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Authors

Yang, Mia
Samper-Ternent, Rafael
Volpi, Elena
et al.

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RESEARCH ARTICLE

The dementia care study (D-CARE): Recruitment strategies and demographic characteristics of participants in a pragmatic randomized trial of dementia care

Mia Yang[1] | Rafael Samper-Ternent[2,3] | Elena Volpi[3,4] | Aval-Na'Ree Green[5] | Maya Lichtenstein[6] | Katy Araujo[7] | Pamela Borek[6] | Peter Charpentier[7] | James Dziura[8] | Thomas M. Gill[7] | Rebecca Galloway[3] | Erich J. Greene[8] | Kristin Lenoir[1] | Peter Peduzzi[8] | Can Meng[8] | Jordan Reese[5] | Amy Shelton[8] | Eleni A. Skokos[8] | Jenny Summapund[9] | Erin Unger[9] | David B. Reuben[9] | Jeff D. Williamson[1] | Alan B. Stevens[5]

[1]Section on Geriatric Medicine & Gerontology and the Sticht Center for Healthy Aging and Alzheimer's Prevention, Department of Internal Medicine, Wake Forest School of Medicine, Atrium Health Wake Forest Baptist, Winston Salem, North Carolina, USA

[2]School of Public Health, and Institute on Aging, The University of Texas Health Science Center in Houston, Houston, Texas, USA

[3]Sealy Center on Aging, The University of Texas Medical Branch- Galveston, Galveston, Texas, USA

[4]Sam and Ann Barshop Institute for Longevity and Aging Studies, The University of Texas Health Science Center at San Antonio, San Antonio, Texas, USA

[5]Center for Applied Health Research, Baylor Scott & White Health & Texas A&M Health Sciences Center, Temple, Texas, USA

[6]Department of Neurology, Geisinger Medical Center, Wilkes-Barre, Pennsylvania, USA

[7]Department of Internal Medicine, Section of Geriatrics, Yale School of Medicine, New Haven, Connecticut, USA

[8]Yale Center for Analytical Sciences, Yale School of Public Health, New Haven, Connecticut, USA

[9]Multicampus Program in Geriatric Medicine & Gerontology, Division of Geriatrics, David Geffen School of Medicine at UCLA, University of California, Los Angeles, California, USA

Correspondence
Mia Yang, 1 Medical Center Blvd., Winston Salem, NC 27157, USA.
Email: miyang@wakehealth.edu

Mia Yang and Rafael Samper-Ternent are co-first authors.

Jeff D. Williamson and Alan B. Stevens are co-senior authors.

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Abstract

INTRODUCTION: Pragmatic research studies that include diverse dyads of persons living with dementia (PLWD) and their family caregivers are rare.

METHODS: Community-dwelling dyads were recruited for a pragmatic clinical trial evaluating three approaches to dementia care. Four clinical trial sites used shared and site-specific recruitment strategies to enroll health system patients.

RESULTS: Electronic health record (EHR) queries of patients with a diagnosis of dementia and engagement of their clinicians were the main recruitment strategies. A total of 2176 dyads were enrolled, with 80% recruited after the onset of the pandemic. PLWD had a mean age of 80.6 years (SD 8.5), 58.4% were women, and 8.8% were Hispanic/Latino, and 11.9% were Black/African American. Caregivers were mostly children of the PLWD (46.5%) or spouses/partners (45.2%), 75.8% were women, 9.4% were Hispanic/Latino, and 11.6% were Black/African American.

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DISCUSSION: Health systems can successfully enroll diverse dyads in a pragmatic clinical trial.

KEYWORDS
caregivers, dementia care, pragmatic clinical trials, recruitment

1 | BACKGROUND

The population of Americans living with Alzheimer's disease and related dementias (ADRD) was estimated to be 6.5 million in 2022—about one in nine persons 65 years or older—and is predicted to increase to 13.8 million by 2050.[1] Randomized controlled trials (RCTs) of healthcare-based interventions such as the University of Indiana Collaborative Care (n = 153),[2] MIND (Maximizing Independence) at Home (n = 303),[3] and the University of California San Francisco's (UCSF's) Care Ecosystem (n = 780)[4] have shown improvements in caregiver distress and reduced behavioral and psychological symptoms in persons living with dementia (PLWD). In addition, community-based dementia care and caregiving interventions such as Benjamin Rose Institute (BRI) Care Consultation (n = 394),[5] REACH (Resources for Enhancing Alzheimer's Caregiver Health) II (n = 642),[6] and Advancing Caregiver Training (n = 272)[7] have demonstrated efficacy in improving caregiver quality of life outcomes such as burden and depression and the management of behavioral symptoms for the PLWD. Wide dissemination of these evidence-based interventions has been limited. Given the pressing need by PLWD and their caregivers for better care, more effective adoption strategies sensitive to diverse populations are needed.[8–11]

Underrepresented older adults are disproportionally more likely to have ADRD compared to other Americans.[12] Black/African Americans and Hispanic/Latinos are projected to account for over half (52%) of the ADRD population in the United States in 2050.[13] Adults from these groups are often not included in clinical trials,[14] and the coronavirus disease 2019 (COVID-19) pandemic has worsened this problem.[15] The changing demographics of the United States call for a national research agenda for ADRD research that is inclusive of participants from underrepresented racial and ethnic groups[16] to provide effectiveness data on which health systems and diverse communities can build models of care that support the best possible outcomes for PLWD and their family caregivers. Thus, the Dementia Care (D-CARE) Study was conducted to compare two evidence-based interventions to usual care, pragmatically within four health systems with the goal of adding generalizable findings to the dementia care literature.

To achieve the goal of producing pragmatic evidence, the challenges of recruiting participants for ADRD clinical trials must be addressed.[17] Dementia is a heterogeneous disorder with many causes and clinical presentations and is often underdiagnosed,[1,18] and due to the potential impact of ADRD on capacity, consenting poses ethical challenges.[19] Additionally, cultural barriers have been identified as added challenges to recruitment[19] and many caregivers are frequently overwhelmed[20] and unwilling to accept the additional burden of completing research protocols. Finally, caregiving responsibilities are often shared by several family members and friends, complicating the identification of a "primary" caregiver or the person legally responsible for decision-making for the PLWD.[21] These recruitment challenges are not recent developments in the field; rather, they have persisted due to the lack of engagement and empowerment of PLWD, family caregivers and implementation decisions.[22]

There are several nonpharmacologic interventions that effectively improve outcomes in PLWD and their families.[7–9] However, adoption of these interventions has been limited, and the care provided to PLWD and their families continues to be unsatisfactory.[8,23,24] Pragmatic trials are designed to provide evidence of effectiveness, not efficacy, offering a unique opportunity to accelerate translation of evidence-based interventions for PLWD and their families into clinical and social care delivery settings in order to address needs and improve outcomes.[8–11,25] Pragmatic trials leverage existing infrastructure (i.e., electronic health records, existing workflows, administrative datasets), reducing implementation time and costs.[9,11] Pragmatic trials also offer an additional benefit: they can help reduce health disparities by delivering interventions where underrepresented populations receive care.[24–26]

To date, pragmatic RCTs inclusive of a large, diverse population of PLWD/family caregiver dyads have not been conducted.[23,27] We recently completed recruitment for D-CARE, the first large sample pragmatic dementia care RCT in the United States (NCT03786471), comparing clinical outcomes and cost-effectiveness of two evidenced-based dementia care interventions. The primary goal of D-CARE was to compare a health system-based dementia care (HSDC) model (based on the Alzheimer's and Dementia Care model at UCLA),[28] to a community-based dementia care (CBDC) model (based on the Benjamin Rose Institute's Care Consultation),[5] versus usual care. We present here a summary of recruitment and enrollment strategies for diverse participants among the four clinical trial sites along with baseline characteristics of participating dyads.

