idea that people should participate in research for the good of society,[16,17] and have equated proactive support, whether financial or other, with undue influence and coercion.[18] However, views of research participation are evolving,[19] with research teams increasingly realizing the need to initiate a trustworthy research partnership that includes transparent communication and the bidirectional flow of health information and resources.[20,21]

The goal of MyAlliance is to create a comprehensive, value-based research recruitment infrastructure by emphasizing service and empowerment of all parties affected by ADRD, including primary care providers (PCPs), social workers, service organizations, and families. With MyAlliance, we proposed a three-pronged, inter-related strategy: (1) a PCP Network to improve dementia care through a financially sustainable Chronic Care Management program, (2) a Patient and Family Network of community members, caregivers, and patients in the community; and (3) a Community Organization Network of diverse parties delivering robust outreach to increase community dementia

capability.[22] Each of these three approaches was created to deliver specific value to the intended population and simultaneously serve as a pathway for referrals into research. And in each approach, the target community defines what is valuable to them. For example, PCPs receive best practice education, informal specialist access, and support from a team of social workers for their patients. Patients and family members receive regular information on ADRD and brain health through access to educational webinars, caregiver support groups, Lifestyle Empowering Alzheimer's Disease Prevention healthy lifestyle courses (leapbrainpower.com), and in-person programming. Community organizations received funding and training of staff to conduct dementia education, screening, and related activities.

MyAlliance is founded on the hypothesis that providing value to PCPs, communities, and families can create a strong, mutually beneficial foundation on which to build relevant and effective research recruitment and participation channels. Our overarching measure of success was increasing the number of participants who enroll in ADRD-related studies, with a particular interest in populations historically under-represented in clinical trials. This manuscript's primary purpose is to broadly describe the three MyAlliance approaches and our overall success in enrollment growth and diversification. We provide specifically selected cases that exemplify our experience implementing these strategies as well as measures of relative success. As such, we hope to lay the foundation for future analyses of the individual approaches.

RESEARCH IN CONTEXT

1. **Systematic review**: The authors reviewed the literature using traditional sources. The science of recruitment is an emerging field in clinical research, with most reports focused on recruitment into a single study or using a single approach. Relevant citations are appropriately cited.

2. **Interpretation**: Our findings extend "return on investment" recruitment analyses to present a multi-pronged approach to recruitment into a research registry, and subsequent enrollment in studies. The approach is portable and scalable for other sites to increase the diversity of enrollment.

3. **Future directions**: The manuscript presents an integrated and holistic approach to research recruitment. Several opportunities for future improvements and research are proposed, including (a) the use of social workers to promote research, (b) the recruitment of participants by partnered organization staff, and (c) unaffiliated providers connecting participants with research and information beyond their practice.

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2 | METHODS

MyAlliance was created to accelerate participation in research and emphasize reaching those populations that are underrepresented or marginalized in modern medical research. We expected the development and testing of new approaches, content, and tools would yield reproducible and portable strategies to enhance national recruitment efforts and change the culture of research recruitment in the community. We hypothesized that the sustaining value of MyAlliance, a commitment to serving community needs before recruiting for research, would contribute to a permanent recruitment infrastructure in the community—linking, aligning, and engaging providers, their patients, and trusted community support with research efforts.

2.1 | Developing MyAlliance

The under-inclusion of minoritized communities is a product of factors at the individual and institutional level, yet the majority of existing research focuses on the individual.[23] We sought to create a program that addressed three major institutional barriers by: (1) preparing PCPs to provide dementia care, including through post-diagnosis support of social workers[24]; (2) creating a continuous stream of resources and communications for patients and families; and (3) improving the dementia support readiness of community-based organizations.[25] These three approaches were designed to be inter-related. That is, PCPs and community organizations could connect their constituents with MyAlliance resources. In turn, MyAlliance communications could promote or feature PCPs or community organizations. And all were points of potential entry for research participation, our ultimate goal.