2 | METHODS

2.1 | Identification of participants

The design of D-CARE has previously been described, including inclusion and exclusion criteria for PLWD and their family/friend caregivers,

primary outcomes, and components of the interventions.[27] Notably, D-CARE included community-dwelling persons with a diagnosis of ADRD who spoke English and/or Spanish and had a partnering healthcare provider such as a primary care clinician, geriatrician, or neurologist. Partnering healthcare providers were clinicians (MD/DO or NP/PA) who could refer eligible participants directly to the study and agreed to review and implement the care plans created with the D-CARE study for PLWD randomized to either the HSDC or CBDC arms. Persons with a diagnosis of ADRD enrolled in hospice or residing in a long-term care facility at the time of enrollment were not eligible. Participants could reside in assisted living facilities or continuing care retirement communities if they were not long-term nursing home residents.[27]

Four health systems in three states (North Carolina, Pennsylvania, and Texas) served as clinical trial sites (CTSs) described in Table 1. CTSs were diverse in the health system's structure (both academic health systems and integrated health systems), and the patient populations served. CTSs committed existing infrastructure to support the clinical and research requirements for study implementation, including a relationship with a community-based organization (CBO) to support the CBDC arm of the study.

The four CTSs engaged 180 clinics resulting in 536 partnering clinicians (see Table 1 for clinic and clinician distribution by site). Each of the four sites was given an initial enrollment target of 538 participant dyads. These targets, however, were later adjusted as the trial progressed based on factors such as the availability of participants, weekly recruitment rates, and the varying impact of COVID-19 on the health systems.

RESEARCH IN CONTEXT

1. **Systematic review**: Most evidence supporting dementia care models for persons living with dementia (PLWD), and their caregivers is based on nonpragmatically conducted studies, have limited diversity, modest sample sizes and do not include PLWD and family caregiver dyads.
2. **Interpretation**: The Dementia Care Study (D-CARE) demonstrated that enrolling PLWD/family caregiver dyads from a variety of communities and cultures into a pragmatic dementia care trial is feasible using recruitment strategies combining electronic health record review with personalized outreach shaped by local Patient and Stakeholder Committees. The COVID-19 pandemic required a greater reliance on telephone outreach but expanded opportunities for community diversity.
3. **Future directions**: Strategies used in D-CARE may inform other investigators who desire to recruit diverse PLWD and their caregivers in collaboration with healthcare systems for pragmatic trials.

2.2 | Core strategies for recruitment of PLWD and caregivers

CTSs introduced the D-CARE study across their respective health systems. D-CARE presentations to potential referring/partnering providers included an overview of the study design, description of the three study arms, randomization protocol, eligibility criteria, participant identification protocols, and mechanisms in which providers could make direct referrals to the study.

All four health systems identified eligible participants utilizing their electronic health records (EHRs), all of which were EPIC-based. Each site generated lists of participants with a diagnosis of ADRD using patient problem lists, past medical history codes, and International Classification of Diseases (ICD) version 9 or 10 billing diagnoses,[27] (ICD9 codes: 290.0, 290.1X, 290.2X, 290.3, 290.4X, 290.8, 290.9, 291.1, 291.2, 292.82, 294.0, 294.10, 294.11, 294.20, 331.0, 331.82, 331.11, and 331.19. ICD-10 codes starting with F01, F02, F03, G30, F04, F05, or F06). Physician referrals of eligible participants occurred by two methods: (1) a departmental level "blanket" approval for referral to the study, which does not necessitate individual PCP review of potentially eligible study participants and allows the study team to reach participants directly, or (2) referral by individual PCPs, who were given the option (but not required) to remove potentially eligible participants whom they felt should not be contacted or for whom they would not be willing to fill the role of the partnering physician. Common reasons for partnering providers to request not contacting a specific participant on the EPIC-generated list included recent patient death, current hospice use, lack of an unpaid caregiver, plans to move out of the area during the study intervention period, and residing in a long-term nursing home (all were study exclusion criteria). Partnering providers were also encouraged to make direct referrals to D-CARE. Self-referrals by family/friend caregivers also originated through several mechanisms, including public postings in collaborating clinics and community organizations, social media, and traditional media coverage. Table 2 summarizes the recruitment strategies used by CTSs. Study sites developed local study-branded materials, such as flyers, posters, pamphlets, and brochures that had both the study logo and the institution's logo. The two Texas sites translated study materials into Spanish with input from both the NPSC and LPSCs. All recruitment materials were approved by central and local institutional review boards (IRBs).

After referrals occurred, CTSs study staff performed an administrative review for exclusion criteria (such as deaths, living in nursing homes, hospice, dementia diagnosis not confirmed) before calling prospective participants on the telephone or approaching participants in clinics prior to the COVID-19 pandemic. A 7:7:1 randomization ratio was used to assign enrolled study participants to the three study arms. In other words, for every dyad randomized to receive usual care with referral to the Alzheimer's Association National help line, seven dyads were assigned to the health system-based dementia care (HSDC) arm and seven dyads were assigned to the community-based dementia care (CBDC) arm, a 93% chance of receiving an active intervention.

TABLE 1 Description of clinical trial sites.

Health system	Clinics engaged in the D-CARE Study (*N*)	Clinicians engaged with the D-CARE Study (*N*)	Geographical region	Ethnic/racial diversity of each site for ages 55+ [a]
Atrium Health Wake Forest Baptist (AHWFB) – Has five hospitals and more than 300 clinics serving 24 counties in North Carolina.	70	174	South—Suburban and Rural	14% Black/African Americans 3% Hispanic/Latinos
Baylor Scott and White health (BSWH)—Largest non-for-profit healthcare system in Texas. Has 51 hospitals and 158 clinics serving counties in Texas.	42	202	Southwest—Suburban	8% Black/African Americans 7% Hispanic/Latinos
Geisinger Medical Center (GMC)—Has 10 hospitals and 130 clinics serving 46 counties in Pennsylvania.	57	93	Mid-Atlantic—Rural	4% Black/African Americans 5% Hispanic/Latinos
The University of Texas Medical Branch Galveston (UTMB)—Has four hospitals and 90 clinics serving four different counties in Texas.	11	67	Southwest—Suburban	16% Black/African Americans 14% Hispanic/Latinos

[a]Totals are not 100% because of other ethnicities and Latinos can be of any race.

TABLE 2 Clinical trial site-specific recruitment strategies.

Site recruitment strategies	AHWFB	BSWH	GMC	UTMB
Total enrolled per site	837	626	235	478
EHR identification & PCP grant permission to contact, *N* (%) enrolled	616 (73.6)	525 (83.9)	233 (99.2)	429 (89.8)
Created patient registry		X		X
Departmental level approval of study			X	X
Matched with clinical appointment		X	X	
EHR referral button creation		X		
Partnering provider direct referral, *N* (%) enrolled	154 (18.4)	78 (12.5)	2 (0.8)	40 (8.4)
Participant self-referral, *N* (%) enrolled	63 (7.5)	20 (3.2)	0 (0.0)	9 (1.9)
News reports/Interviews/radio ads	X	X	X	
Social media				X
Community partner organization referrals, *N* (%) enrolled	4 (0.5)	3 (0.5)	0 (0.0)	0 (0.0)
Referrals from adult day programs	X		X	
Adapted materials to Spanish		X		X

Note: Partnering Providers are primary care provider (PCP) or specialists such as neurologists, geriatricians.
Abbreviations: AHWFB, Atrium Health Wake Forest Baptist; BSWH, Baylor Scott & White Health; EHR, electronic health record; GMC, Geisinger Medical Center; PCP, primary care provider; UTMB, University of Texas Medical Branch at Galveston.

These key design features were highlighted when the study was presented to potential partnering providers and eligible participants. At the screening visit, all potential PLWD's cognitive status was assessed with the Montreal Cognitive Assessment (MoCA) telephone version.[29,30] When administering the shortened (Dong) version of MoCA over the phone, 12 points were calculated using a 5-word recall, F-word fluency, and orientation.[31] If these initial points were < 8, the MoCA was stopped.[31] If the score was ≥ 8, then the full telephone MoCA out of 22 points was administered.[29,30] PLWD scoring $< 8/12$ or $\leq 16/22$ on the Dong and telephone versions of MoCA, respectively, were considered unable to consent and instead were asked for verbal assent to grant their permission to ask caregiver questions.[32] If the PLWD refused, the dyad was not enrolled in the study. While measuring cognition with a screening test is not a substitute for a capacity assessment,[32] a cutoff score of < 8 on the Dong MoCA or $\leq 16/22$ on telephone MoCA was selected to determine that a participant did not have capacity with high specificity. This decision intended to maximize the autonomy of the person living with dementia to consent for this minimal-risk study when possible.