The initial phase of the project focused on building the necessary infrastructure to support the proposed activities. This included assembling a group of community organizations that predominantly serve people commonly underrepresented in medical research, developing and administering dementia trainings to community organization staff, educating health care providers during brief informational lectures, and assembling a team of social workers. Throughout the development and execution of the project, monthly meetings were held with a Community Organization Advisory Board of partner leadership, and with a separate Patient Advisory Board. We relied on a user-centered design framework to iteratively and flexibly adjust our portfolio of service-oriented activities.[26] This design framework involved several rounds of initial meetings to define needs and goals, followed by ongoing development and updating on regular input. At the onset of this work, we also dedicated time to developing and nurturing relationships with PCPs and community organizations, establishing a mutual commitment to shared values, mission, and decision-making. In our prior community-based projects, the most sustainable, engaging, and successful programs were those in which all parties shared and valued the common goal, and we carried these lessons into MyAlliance.[27–31]

We approached the creation and evolution of MyAlliance with intentionality toward active partnership with communities historically underrepresented in medical research. In Kansas and western Missouri, that is most commonly people who identify as Black/African

American or Latino, and people living in rural areas. Thus, initial partnerships in the MyAlliance project began from existing interpersonal relationships between the KU ADRC staff, PCPs, and community organizations that explicitly serve, support, and are part of the communities we wanted to reach. We also worked to hire a MyAlliance team that possessed cultural, language, and place-based knowledge of the communities in which they worked.

We have previously reported on the backbone of our data collection and evaluation, our centralized recruitment model we call the MyAlliance Participant Relations and Outreach Manager for Trials (PROMpT) Research Registry.[32] This structure is similar to recruitment efforts at many contract research organizations.[32] Briefly, rather than requiring study coordinators who are already burdened with trial demand to identify and pre-screen potential participants, we employ a research intake team solely dedicated to performing research outreach, engagement, intake, and pre-screening operations, on behalf of the study teams. Individuals interested in connecting with brain health and dementia resources and/or research opportunities are centrally routed to this team for high-level consultation and navigation to resources and studies relevant to the individual's health status and personal interests. Contacts are recorded to create continuity, track timely interactions, and track study participation under two institutional review board (IRB)-approved research recruitment protocols.

Prior to and during MyAlliance, we tracked registry and supported study enrollments allowing us to evaluate changes in research recruitment over time, and in response to specific engagement methods. The following sections outline the activities, services, and preliminary results of the three MyAlliance networks. Our logic model for each branch of the MyAlliance model is presented in Table 1. Each potential referral network begins with a case exemplar from the MyAlliance PROMpT Research Registry to illustrate the access point, then discusses opportunities and challenges of the referral pathway. For quantitative comparisons, we look at research referrals and enrollments in the 3 years following the start of the MyAlliance Project on April 1, 2020, and the 3 years prior. Table 2 provides details on the number of individuals consenting to our research registry, as well as those who enrolled in a study. Demographic and health information, including race, ethnicity, and ZIP code were self-reported. Rural ZIP codes were defined according to Federal Office of Rural Health Policy guidance.[33]

2.2 | Deploying MyAlliance

After initial development steps, we began deploying MyAlliance, focusing on our pathways to research participation, providers, families, and organizations. We continued to revise and improve each pathway as challenges and opportunities were identified by the study team and partners alike. The following section details a case example of each research recruitment pathway and explores the strengths and weaknesses of the strategy.

3 | RESULTS

As a brief synopsis, between April 2020 and March 2023, the KU ADRC implemented the MyAlliance strategy to enhance an already mature and effective recruitment infrastructure. Table 2 summarizes research recruitment before and during MyAlliance. Our overall hypothesis was that the multi-pronged, service-based approach would increase the diversity of our research participants. We tested change from pre-MyAlliance to the MyAlliance period. using Chi-squared tests with Yates' continuity correction. Though the overall number of individuals who ultimately joined our research registry dropped by 26%, likely attributable to the impact of COVID-19, with MyAlliance we saw an increase in diverse representation. Those who identified with any non-White race identity alone, identified as Latino, lived in a rural area, or had a suspected cognitive disorder enrolled in our research registry at a greater rate during MyAlliance ($p < 0.05$). We also saw all groups except rural-dwelling individuals increase their enrollment in supported studies. Regarding referral sources, individuals identified their provider, social worker, a community organization, or other word-of-mouth sources such as a friend or family member as the source of their referral to our registry more frequently ($p < 0.05$). Direct study-specific promotions decreased as a source of referral. As might be expected, these results held for those ultimately enrolling in a supported study.

3.1 | Referral pathway 1: Primary care provider network

Case Example: A 70-year-old man, who was seen by his primary care physician for a non-cognition related concern. He had a past medical history of chronic kidney disease, Type 2 diabetes, hypertension, and hyperlipidemia. He identified as African American, non-Latino, non-veteran, and lived in an urban area with an Area Deprivation Index (ADI)[34] in the tenth decile nationally. His physician suggested a lifestyle (exercise) study and referred him via an electronic referral. He consented to enroll in the MyAlliance PROMpT Research Registry, and after 2 months of communication and time for review of the consent document, the patient consented to the exercise study. He was ultimately withdrawn after a previously unknown cardiovascular condition was identified.

Research indicates that healthcare providers can influence participant recruitment and retention rates, and when providers are engaged, available, and trusted, research participation rates improve.[35,36] PCPs provide person-centered, lifespan care,[37] and are well positioned to manage the vast majority of patients with dementia and their caregiving partners. Yet, many PCPs feel insufficiently trained and resourced for diagnosis or adequately prepared for post-diagnostic care.[38,39] Thus, the goals of the MyAlliance PCP Network were to improve clinical care for dementia patients and their families and better equip PCPs and their clinic teams with clinical research resources to improve research referral rates.

TABLE 1 MyAlliance logic model

Alzheimer's disease and related dementia (ADRD) clinical research needs a large and diverse participant pool.					
Hypothesis- Providing value and support to primary care providers (PCPs), communities, and families will create a strong, mutually beneficial foundation on which to build relevant and effective research recruitment and participation channels.					
Partner with primary care practices to increase research referral of patients with ADRD.					
Objective	**Inputs**	**Activities**	**Outputs**	**Outcomes**	**Impact**
- Increase primary care provider dementia care confidence	- Trainings - Information, activities, and options for patients - Social work support	- Dementia care trainings - Educational communications - Cognitive Care Network social work team	- Increased physicians referring - Increased participant referrals - Increased hours of care support	- Increased confidence in clinical dementia care	- Persistent pipeline of potential research participants from practices serving a diverse community
Increase visibility of trustworthy ADRD resources to encourage research participation					
Objective	**Inputs**	**Activities**	**Outputs**	**Outcomes**	**Impact**
- Increase interest in research participation	- "Brand development" - Educational content development - Communications platforms	- Newsletters - In-person events - Webinars - Care support app - LEAP! Dementia risk reduction classes	- Increased engagement in research - Increased reach of communications	- Increased trust in research	- Persistent communications and education tailored for diverse needs and communities
Enhance community-level dementia-capable care support					
Objective	**Inputs**	**Activities**	**Outputs**	**Outcomes**	**Impact**
- Increase dementia capability of community-based organizations	- Community educational content development - Tailored communications	- Trainings - Co-sponsored, tailored events - Social work support - Tailored communications	- Increased research referrals via organization contacts - Increased reach of communications	- Increased trust in research - Increased ability to support constituents with dementia	- Persistent dementia capability and trained workforce throughout region

MyAlliance PCPs and other healthcare providers were offered accessible training (in-person or online) to enhance skills in dementia diagnosis, counseling, and treatment. We have previously published on the success of the in-person, *MyAlliance Dementia Update Course* opportunities.[40] Notably, we made a significant effort to incorporate the identified needs of regional providers in this training.[41] We also hosted a bi-monthly series of 20-min "Pocket Talks". These lunchtime, live video conferences (Zoom Video Communications, Inc., zoom.us) presented by KU ADRC clinical staff provided short lectures or case presentations on dementia diagnosis and care. This format allowed for participant engagement and aligned with PCP preferences on timing and length. These easily accessible continuing education credit opportunities also served as an access point to inform PCPs about currently enrolling studies and engage them in research efforts. In addition to educational opportunities, a streamlined research referral workflow was adopted in which PCPs could refer a participant for research opportunities via MyAlliance materials in their office, a direct online referral portal, or other standard communication means. Providers within the University of Kansas Health System could refer through a research referral mechanism built into the electronic medical record that was received directly by the research intake team. Providers were not expected to stay current on all available research studies and their respective inclusion/exclusion criteria. Instead, providers were encour-

aged to discuss the value of research participation with patients and families and answer their general questions about research. When providers submitted a research referral to the recruitment team, that team would coordinate with the patient to determine the research study that best aligns with their interest, medical history, and time commitment allotment.