2.3 | Role of national and local patient and stakeholder committees in recruitment

D-CARE recruitment strategies were strengthened by the contributions of one National and four Local Patient Stakeholder Committees (NPSC & LPSCs). These committees consisted of PLWD, family members with current and/or past caregiving roles, community agency practitioners and advocates, faith leaders, and interdisciplinary healthcare providers. Each LPSC included members of the local community with an explicit goal of representing the local culture and diversity of their community. The LPSCs initially met in person, then transitioned to virtual meetings during COVID-19. The LPSCs discussed all aspects of the study with a particular focus on the primary areas of (1) readability and acceptability of participant- and caregiver-facing materials, (2) recruitment and retention efforts including inclusion of diverse participants and identification of community resources, and (3) offering feedback on study-related challenges.

The LPSCs and NPSC were critical in the transition of D-CARE recruitment and enrollment protocols and the health system-based dementia care intervention from in-person to virtual interactions at the outset of the COVID-19 pandemic. For example, LPSC members provided feedback to improve clarity of the recruitment scripts, verbal consent scripts, and study questionnaires included in the packet of D-CARE materials mailed to each dyad who agreed to participate. LPSC representatives from all four CTSs also met with the NPSC team so that site-specific feedback was shared across the four trial sites, resulting in an iterative approach to the recruitment and enrollment strategies.

Embracing the pragmatic nature of this RCT, all recruitment and direct communications from the CTSs study teams described the study in terms of "memory loss" or "memory problems" and avoided the word "dementia" due to the stigma associated with the diagnosis and possible lack of awareness of patients and families to their dementia diagnosis despite electronic medical record (EMR) documentation of ADRD. Additionally, the study avoided the term "burden" when interviewing caregivers as this term may be inappropriate given personal and/or cultural expectations held by the caregiver. Given the changing family structure in the United States, the number of recruitment calls was increased to accommodate the involvement of multiple family/friend members in the consenting and enrollment process. Lastly, an essential cultural adaptation required that all recruitment and screening materials be available in Spanish with the availability of Spanish-speaking team members at the Texas CTSs.

2.4 | Adapting to the COVID-19 pandemic

Recruitment for D-CARE started in-person in June 2019, with study coordinators obtaining written consent in clinics, family homes, or assisted living facilities. Due to the COVID-19 pandemic, in-person enrollment was halted in March 2020 (week 39 of enrollment). After obtaining IRB approval, telephone-based recruitment, and enrollment of the caregiver and PLWD consent for PLWDs scoring ≥17/22 on the MoCA telephone version[31] resumed in May 2020 (week 44) and remained in effect for the rest of the 136-week recruitment period. The modified recruitment protocol specified a minimum of five telephone call attempts to the home of the EHR-identified patient with dementia, with at least one call after business hours and at least one call on weekends, with the goal of identifying and speaking to a family/friend caregiver. In some cases, the family/friend caregiver was identified in the EHR of the patient with dementia, in which case the introductory call about D-CARE was made directly to the family caregiver. There was no prespecified maximum number of calls to attempts. The effectiveness of these recruitment strategies was enhanced over the course of D-CARE via monthly virtual meetings in which staff from each CTS shared experiences in using the EHR to identify PLWD, locating family/friend caregiver information within the EHR, engaging clinicians of PLWD, and techniques to maximize the utility of telephone-based communications with PLWD and their family caregivers.

2.5 | Site-specific recruitment strategies

To enhance enrollment in D-CARE, all sites were encouraged to develop innovative recruitment strategies to meet local preferences and challenges. Each of the four sites identified a pool of eligible participants that included underrepresented populations such as Black/African American, Hispanic/Latino, and PLWD and caregivers in rural areas. In addition to the strategies listed in Table 2, we highlight specific strategies for each site below.

Atrium Health Wake Forest Baptist (AHWFB):

1. The study team refreshed their EPIC-generated list of PLWD monthly.
2. The study team obtained individual blanket referrals from PCPs, geriatricians, and neurologists through personalized EPIC messages from the site PI or co-Investigator who were geriatricians and/or memory specialists within the health system. Each message briefly introduced D-CARE (two to three sentences) and assured the provider that D-CARE would not add any work to their day and provided a care option previously unavailable to PLWD and their caregivers. The PI's or Co-I's personal cell phone number was also given to the partnering providers for questions about D-CARE.
3. To foster increased personal connection and ease of contact by participants, AHWFB research staff used study-designated cell phones with local area codes. Recruitment staff emphasized the partnering provider's approval of the study within the first 30 s of the phone call.
4. The study team prioritized recruitment from established adult day centers in the community.
5. One LPSC member, a local TV meteorologist who cared for her mother with dementia, sponsored a recruitment telethon for D-CARE (https://vimeo.com/799873917/5bbd1b3b3e).

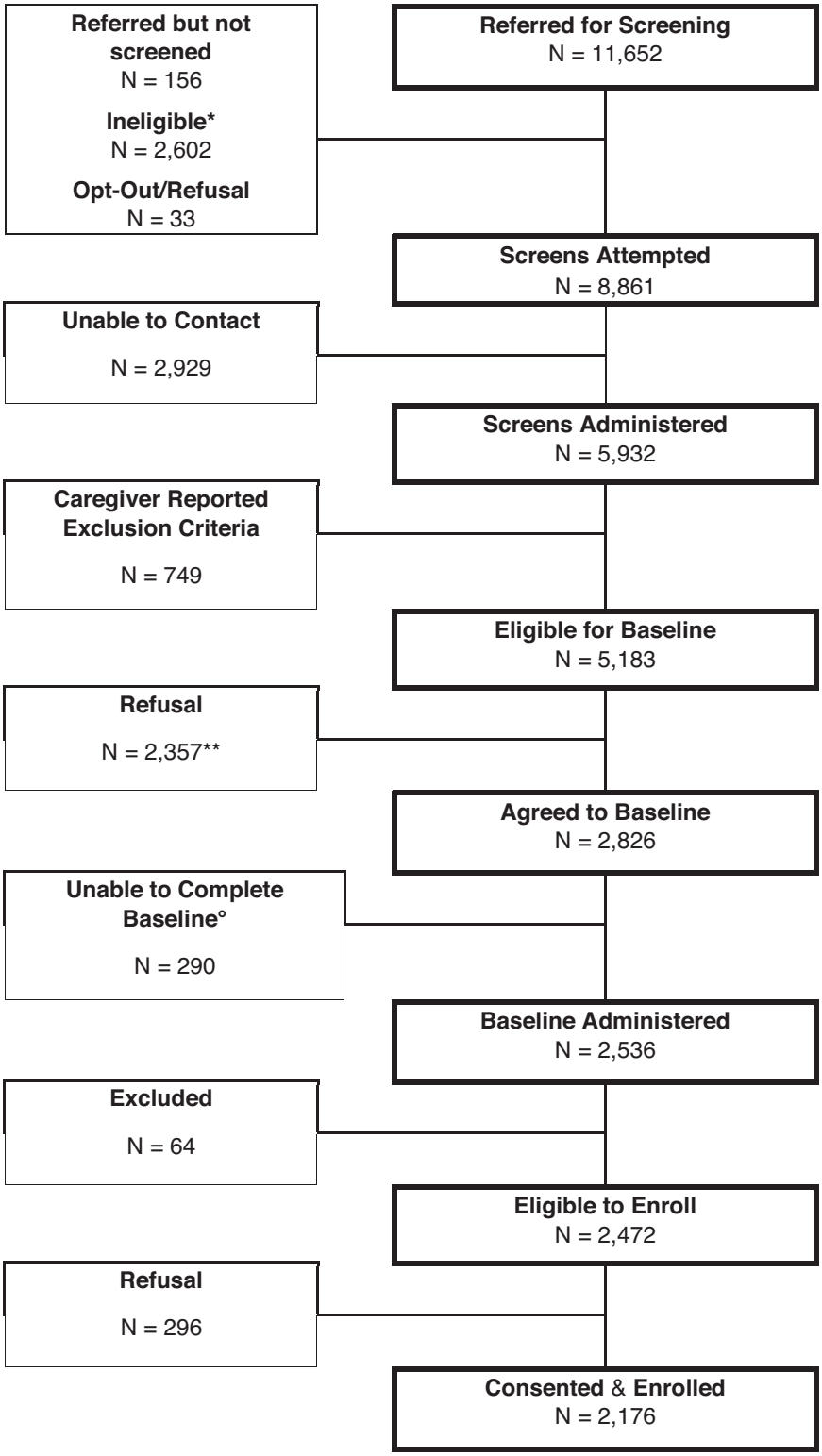

FIGURE 1 **Overall screening and enrollment flowchart legend**. *Ineligible mainly because of exclusions not captured on EPIC such as deaths, nursing home residence; **refusal mainly by caregivers; ° unable to complete baseline mainly because of inability to contact by telephone despite initial agreement to participate. For more details see Table 3.