In the 3 years prior to MyAlliance, about 21% of our referrals to research came from providers. During the MyAlliance project, that increased to nearly 29%. This may account for the increase in the number of individuals in the MyAlliance PROMpT Research Registry with a known or suspected cognitive disorder, from 21% of new participants to 32%. The number of new research registrants ultimately enrolling in a study paralleled these increases, such that during MyAlliance, 1/3 of new participants had a suspected cognitive disorder.

3.2 │ Referral pathway 1b: Social work support

Case Example: A 71-year-old man, with a diagnosis of mild cognitive impairment and a history of depression, diabetes, hearing loss, and cervical and lumbar pain. He was seen in a local memory clinic affiliated with MyAlliance. After diagnosis, he was connected to a Social Work Navigator who referred him to research opportunities. He identified as White, non-Latino,

TABLE 2 Recruitment results before and during MyAlliance

Prameter	In Research registry			Ultimately enrolled in a supported study		
	Prior to MyAlliance	During MyAlliance	X^2	Prior to MyAlliance	During MyAlliance	X^2
Total	3933	2897	–	1021	765	–
Participant communities sampled						
Any non-White Alone Race identity	248 (6.3)	380 (13.1)	91.9^	86 (8.4)	131 (17.1)	30.2^
Latino identity, any race	143 (3.6)	142 (4.9)	6.4[a]	65 (6.4)	69 (9)	4.1[a]
Suspected cognitive disorder	813 (20.7)	930 (32.1)	114.1^	210 (20.6)	252 (32.9)	34.3^
Rural-dwelling	325 (8.3)	294 (10.1)	7.0[a]	68 (6.7)	52 (6.8)	0.9
– No. of unique rural zip codes	161 (37.2)	142 (34.2)	–	–	–	–
Unique individuals from a marginalized community	686 (17.4)	778 (26.9)	87.2^	211 (20.7)	239 (31.2)	25.4^
Referral sources						
Provider	817 (20.8)	827 (28.5)	55.2^	188 (18.4)	189 (24.7)	10.4[a]
– Unique providers referring	150	149	–	–	–	
Social worker	1 (0)	17 (0.6)	20.0^	0 (0)	6 (0.8)	8.0[a]
Word-of-mouth	501 (12.7)	929 (32.1)	376.5^	173 (16.9)	285 (37.3)	94.6^
Promotions	2286 (58.1)	1038 (35.8)	331.9^	586 (57.4)	265 (34.6)	90.8^
Community organizations	0 (0)	21 (0.7)	28.6^	0 (0)	9 (1.1)	12.1[a]
Other/unknown	328 (8.3)	65 (2.2)	–	74 (7.2)	20 (30.8)	–

Note: Any Non-White Alone Race includes any individuals with a racial identity other than solely White. Unique Individuals from a Marginalized Community include all unique individuals identifying as Latino, rural-dwelling, or having a racial identity other than solely White. Both 3 year periods only include those new individuals participating in our research registry, not existing individuals. The Prior to MyAlliance time period was April 2017–March 2020. The During MyAlliance period was April 2020–March 2023.

[a]All values are count (% of total). * = $p < 0.05$. ^ = $p < 0.001$.

non-veteran, and lived in a suburban area with an ADI in the first decile nationally. After a discussion with staff, he consented to enroll in the MyAlliance PROMpT Research Registry and expressed interest in exercise and investigational medication trials. He was contacted by recruitment staff 12 times at his request over 183 days and deferred consideration before ultimately enrolling in an at-home exercise study 343 days after initial contact.

Physicians in the MyAlliance PCP Network had access to a specialized team of social work navigators we called the Cognitive Care Network (CCN) who delivered chronic care management services to patients. The CCN supported both patients and providers in delivering chronic care management support, engaging in regular contact with them, establishing trust over time, and liaising with providers. These interactions became an opportunity to provide direct patient education about and referrals to clinical research.

Prior to MyAlliance, there was no CCN and no equivalent service as a point of comparison. A single participant in our research registry identified a social worker as their referral point prior to MyAlliance. Beginning with the MyAlliance program, there have been 17 participants directly referred to the MyAlliance PROMpT Research Registry. Of those, six ultimately enrolled in a study. While some connections to research came from direct referrals from a CCN navigator, some referrals were the result of strengthened lines of communication between the CCN navigator and doctors or other healthcare

professionals, through which the CCN navigator was able to promote research opportunities. Although no data were collected to track these communications, it is possible that more healthcare providers referred patients to research because of the exposure to social workers familiar with this topic.