Baylor Scott & White Health (BSWH):

1. D-CARE was specifically endorsed by the institution's chief medical officer and the chairs of the Departments of Internal Medicine, Family Medicine, and Neurology.
2. Vice Presidents of Operations at BSWH facilitated meetings with regional leaders and clinic Medical Directors to introduce the study.
3. Information technology created a referral button in EPIC to facilitate providers' direct referral to D-CARE.

4. The study team refreshed their EPIC-generated list of PLWD periodically.
5. Study team members (30%) were bilingual in English and Spanish.
6. Study staff completed screening calls to potential participants immediately prior to an upcoming clinic visit with their PCPs.
7. The study team sent EPIC D-CARE reminders to clinicians about upcoming scheduled clinic visits with PLWD to remind providers of the study and encourage discussions in the clinic.

Geisinger Medical Center (GMC):

1. The study team obtained health system level agreement (chairs of Internal Medicine, Family Medicine, and Neurology) to recruit participants from all Geisinger providers in those departments.
2. The study team built a dynamic, logic-based, daily refreshable EPIC list that prioritized contacting participants with respect to geographic location and recent and/or upcoming clinic visits with Geisinger neurology or PCPs. Screening calls were attempted to potential participants either prior to or following scheduled appointments.
3. The study team met with regional case managers and in-home care teams to introduce the study and provided direct individual referrals.
4. The study team focused recruitment on "Geisinger65 Forward," primary care clinics dedicated to outpatient care for older adults 65+, and Geisinger's Memory and Cognition Program which specializes in dementia care.
5. The study team assigned one staff member to communicate with each dyad throughout the duration of the study, from recruitment to close-out, to foster a personal connection and build rapport, facilitate ease of contact, and ensure consistency in all study communication.
6. Study staff called participants using the Cisco Jabber app so that each call displayed the assigned study team member's phone number on the participant's caller ID.

The University of Texas Medical Branch at Galveston (UTMB):

1. The study team created a dementia registry in EPIC that automatically refreshed every night and extracted > 3000 patients on any given day. The registry was queried weekly, filtering the results by upcoming clinic appointments to create a worklist of PLWD scheduled for a clinic visit. The first contact was attempted at the clinic visit (pre-COVID-19) or by telephone after the visit.
2. Study team received study referral permission by departmental leadership (e.g., Internal Medicine chair), which allowed research staff to contact all potentially eligible participants of that department's providers without explicit consent from individual primary care providers (PCPs).
3. The study team led the translation of all screening, recruitment, and intervention materials into Spanish.
4. Half of the study team members were Hispanic and bilingual in English and Spanish.
5. Recruiters were given cell phones linked to local area codes and the Doximity app for calls that displayed the study team's office phone number on caller ID.
6. The study team intentionally fostered discussions of D-CARE with multiple family members of the PLWD (more than the single caregiver) before obtaining consent to respect the Hispanic cultural family norms of decision-making.

3 | RESULTS

D-CARE enrollment was completed in January 2022. Over the 30-month recruitment period, 2176 participant dyads were enrolled, exceeding the original target of 2150. There were 837 (38.5%) dyads recruited by AHWFB, 626 (28.8%) by BSWH, 478 (22.0%) by UTMB, and 235 (10.8%) by GMC. The recruitment CONSORT diagram is shown in Figure 1 with 11,652 patients referred for screening from EPIC in addition to direct referrals. A total of 2602 (22.3%) referred patients were not screened due to ineligibility. Major reasons included EHR dementia diagnoses that were not confirmed (n = 700, 7.4%), patients living in long-term nursing homes (n = 604, 6.4%), and patients having died (n = 582, 6.1%). Site/health system-specific reasons for ineligibility after initial EPIC screening are shown in Table 3. The most common and successful recruitment strategy at all sites among those enrolled participants was EHR identification based on PCP and telephone recruitment after PCPs granted permission to contact (Table 2). Direct referrals from partnering providers were the next most common strategy for enrollment, although that varied significantly at sites.

The study teams at the four sites attempted screens by phone on 8861 (76.0%) potential participants, of which 25.1% (n = 2929) could not be contacted. Screens were administered to 5932 (50.9%) potential participants, of whom 749 (6.4%) were excluded, primarily due to the caregiver reporting that the patient had become a long-term care resident (n = 298, 4.3%); had unconfirmed dementia diagnoses (n = 137, 1.4%); or current hospice enrollment (n = 85, 0.9%). Of the 11,652 patients referred for screening, 5183 (44.5%) were eligible participants, and 2357 (20.2%) declined a baseline interview. Among the 2826 (24.3%) remaining dyads, 290 (2.5%) were unable to complete the baseline assessment for a variety of reasons. The 2176 enrolled dyads represented 18.7% of those referred for screening, 24.6% of those in whom screening was attempted, and 42.0% of those eligible for a baseline interview.

The most common reasons for exclusion between screening and baseline interviews were failure to complete a screening visit (N = 2929, 25.1%) despite more than five contact attempts, followed by the PLWD being reported as deceased and refusing the baseline interview (N = 2357, 20.2%) (Table 3).

3.1 | Characteristics of enrolled PLWD

At baseline (Table 4), PLWD had a mean age of 80.6 years (SD 8.5), 58.4% were women, 8.8% were Hispanic/Latino, and 11.9%

TABLE 3 Primary reason for exclusion by healthcare system.