Social work referral to research was among the least common pathways to the MyAlliance PROMpT Research Registry. Through the MyAlliance project, new lines of communication were created between research recruitment staff and clinically engaged social workers to support knowledge sharing through research orientation, study enrollment updates, and case consultation with research staff. Even with these developing professional collaborations and the proximity of social workers to study teams, the number of referrals for research from social workers was not as anticipated. There are several possible reasons why this pathway, although promising, did not yield a high number of research referrals. One significant challenge was that social workers were often assisting patients and families in crisis situations where the priority was to manage immediate needs rather than discuss clinical research. Anecdotally, social workers perceived clients in rural areas as expressing greater concerns about the trustworthiness of our urban health system and reservations about travel, including limited travel funds. It is important to note, however, that despite the low referral rate, there was an impressive conversion rate of over one in three, suggesting that social workers effectively

establish the groundwork for successful research enrollment. This pathway represents a potentially fruitful area of exploration for future efforts to increase participants from diverse backgrounds in clinical research.

3.3 | Referral pathway 2: MyAlliance patient and family network

Case Example: A 69-year-old woman, with no reported cognitive concerns and a history of hypothyroidism. She identified as White, non-Latina, non-veteran, and lived in a rural area with an ADI in the seventh decile nationally. She received an email from a purchased list for the MyAlliance program regarding an exercise intervention study. The participant was randomized 77 days after contact.

Prior to MyAlliance, the KU ADRC was already using standard outreach strategies[7] such as targeted mailings, advertisements, health fairs, in-person talks, social media, and more to notify the public about research opportunities. MyAlliance expanded our approach to these common strategies through major enhancement and identifiable "branding" of our engagement efforts. Our Patient Advisory Board was heavily involved in the branding efforts that eventually yielded a logo, color scheme, template for newsletters and slides, consistent email strategy, and other standardized approaches to MyAlliance events and materials. The MyAlliance branded materials were also provided to the PCP network and CCN teams to provide to patients who were curious about research participation, but not ready to engage. For example, patients had the opportunity to be passively engaged through informational newsletters and easily accessible online content to learn more about supporting brain health, available research opportunities, and the work of the research organization.

The MyAlliance Patient and Family Network outreach efforts included a series of weekly 30-min virtual webinars featuring brain health-related topics from educational, medical, and research experts. Furthermore, customized weekly email newsletters with brain health tips, research opportunities, information about upcoming virtual and in-person events, current brain health topics, and caregiver advice were sent each week. These opportunities allowed patients and families to make meaningful and value-based connections with research opportunities on their terms. The weekly emails and social media outreach were initiated in English, but communications expanded in 2022 to include Spanish-language messaging. This addition was made in response to requests from the Patient Advisory Board and our Community Organization Advisory Board and was complemented by a separate, text-messaging based Spanish-language outreach program focused on caregiver support that was initiated during the same time frame.[42,43]

Notably, though we refer to the network as "Patient and Family", all members of the public were welcome, recognizing that nearly all people have some connection to ADRD, and many cognitively healthy individuals are helping to care for someone with ADRD regardless of familial relationship, or are interested in preserving cognitive function and preventing dementia.

In an example of our iterative user-centered design, after initially emphasizing our MyAlliance PROMpT Research Registry as the primary entry point for research engagement, our Patient and Community Organization Advisory Boards recommended we provide an opportunity for "easing into" engagement. In response, we created what was essentially a MyAlliance listserv, a database of minimal contact, demographic, and needs information, approved under an IRB Quality Improvement determination that served as a less-intrusive "contact list" compared to immediately registering for consideration in studies. As signups for this listserv increased, we noticed a sizeable drop in participants' MyAlliance PROMpT Research Registry enrollments, $n = 3933$ to $n = 2897$, before and after the start of our MyAlliance project. During the MyAlliance project, 2268 individuals signed up for the listserv without progressing on to enroll in the MyAlliance PROMpT Research Registry. As a quality improvement project, it is unclear if this shift in signups away from a high burden registry is a generalizable finding for other sites.

Considered without context, these changes could be interpreted as a failure of MyAlliance to increase participation in research. However, as noted in Table 2, the percentage of new MyAlliance PROMpT Research Registry participants who ultimately enrolled in a study, slightly increased during the MyAlliance period, despite the absolute reduction in Research Registry enrollment. Further, through the MyAlliance program, we increased culturally and linguistically-tailored materials, educational offerings, and participant engagement opportunities, including more events in rural locations. We believe that our increase in individuals who identify with an underrepresented community, from 17.4% to 26.9% of those entering our MyAlliance PROMpT Research Registry, was a direct result of providing a space for individuals to learn about research without committing to a study and tailoring engagement opportunities to what patients and families needed.

3.4 | Referral pathway 3: Community organization network

Case Example: A 71-year-old woman referred by a MyAlliance community partner organization for an observational study focused on biomarker development. She had no reported cognitive concerns, hypercholesterolemia, and multiple joint replacements. The woman identified as African American, non-Latina, non-veteran, and lived in an urban area with an ADI in the ninth decile nationally. The team and participant had difficulty scheduling due, in part, to grandchild care responsibilities and she was ultimately unable to be enrolled before the closure of the study. However, the individual remained in the MyAlliance PROMpT Research Registry and wished to be considered for other or future studies.

The goal of the Community Organization Network approach was to create a dementia-capable, research-ready community partnership arm, decentralized from the KU ADRC. At the crux of this approach was a network of contracted partners that serve underrepresented and minoritized communities, including Black/African American, Latino, and rural populations. Structured collaborations with partner organizations created clear opportunities for engagement based on trust

and mutual benefit and expanded strengths-based partnerships.[23,44,45] The scope of work for each contract included, participation in regular leadership events, enhance identification and care of individuals with cognitive changes and encourage research participation, host training of staff on dementia identification and resource access, and maintain records of activity related to client dementia support and research referral.

Partner organizations developed bridges into the community through direct outreach and provided essential strategic direction on the design and content of MyAlliance activities and materials. These organizations also directly increased community dementia awareness and knowledge through their networks of staff, including community health workers (CHW). During MyAlliance development, our community organization partners specifically identified staff training in ADRD as a priority. Numerous studies have demonstrated the efficacy of CHW programs for health education.[46,47] Therefore, we asked partner organizations to help define a curriculum called "Assess. Connect. Educate." (ACE) and included training on the AD8 screen, foundational dementia information,[48,] and regionally-appropriate resource referral support tools.

With the guidance and expertise of partner organizations, the CHW trainings developed for this project were culturally tailored and included content personalized to the communities served by the agencies, as we have done previously.[30,31] The trainings were separated into two tiers that addressed the ACE core concepts both at an introductory level (Tier 1, approximately 2 h) and more complex, detailed information (Tier 2, approximately 4 h, including case discussions and family conversation tips). This two-tiered structure allowed trainers to best meet the learning needs of a range of audiences in our partner groups and trainings were offered in both English and Spanish.

Leaders from our contracted partners gathered for monthly, 1 hour, virtual meetings to discuss their efforts around dementia outreach and community education, the challenges and successes they encountered, and the lessons learned. The leadership team served as a Community Organization Advisory Board for the project and as peer collaborators to each other. In developing meeting and reporting infrastructure with our partners, many of whom work with significant time and staff constraints, it was critical to strike a balance between collecting relevant information to measure impact and avoiding overburdening agencies.

An unexpected benefit of working with contracted partner organizations was building connections to non-contracted agencies, which increased awareness of clinical research and expanded partnerships beyond the original scope of the project. For example, organization interconnectedness and relationship-building led to the eventual addition of a fourth contracted partner serving underrepresented individuals in the urban core, and discussions with a potential fifth partner serving the community with Down syndrome. A commitment to meaningful, long-lasting, and sustainable relationships is a best practice identified in prior literature[49,50] and each community organization contracted with this project had worked with the KU ADRC for at least 5 years. Interactions were not dependent on project funding, but rather a solidarity born of time and shared values. However, providing financial support through contracts was a key component of recognizing the efforts and value of these partners.