Reasons not enrolled	Overall *N* (%)	AHWFB *N* (%)	BSWH *N* (%)	GMC *N* (%)	UTMB *N* (%)
Not screened due to recruitment ended	156 (1.6)	0 (0.0)	21 (0.5)	135 (7.2)	0 (0.0)
Not screened subtotal	**156 (1.6)**	**0 (0.0)**	**21 (0.5)**	**135 (7.2)**	**0 (0.0)**
Dementia diagnoses not confirmed	700 (7.4)	25 (1.5)	217 (5.5)	0 (0.0)	458 (23.1)
Living in nursing home	604 (6.4)	45 (2.7)	403 (10.2)	35 (1.9)	121 (6.1)
Died	582 (6.1)	67 (4.0)	281 (7.1)	25 (1.3)	209 (10.5)
Not current patient or location issue	366 (3.9)	54 (3.2)	17 (0.4)	0 (0.0)	295 (14.9)
Living in hospice	162 (1.7)	18 (1.1)	72 (1.8)	6 (0.3)	66 (3.3)
Administrative exclusion	97 (1.0)	30 (1.8)	24 (0.6)	2 (0.1)	41 (2.1)
Speaks neither English nor Spanish	41 (0.4)	14 (0.8)	25 (0.6)	0 (0.0)	2 (0.1)
No caregiver	28 (0.3)	14 (0.8)	10 (0.3)	0 (0.0)	4 (0.2)
PCP request	14 (0.1)	14 (0.8)	0 (0.0)	0 (0.0)	0 (0.0)
Both patient and caregiver have diagnosis	6 (0.1)	4 (0.2)	2 (0.1)	0 (0.0)	0 (0.0)
Letter returned as undeliverable	2 (0.0)	0 (0.0)	2 (0.1)	0 (0.0)	0 (0.0)
Ineligible for screening subtotal	**2602 (27.5)**	**285 (17.0)**	**1053 (26.7)**	**68 (3.6)**	**1196 (60.3)**
Mailed or called in to opt-out	23 (0.2)	4 (0.2)	13 (0.3)	5 (0.3)	1 (0.1)
Opted out by other means	10 (0.1)	0 (0.0)	5 (0.1)	5 (0.3)	0 (0.0)
Opted out/Refusal subtotal	**33 (0.3)**	**4 (0.2)**	**18 (0.5)**	**10 (0.5)**	**1 (0.1)**
Unable to contact after five attempts	1593 (16.8)	296 (17.7)	335 (8.5)	877 (46.7)	85 (4.3)
Contact made but no screening	667 (7.0)	64 (3.8)	410 (10.4)	161 (8.6)	32 (1.6)
Patient died	474 (5.0)	67 (4.0)	346 (8.8)	8 (0.4)	53 (2.7)
Unable to contact due to wrong contact information	109 (1.2)	27 (1.6)	21 (0.5)	59 (3.1)	2 (0.1)
Screening Interview not completed due to other reasons	86 (0.9)	7 (0.4)	18 (0.5)	16 (0.9)	45 (2.3)
Unable to contact subtotal	**2929 (30.9)**	**461 (27.5)**	**1130 (28.7)**	**1121 (59.7)**	**217 (10.9)**
Living in nursing home	298 (3.1)	103 (6.1)	126 (3.2)	19 (1.0)	50 (2.5)
Dementia diagnoses not confirmed	137 (1.4)	25 (1.5)	30 (0.8)	16 (0.9)	66 (3.3)
Living in hospice	85 (0.9)	32 (1.9)	26 (0.7)	0 (0.0)	27 (1.4)
Other eligibility reasons for screen fail	229 (4.3)	49 (3.0)	89 (2.2)	13 (0.7)	78 (3.9)
Caregiver reported exclusion criteria subtotal	**749 (7.9)**	**209 (12.5)**	**271 (6.9)**	**48 (2.6)**	**221 (11.1)**
Refused by PLWD	243 (2.6)	32 (1.9)	132 (3.4)	53 (2.8)	26 (1.3)
Refused by caregiver or others	2093 (22.1)	543 (32.4)	1024 (26.0)	353 (18.8)	173 (8.7)
Mailed or called in opt-out after screening	21 (0.2)	6 (0.4)	12 (0.3)	1 (0.1)	2 (0.1)
Refused baseline subtotal	**2357 (24.9)**	**581 (34.6)**	**1168 (29.7)**	**407 (21.7)**	**201 (10.1)**
Unable to contact after five attempts	93 (1.0)	17 (1.0)	45 (1.1)	0 (0.0)	31 (1.6)
Baseline not complete due to recruitment ended	85 (0.9)	4 (0.2)	5 (0.1)	71 (3.8)	5 (0.3)
PLWD died between screening and baseline visit	37 (0.4)	2 (0.1)	18 (0.5)	0 (0.0)	17 (0.9)
PLWD indicated opt-out	34 (0.4)	15 (0.9)	15 (0.4)	0 (0.0)	4 (0.2)
Baseline not completed due to other reasons	41 (0.4)	16 (1.0)	11 (0.3)	0 (0.0)	14 (0.6)
Unable to complete baseline subtotal	**290 (3.1)**	**54 (3.2)**	**94 (2.4)**	**71 (3.8)**	**71 (3.6)**
Time commitment too great	19 (0.2)	1 (0.1)	0 (0.0)	0 (0.0)	18 (0.9)
Patient living in hospice at time of baseline visit	17 (0.2)	5 (0.3)	6 (0.2)	0 (0.0)	6 (0.3)
Patient living in nursing home at time of baseline visit	16 (0.2)	5 (0.3)	5 (0.1)	0 (0.0)	6 (0.3)
Other reasons for eligibility exclusion at time of baseline visit	12 (0.1)	2 (0.1)	3 (0.1)	0 (0.0)	7 (0.4)

(Continues)

TABLE 3 (Continued)

Reasons not enrolled	Overall *N* (%)	AHWFB *N* (%)	BSWH *N* (%)	GMC *N* (%)	UTMB *N* (%)
Excluded at baseline visit subtotal	**64 (0.7)**	**13 (0.8)**	**14 (0.4)**	**0 (0.0)**	**37 (1.9)**
Refused to enroll	266 (2.8)	64 (3.8)	162 (4.1)	12 (0.6)	28 (1.4)
Caregiver refused consent	18 (0.2)	6 (0.4)	1 (0.0)	2 (0.1)	9 (0.5)
Patient with dementia refused assent	12 (0.1)	0 (0.0)	5 (0.1)	3 (0.2)	4 (0.2)
Refusal at baseline visit subtotal	**296 (3.1)**	**70 (4.2)**	**168 (4.3)**	**17 (0.9)**	**41 (2.1)**
Total from screening to baseline exclusions	**9476 (100.0)**	**1677 (100.0)**	**3937 (100.0)**	**1877 (100.0)**	**1985 (100.0)**

Abbreviations: AFWHB, Atrium Health Wake Forest Baptist; BSWH, Baylor Scott & White Health; GMC, Geisinger Medical Center; PCP, primary care provider or other partnering providers; PLWD, persons living with dementia; UTMB, University of Texas Medical Branch at Galveston.

were Black/African American (20.6% total participants from underrepresented groups). Over half (53.5%) were married, 25.3% were high school graduates only, 55.5% had some college education or higher, and 17.7% of PLWD reported living alone. The mean shortened MoCA (Dong version)[31] was 3.8 out of a total of 12 (SD 2.8), with higher scores indicating less impairment. AHWFB had the lowest mean MoCA scores among all four sites (3.5, SD 2.9). Overall, 251 participants (11.5%) were unable to complete the MoCA due to hearing impairment, and 274 participants (12.6%) refused to complete it. More than half of PLWD had no alterations in the majority of activities of daily living such as bathing and dressing, as measured on the Katz Index of Independence,[33] mean 4.4 of 6 (SD 1.8) with higher scores indicating greater independence.

The majority of Hispanic/Latino PLWD were enrolled at UTMB ($n = 104$) and BSWH ($n = 78$). Among 191 PLWD who self-identified as Hispanic/Latino, 40 spoke Spanish for the study interview (22 at UTMB, 17 at BSWH, and 1 at AHWFB). Almost half of all Black/African American PLWD were enrolled at AHWFB ($n = 111$), followed by UTMB ($n = 83$) and BSWH ($n = 61$).

3.2 | Characteristics of enrolled caregivers

Caregivers at baseline were on average 65.2 years old (SD 12.3) (Table 5) with most of the caregivers being either a spouse/partner (spouse: mean age 76.5 [SD 8.2]; partner: mean age 72.8 [SD 11.1]) or an adult child (son/son-in-law or daughter/daughter-in-law) (son/daughter: mean age 59.3 [SD 8.5]; son-in-law/daughter-in-law: mean age 57.7 [SD 9.3]). Seventy-six percent of caregivers were women, 9.4% were Hispanic or Latino, and > 99% spoke English. Black/African American caregivers represented 11.6% of the sample. Almost all caregivers were spouses (44.7%) or children/children-in-law (49.0%). At baseline, more than a quarter (27%) of caregivers did not live with the PLWD. A total of 16.4% of caregivers had a high school or General Educational Development (GED) level of education, and 80.4% had some college education or higher.

3.3 | Impact of COVID-19 pandemic on recruitment and recruitment strategies

When recruitment for D-CARE was halted due to COVID-19 on March 14, 2020, 412 dyads had been recruited. As shown in Figure S1, the trial suspended all in-person visits with a plateau in enrollment between weeks 39 and 44. More than 80% of the D-CARE participants were enrolled after the conversion of in-person baseline visits to virtual visits only. Enrollment over the 30-month recruitment period was initially slow but surpassed the original goal in the final months of recruitment. Figure S2 shows the enrollment trajectories for the four sites. Enrollment rates were quite different between clinical sites, especially after the COVID-19-related pause (starting week 39); however, each site was consistent in its ability to recruit throughout the recruitment phase.