Our community partnerships were critical in efforts to engage and provide value. As noted with the Patient and Family Network, positive trends in the percentage of individuals participating in the MyAlliance PROMpT Research Registry from a racial, ethnic, or geographic background underrepresented in research indicate that efforts to encourage research participation were effective. Our community partners were a message multiplier for MyAlliance and awareness of KU ADRC and enhanced the quality and validity of research by shaping our understanding and approach to regional service. As one example, our community partner identified that their clients encountered financial barriers related to neurology care. With the assistance of the KU Medical Center Neurology department, we established a substantial fund for neurology clinical care support for those unable to pay.

We received 21 referrals from our partner organizations during the MyAlliance project. These direct partner referrals were an important part of this pathway, but equally important and more difficult to quantify, are the secondary benefits of these partnerships. By working with organizations that were well-established and highly regarded in the community, KU ADRC benefitted from increased awareness and an association with these agencies that held a trusted status. Additionally, each of these partner organizations had their own set of partners, and additional referrals were received from non-contracted agencies.

Another unexpected outcome of these relationships was the expansion of supported dementia-capable projects across the region. During the project period, one of the partner organizations applied for and received a major US Department of Health and Human Services Administration for Community Living cooperative agreement to extend dementia support access points across rural regions of Kansas. This cooperative agreement heavily leveraged the KU ADRC and was considered a major success for the partner organization.

4 | DISCUSSION

Recent years have seen an increase in inclusive research recruitment approaches including targeted unsolicited advertisements, locally-relevant, community-based events and outreach, and recruitment in academic and clinical settings. But as demonstrated in a recent systematic review, the scope of evidence for effective strategies for recruitment and retention of underrepresented populations is limited and would greatly benefit from evidence-based, theoretical frameworks.[7] We see elements of MyAlliance reflected in the Participant and Relationship-Centered Research Engagement Model, especially in the emphasis on sustained, bidirectional relationships, facilitation of fit through a broad menu of research and research-adjacent opportunities, and an openness to ongoing activities as readiness evolves.[23]

A value-driven and multi-pronged approach holds great promise for the recruitment of a diverse cohort of research participants over time. At the start of the MyAlliance Program, less than 1/5 of new individuals to our MyAlliance PROMpT Research Registry were known to identify with a racial or ethnic community underrepresented in science or live in a rural area. As conducted, our work does not make it possible to parse out which approach was most effective or where the positive results originate from. However, we believe the overall effect

of the approach is clear, and the collective impact of MyAlliance has been to improve the inclusiveness of our studies. The broad-reaching and service-oriented approach that MyAlliance took was effective in reaching diverse populations, thereby creating an opportunity for long-term relationship development and trust building that is so critical to research participation partnerships.

The direct research referrals received through the MyAlliance referral pathways represent just one potential area of impact of this project. Though the efforts of this work did produce measurable improvement in the diversity of research referrals and study participation, the foundational work that was done through this project will set the stage for future engagement and awareness around research opportunities in our region. This work further extended already functioning and trusted relationships between an academic medical center and community serving organizations, including non-profits and the medical community, and fostered increased awareness and participation in communities that have been historically underrepresented in research.

A key component of this work was the reliance on multiple advisory boards, touched on briefly above. Our advisory boards provided ongoing community relevant insight and direction for MyAlliance. The Patient Advisory Board was comprised of a group of patients and family members who provided perspective and influence across all four of the referral pathways. Patient Advisory Board members included caregivers, persons with cognitive change, and individuals who identified with minoritized racial, ethnic, or lesbian/gay/bisexual/transgender/plus (LGBT+) identity. This group convened regularly to discuss outreach efforts (including messaging, relevance of topics, etc.) and share insight. Patient Advisory Board members felt valued, with one member sharing, "We have a powerful advisory board; everyone feels extremely comfortable in sharing thoughts and ideas and often works from each other to produce creative suggestions for the MyAlliance program." Through the Patient Advisory Board, patients and families had a direct line of communication with project staff and were able to help shape the direction of MyAlliance activities. The Community Organization Advisory Board, comprised of leadership from organizational partners identified areas of synergy, shared community and organization needs, and planned activities. These meetings proved pivotal for a flexible approach. For example, when the coronavirus disease 2019 (COVID-19) pandemic shut down most public activity, many of our partner organizations shifted to safety and vaccination protocols. The network was able to provide information about keeping older adults safe, managing dementia during the COVID-19 pandemic, and provide dementia information at community vaccination and other events.