4 | DISCUSSION

D-CARE demonstrated the feasibility of recruiting nearly 2200 dyads of PLWD and their caregivers in a pragmatic trial across multiple health systems. The pragmatic design of this trial was conducive to adapting recruitment strategies due to the COVID-19 pandemic. The 7:7:1 randomization allocation resulted in each participating dyad having an extremely high (93%) chance of being assigned to one of the intervention arms, which could have contributed to the participant's willingness to enroll as almost all would be receiving more care than usual. Moreover, the randomization allocation increased health system and provider receptivity to the study. D-CARE also demonstrated that it is feasible to recruit a more diverse cohort of PLWD and their caregiver dyads compared to prior trials, even in the context of the COVID-19 pandemic that halted clinical research globally. The most successful and most used recruitment method for all four sites was the core strategy of EMR identification and prescreening plus telephonic recruitment with specific reference to partnering healthcare provider by name, conducted by study staff who were either well known within their health systems or communities, or had personal experiences with caregiving for persons living with dementia. The variability in direct

TABLE 4 Demographic characteristics of enrolled participants living with dementia at baseline.

All enrolled(*N* = 2176)		AHWFB*N* = 837	BSWH*N* = 626	GMC*N* = 235	UTMB*N* = 478
Characteristics	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Age at enrollment, Mean [SD]	80.6 [8.5]	80.4 [8.5]	81.0 [8.4]	78.1 [8.6]	81.8 [8.2]
Gender					
Male	905 (41.6)	361 (43.1)	258 (41.2)	110 (46.8)	176 (36.8)
Female	1271 (58.4)	476 (56.9)	368 (58.8)	125 (53.2)	302 (63.2)
Ethnic Origin					
Hispanic or Latino	191 (8.8)	9 (1.1)	78 (12.5)	0 (0%)	104 (21.8)
Non-Hispanic/Latino	1983 (91.1)	828 (98.9)	547 (87.4)	234 (99.6)	374 (78.2)
Missing information	2 (0.1)	0 (0.0)	1 (0.2)	1 (0.4)	0 (0.0)
Race					
American Indian/Alaska Native	9 (0.4)	3 (0.4)	1 (0.2)	0 (0)	5 (1.0)
Asian	13 (0.6)	5 (0.6)	6 (1.0)	0 (0)	2 (0.4)
Black/African American	259 (11.9)	111 (13.3)	61 (9.7)	4 (1.7)	83 (17.4)
White	1839 (84.5)	707 (84.5)	524 (83.7)	229 (97.4)	379 (79.3)
More than one race	13 (0.6)	7 (0.8)	3 (0.5)	0 (0)	3 (0.6)
Other	41 (1.9)	4 (0.5)	31 (5)	1 (0.4)	5 (1.0)
Missing information	2 (0.1)	0 (0)	0 (0)	1 (0.4)	1 (0.2)
Black/African American and/or Hispanic or Latino					
Yes	448 (20.6)	120 (14.3)	139 (22.2)	4 (1.7)	185 (38.7)
No	1726 (79.3)	717 (85.7)	486 (77.6)	230 (97.9)	293 (61.3)
Missing information	2 (0.1)	0 (0)	1 (0.2)	1 (0.4)	0 (0)
Marital status					
Married	1165 (53.5)	458 (54.7)	339 (54.2)	147 (62.6)	221 (46.2)
Partner	6 (0.3)	3 (0.4)	1 (0.2)	1 (0.4)	1 (0.2)
Widowed	719 (33.0)	268 (32.0)	199 (31.8)	65 (27.7)	187 (39.1)
Divorced	208 (9.6)	77 (9.2)	66 (10.5)	15 (6.4)	50 (10.5)
Single	65 (3.0)	25 (3.0)	18 (2.9)	3 (1.3)	19 (4.0)
Other	13 (0.6)	6 (0.7)	3 (0.5)	4 (1.7)	0 (0)
Education					
No formal education	11 (0.5)	1 (0.1)	6 (1.0)	0 (0)	4 (0.8)
Some elementary school	94 (4.3)	27 (3.2)	29 (4.6)	2 (0.9)	36 (7.5)
Completed grade 8	64 (2.9)	28 (3.3)	19 (3.0)	4 (1.7)	13 (2.7)
Some high school	170 (7.8)	67 (8.0)	37 (5.9)	19 (8.1)	47 (9.8)
High school graduate	551 (25.3)	214 (25.6)	133 (21.2)	86 (36.6)	118 (24.7)
General educational development (GED)	76 (3.5)	28 (3.3)	22 (3.5)	7 (3.0)	19 (4.0)
Some college or post-secondary education	511 (23.5)	186 (22.2)	156 (24.9)	60 (25.5)	109 (22.8)
Graduated from college	395 (18.2)	157 (18.8)	131 (20.0)	22 (9.4)	85 (17.8)
Graduate or professional college degree	300 (13.8)	129 (15.4)	91 (14.5)	33 (14)	47 (9.8)
Missing information	4 (0.2)	0	2 (0.3)	2 (0.9)	0 (0)
Living alone					
Yes	386 (17.7)	162 (19.4)	111 (17.7)	40 (17.0)	73 (15.3)
No	1790 (82.3)	675 (80.7)	515 (82.3)	195 (83)	405 (84.7)
Assisted living	113 (5.2)	47 (5.6)	39 (6.2)	2 (0.9)	25 (5.2)

(Continues)

TABLE 4 (Continued)

All enrolled(*N* = 2176)		AHWFB*N* = 837	BSWH*N* = 626	GMC*N* = 235	UTMB*N* = 478
Characteristics	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Montreal Cognitive Assessment[a]					
N (%)	1599 (73.5)	461 (55.1)	469 (74.9)	210 (89.4)	459 (96.0)
Mean [SD]	3.8 [2.8]	3.5 [2.9]	3.8 [2.7]	4.0 [2.9]	3.9 [2.9]
Median	3	3	3	4	3
Missing: hearing impairment *N* (%)	251 (11.5)	174 (20.8)	58 (9.3)	11 (4.7)	8 (1.7)
Missing: participant refusal *N* (%)	274 (12.6)	183 (21.9)	72 (11.5)	14 (6.0)	5 (1.0)
Missing: clinical decision *N* (%)	28 (1.3)	8 (1.0)	19 (3.0)	0 (0)	1 (0.2)
Missing: partial data *N* (%)	24 (1.1)	11 (1,3)	8 (1.3)	0 (0)	5 (1.0)
Katz Index of Independence[b]					
N (%)	2167 (99.6)	835 (99.8)	620 (99.0)	235 (100)	477 (99.8)
Mean [SD]	4.4 [1.8]	4.5 [1.8]	4.4 [1.8]	4.7 [1.7]	4.2 [1.9]
Median	5	5	5	5	5
Missing: *N* (%)	9 (0.4)	2 (0.2)	6 (1.0)	0 (0)	1 (0.2)

Abbreviations: AFWHB, Atrium Health Wake Forest Baptist; BSWH, Baylor Scott & White Health; GMC, Geisinger Medical Center; UTMB, University of Texas Medical Branch at Galveston.

[a]MoCA Dong version, 0–12, higher scores indicate less impairment.

[b]Katz Index of Independence: 0–6, higher scores indicate greater independence.

referrals at four sites was likely related to CTSs access to PCPs. That is, some sites received department-level blanket permission from central leadership to contact participants versus the need for a CTS to individually approach PCPs and clinics (AHWFB and BSWH) after identifying potential participants in EPIC. The COVID-19 pandemic had both negative and positive effects on D-CARE recruitment. As sites could not continue with in-person recruitment efforts, the COVID-19 pandemic resulted in a temporary halt to recruitment and an extension of the timeline necessary to meet original recruitment target goals. However, telephone-based recruitment and the availability of virtual visits for the HSDC intervention arm expanded the opportunity for participation from more rural communities and may have helped recruitment by increasing convenience, improving efficiency, and reducing travel time to in-person study visits in clinics or in participants' homes. Due to the pandemic-related public health emergency, Medicare allowed the health systems to bill for virtual telehealth visits and audio-only visits, allowing for expanded recruitment into more remote geographic areas. It is also possible that transitioning the delivery of both intervention arms to phone or telehealth-based (93% of randomized participants) was especially helpful to caregivers who were isolated at home and available to answer recruitment telephone calls, especially since most community resources for dementia care were limited due to social isolation.

Enrollment rates for D-CARE are similar to those reported in a systematic review where 43% of eligible persons with AD agreed to participate in an intervention study,[34] and higher than a recent clinical trial testing the effectiveness of a collaborative dementia care model in improving outcomes among PLWD, their caregivers and payers beyond usual care (30.2%).[35] A notable achievement of D-CARE is enrollment of the largest nonpharmacologic dementia care clinical trial of 2176 dyads (previous clinical trials had 100–780 participants)[6,35-39] with more than 20% who self-identified as either Black/African American or Hispanic/Latino. This resulted from intentionally choosing health systems with large Black/African American (AHWFB) and Hispanic populations (BSWH and UTMB). This strategy resulted in more diverse participants and a cohort better aligned with the population described by the Alzheimer's Disease Research Centers across the nation. Texas-based CTSs (BSWH and UTMB) and associated LPSCs translated all patient-facing materials into Spanish and ensured that they were culturally appropriate. The two Texas CTSs also employed bilingual research personnel, who were known within their local Hispanic communities, to support D-CARE recruitment and enrollment activities. This proved valuable to culturally appropriate recruitment strategies, which extended well beyond translating materials into Spanish.[34] The pandemic and the pragmatic design of D-CARE helped the study address a major need nationally for research on innovative care models that can reach a diversity of communities.

The lessons learned from D-CARE can inform the design and implementation of future pragmatic randomized trials and provide guidance for the successful inclusion of diverse participants. The most successful recruitment strategy was direct telephone calls over multiple days and at various times of the day/week to potential participants identified in the EHR linked to a partnering clinician embedded within trusted health systems. Community events, direct mailing, clinic-based sign postage, and mass media enhanced community awareness but contributed to a lesser extent to successful recruitment. The practicality of conducting study-based interactions via telephone and telemedicine platforms also reduced the burden of participation (e.g., travel time by

TABLE 5 Demographic characteristics of enrolled caregivers at baseline.

All enrolled *N* = 2176		AHWFB *N* = 837	BSWHN = 626	GMC *N* = 235	UTMB *N* = 478
Characteristics	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Age at enrollment					
Overall mean [SD]	65.2 [12.3]	65.1 [11.9]	65.7 [13.3]	65.8 [11.7]	64.6 [11.9]
Gender					
Male	526 (24.2)	204 (24.4)	151 (24.1)	65 (27.7)	106 (22.2)
Female	1650 (75.8)	633 (75.6)	475 (75.9)	170 (72.3)	372 (77.8)
Ethnic Origin					
Hispanic or Latino	205 (9.4)	13 (1.6)	82 (13.1)	3 (1.3)	107 (22.4)
Non-Hispanic/Latino	1969 (90.5)	823 (98.3)	543 (86.7)	232 (98.7)	371 (77.6)
Missing information	2 (0.1)	1 (0.1)	1 (0.2)	0 (0)	0 (0)
Race					
American Indian/Alaska Native	8 (0.4)	3 (0.4)	3 (0.5)	0 (0)	2 (0.4)
Asian	11 (0.5)	4 (0.5)	4 (0.6)	0 (0)	3 (0.6)
Black/African American	252 (11.6)	111 (13.3)	56 (8.9)	4 (1.7)	81 (16.9)
White	1846 (84.8)	707 (84.5)	524 (83.7)	230 (97.9)	385 (80.5)
More than one race	23 (1.1)	5 (0.6)	14 (2.2)	0 (0)	4 (0.8)
Other	34 (1.6)	6 (0.7)	25 (4.0)	1 (0.4)	2 (0.4)
Missing information	2 (0.1)	1 (0.1)	0 (0)	0 (0)	1 (0.2)
Black/African American and/or Hispanic or Latino					
Yes	452 (20.8)	123 (14.7)	137 (21.9)	7 (3.0)	185 (38.7)
No	1722 (79.1)	713 (85.2)	488 (78.0)	228 (97.0)	293 (61.3)
Missing information	2 (0.1)	1 (0.1)	1 (0.2)	0 (0)	0 (0)
Marital status					
Married	1678 (77.1)	655 (78.3)	502 (80.2)	194 (82.6)	327 (68.4)
Partner	19 (0.9)	9 (1.1)	4 (0.6)	1 (0.4)	5 (1.0)
Widowed	53 (2.4)	19 (2.3)	19 (3.0)	2 (0.9)	13 (2.7)
Divorced	208 (9.6)	78 (9.3)	43 (6.9)	19 (8.1)	68 (14.2)
Single	198 (9.1)	69 (8.2)	53 (8.5)	16 (6.8)	60 (12.6)
Other	20 (0.9)	7 (0.8)	5 (0.8)	3 (1.3)	5 (1.0)
Education					
No formal education	1 (0.0)	1 (0.1)	0 (0)	0 (0)	0 (0)
Some elementary school	7 (0.3)	1 (0.1)	2 (0.3)	0 (0)	4 (0.8)
Completed grade 8	6 (0.3)	2 (0.2)	2 (0.3)	1 (0.4)	1 (0.2)
Some high school	54 (2.5)	20 (2.4)	12 (1.9)	3 (1.3)	19 (4.0)
High school graduate	296 (13.6)	100 (11.9)	63 (10.1)	61 (26.0)	72 (15.1)
General educational development	62 (2.8)	19 (2.3)	19 (3.0)	3 (1.3)	21 (4.4)
Some college or post-secondary education	647 (29.7)	248 (29.6)	193 (30.8)	61 (26.0)	145 (30.3)
Graduated from college	675 (31.0)	269 (32.1)	209 (33.4)	63 (26.8)	134 (28.0)
Graduate or professional college degree	428 (19.7)	177 (21.1)	126 (20.1)	43 (18.3)	82 (17.2)
Relationship to patient					
Spouse	972 (44.7)	368 (44.0)	286 (45.7)	136 (57.9)	182 (38.1)
Partner	11 (0.5)	4 (0.5)	2 (0.3)	1 (0.4)	4 (0.8)
Son or daughter	1011 (46.5)	394 (47.1)	283 (45.2)	86 (36.6)	248 (51.9)
Son/daughter-in-law	54 (2.5)	18 (2.2)	20 (3.2)	3 (1.3)	13 (2.7)

(Continues)

TABLE 5 (Continued)

All enrolled*N* = 2176		AHWFB*N* = 837	BSWH*N* = 626	GMC*N* = 235	UTMB*N* = 478
Characteristics	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**	***N* (%)**
Niece or nephew	17 (0.8)	11 (1.3)	2 (0.3)	1 (0.4)	3 (0.6)
Grandchild	24 (1.1)	7 (0.8)	10 (1.6)	1 (0.4)	6 (1.3)
Brother or sister	38 (1.7)	16 (1.9)	12 (1.9)	1 (0.4)	9 (1.9)
Friend or neighbor	24 (1.1)	12 (1.4)	5 (0.8)	1 (0.4)	6 (1.3)
Other	25 (1.1)	7 (0.8)	6 (1.0)	5 (2.1)	7 (1.5)
Living with patient					
Yes	1588 (73.0)	579 (69.2)	462 (73.8)	180 (76.6)	367 (76.8)
No	587 (27.0)	258 (30.8)	163 (26.0)	55 (23.4)	111 (23.2)
Missing information	1 (0.0)	0	1 (0.2)	0 (0)	0 (0)

Abbreviations: AFWHB, Atrium Health Wake Forest Baptist; BSWH, Baylor Scott & White Health; GMC, Geisinger Medical Center; UTMB, University of Texas Medical Branch at Galveston.

staff and caregivers, disruption of the PLWD's daily routine for clinic visits). The feedback and input provided in all stages of D-CARE by the NPSC and LPSCs highlight the importance of adapting recruitment, enrollment, and study activities to accommodate the diverse situations in which families care for PLWD and impact of culture on family caregiving.