A broad objective of MyAlliance was to create a paradigm shift for dementia research recruitment in order to redistribute power, resources, and knowledge more equitably and engage in a bi-directional transfer of expertise and support. MyAlliance is designed to increase awareness of cognitive status and empower people to regularly consider and take action to support their brain health, including research participation. It also lays the groundwork within our own institution and supports projects to ensure more efforts are made to make study participation accessible to diverse communities. The Social Work Navigators and Community Health Worker at partner organizations

hold great potential as a research recruitment resource for patients and providers. In future iterations of this work, equipping social workers with intentional materials, language, and information for having research discussions as part of ongoing care management could make this even more impactful.

4.1 | Limitations and considerations

There are limitations in our ability to evaluate the efficacy of a project such as MyAlliance. Though we have endeavored to tie our objectives to measurable outcomes and outputs, these identified outcomes may have been impacted by a rapidly changing scientific environment. Some prior work has found that though COVID-19 observation and treatment trials did exceptionally well during the height of the pandemic,[51] though other clinical trials may have struggled for over a year to return to normal enrollment.[52] Further work remains to be done on the long-term impact of the COVID-19 pandemic on research participation. The impact of COVID-19 on a service-oriented approach to research participation such as MyAlliance is also unknown. As future literature is published, it will be important to evaluate MyAlliance in the context of other reported shifts in research perception and participation, whether positive or negative.

One consideration with this type of project is that while it yielded positive outcomes related to research engagement, the financial inputs were extensive. This type of work requires investment to build infrastructure, support staff time, compensate partner organizations, and support a range of training and educational activities. We and others have previously found that costs of recruitment can commonly be greater than $600 per enrolled participant, with increasing costs associated with increasing medical complexity.[52–54] Project activities had a high administrative burden, both for the academic medical center doing project management and the partner organizations. Primary staff for overseeing MyAlliance at the KU ADRC fluctuated but generally included between four and six full-time equivalent staff and leadership positions and two to three full-time equivalent social work positions. Salary and fringe expenditures averaged $462,219 annually. Additionally, the partnering community organizations were contracted at standard rates each year, invoicing the award as activities occurred. Total invoiced activity by the organizational partners averaged $26,247 annually. An additional $26,754 annually was spent on average for promotional activities such as Alzheimer's Walk tables, print flyers, an email, newsletter, and signup management system, graphic design, copywriting, and other essentials to professionalize communications. NIH grant funding was secured to support portions of this work. Supplementary financial support was provided by a mix of philanthropic funds and the support of aligned studies. These factors make it difficult to specifically evaluate return on investment for any one approach. Even without implementing an ADRC-wide program like MyAlliance, we hope this work informs other researchers on budget considerations for recruitment and retention in future ADRD research grants.

A final limitation was our decision to limit the capture of additional experiences, identities, and backgrounds that undoubtedly add

richness to a research sample and increase generalizability. In some instances, the decision to not capture information on potential participants was made to protect the safety of those in our community, such as those with a minoritized sexual or gender identity or the immigration documentation status of those we encountered. Though research comes with certain guarantees of privacy, there remain inherent risks and organizations that reserve the right to review data. In consultation with our community, we chose to value discretion over deeper characterization of our potential participants.

4.2 | Summary

There is a clear and important national imperative to make Alzheimer's disease research more inclusive. The MyAlliance model provides an example of a multi-pronged approach toward meaningful change in the diversity of participants in ADRD research. The project offers several promising lessons to build a sustainable, service-based infrastructure of research recruitment. Successful research recruitment efforts are largely the product of a sustained local activity that understands, respects, collaborates with, and serves the communities around a research site, and MyAlliance is no exception. Key to success were the bidirectional efforts across health systems and personnel, advisory boards, and community-based organizations working together. The project relied on regional cultural understanding and experience, as well as interpersonal relationships and name recognition. A similar approach taken out of context may yield different results in another region, nevertheless, MyAlliance offers promising tools and methods to move towards more inclusive ADRD research. We encourage other ADRD research entities needing participants to work with relevant partners in their regions and consider a community-centered and service-oriented approach to research recruitment.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts to disclose. Author disclosures are available in the supporting information.

CONSENT STATEMENT

All data regarding enrollments were obtained under two protocols approved by the University of Kansas Medical Center Human Subjects Committee. Informed consent was obtained from all participating individuals.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.