In summary, D-CARE successfully enrolled 2176 racially/ethnically diverse community-living persons with ADRD and their family/friend caregivers. The study demonstrated the feasibility and effectiveness of coordinating information from health systems' EHRs, engagement of clinicians who care for PLWD, and culturally respectful and personalized telephone recruitment to families within four health systems. The lessons learned from D-CARE will assist other investigators in planning future pragmatic trials of diverse PLWD and their caregivers.

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CONFLICT OF INTEREST STATEMENT

All authors listed have no relevant disclosures on conflicts of interest. Author disclosures are available in the supporting information.

CONSENT STATEMENT

All human subjects provided informed consent and the study was both approved by University of California- Los Angeles central Institutional Review Board as well as local Institutional Review Boards at Atrium Health Wake Forest Baptist Health, Baylor Scott & White Health, Geisinger Health, and University of Texas-Medical Branch at Galveston.

ORCID

Mia Yang https://orcid.org/0000-0002-5439-3706

REFERENCES

1. Alzheimer's Association. 2023 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2023;19:1598-1695.
2. Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care*. 2002;40:771-781.
3. Tanner JA, Black BS, Johnston D, et al. A randomized controlled trial of a community-based dementia care coordination intervention: effects of MIND at home on caregiver outcomes. *Am J Geriatr Psychiatry*. 2015;23:391-402.
4. Possin KL, Merrilees JJ, Dulaney S, et al. Effect of collaborative dementia care via telephone and internet on quality of life, caregiver well-being, and health care use: the care ecosystem randomized clinical trial. *JAMA Intern Med*. 2019;179(12):1658-1667.
5. Bass DE L, Primetica B, Holloway C. Reflections on implementing the evidence-based BRI care consultation with RCI in Georgia. *Generations*. 2015;39(4):49-56.
6. Belle SH, Burgio L, Burns R, et al. Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: a randomized, controlled trial. *Ann Intern Med*. 2006;145:727-738.
7. Gitlin LN, Winter L, Dennis MP, Hodgson N, Hauck WW. Targeting and managing behavioral symptoms in individuals with dementia: a randomized trial of a nonpharmacological intervention. *J Am Geriatr Soc*. 2010;58:1465-1474.
8. Baier RR, Mitchell SL, Jutkowitz E, Mor V. Identifying and supporting nonpharmacological dementia interventions ready for pragmatic trials: results from an expert workshop. *J Am Med Dir Assoc*. 2018;19:560-562.

9. Gitlin LN, Baier RR, Jutkowitz E, et al. Dissemination and implementation of evidence-based dementia care using embedded pragmatic trials. *J Am Geriatr Soc*. 2020;68(2)(suppl 2):S28-S36.
10. Glymour MM, Mor V. A large pragmatic trial is the right solution for testing anti-amyloid therapies for Alzheimer's disease. *J Am Geriatr Soc*. 2022;70:1595-1598.
11. Weinfurt KP, Hernandez AF, Coronado GD, et al. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. *Bmc Med Res Methodol*. 2017;17:144.
12. Lennon JC, Aita SL, Bene VAD, et al. Black and White individuals differ in dementia prevalence, risk factors, and symptomatic presentation. *Alzheimers Dement*. 2022;18:1461-1471.
13. Alzheimer's Association. 2021 Alzheimer's Disease facts and figures—special report: race, ethnicity, and Alzheimer's in America. *Alzheimers Dement*. 2021;17(3):327-406.
14. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*. 2014;104:e16-e31.
15. Lackland DT, Sims-Robinson C, Jones Buie JN, Voeks JH. Impact of COVID-19 on clinical research and inclusion of diverse populations. *Ethn Dis*. 2020;30:429-432.
16. Elliott CL. Together we make the difference: national strategy for recruitment and participation in Alzheimer's and related dementias clinical research. *Ethn Dis*. 2020;30:705-708.
17. Morrison K, Winter L, Gitlin LN. Recruiting community-based dementia patients and caregivers in a nonpharmacologic randomized trial: what works and how much does it cost? *J Appl Gerontol*. 2016;35:788-800.
18. Ryan J, Fransquet P, Wrigglesworth J, Lacaze P. Phenotypic heterogeneity in dementia: a challenge for epidemiology and biomarker studies. *Front Public Health*. 2018;6:181.
19. Ritchie CW, Terrera GM, Quinn TJ. Dementia trials and dementia tribulations: methodological and analytical challenges in dementia research. *Alzheimers Res Ther*. 2015;7:31.
20. Reuben DB, Romero T, Evertson LC, Jennings LA. Overwhelmed: a dementia caregiver vital sign. *J Gen Intern Med*. 2022;37:2469-2474.
21. Spillman BC, Freedman VA, Kasper JD, Wolff JL. Change over time in caregiving networks for older adults with and without dementia. *J Gerontol B Psychol Sci Soc Sci*. 2020;75:1563-1572.
22. Sheridan S, Schrandt S, Forsythe L, Hilliard TS, Paez KA. Advisory panel on patient E. the PCORI engagement rubric: promising practices for partnering in research. *Ann Fam Med*. 2017;15:165-170.
23. Callahan CM, Sachs GA, Lamantia MA, Unroe KT, Arling GA, Boustani MA, Redesigning systems of care for older adults with Alzheimer' disease. *Health Aff*. 2014;33(4):626-632.
24. Ware JH, Hamel MB. Pragmatic trials–guides to better patient care? *N Engl J Med*. 2011;364:1685-1687.
25. Mitchell SL, Mor V, Harrison J, McCarthy EP. Embedded pragmatic trials in dementia care: realizing the vision of the NIA Impact Collaboratory. *J Am Geriatr Soc*. 2020;68(2)(suppl 2):S1-S7.
26. Kalkman S, van Thiel G, van der Graaf R, et al. The social value of pragmatic trials. *Bioeth*. 2017;31:136-143.
27. Reuben DB, Gill TM, Stevens A, et al. D-CARE: the dementia care study: design of a pragmatic trial of the effectiveness and cost effectiveness of health system–based versus community-based dementia care versus usual dementia care. *J Am Geriatr Soc*. 2020;68:2492-2499.
28. Reuben DB, Evertson LC, Wenger NS, et al. The university of California at Los Angeles Alzheimer's and Dementia care program for comprehensive, coordinated, patient-centered care: preliminary data. *J Am Geriatr Soc*. 2013;61:2214-2218.
29. Wittich W, Phillips N, Nasreddine ZS, Chertkow H. Sensitivity and specificity of the Montreal cognitive assessment modified for individuals who are visually impaired. *J Vis Impair Blind*. 2010;104:360-368.
30. Pendlebury ST, Welch SJ, Cuthbertson FC, Mariz J, Mehta Z, Rothwell PM. Telephone assessment of cognition after transient ischemic attack and stroke: modified telephone interview of cognitive status and telephone Montreal Cognitive Assessment versus face-to-face Montreal Cognitive Assessment and neuropsychological battery. *Stroke*. 2013;44:227-229.
31. Dong Y, Xu J, Chan BP-L, et al. The Montreal Cognitive Assessment is superior to national institute of neurological disease and stroke-Canadian stroke network 5-minute protocol in predicting vascular cognitive impairment at 1 year. *BMC Neurology*. 2016;16:46.
32. Karlawish J, Cary M, Moelter ST, et al. Cognitive impairment and PD patients' capacity to consent to research. *Neurology*. 2013;81:801-807.
33. Katz S. Assessing self-maintenance: activities of daily living, mobility, and instrumental activities of daily living. *J Am Geriatr Soc*. 1983;31:721-727.
34. Cooper C, Ketley D, Livingston G. Systematic review and meta-analysis to estimate potential recruitment to dementia intervention studies. *Int J Geriatr Psychiatry*. 2014;29:515-525.
35. Possin KL, Merrilees JJ, Dulaney S, et al. Effect of collaborative dementia care via telephone and internet on quality of life, caregiver well-being, and health care use: the care ecosystem randomized clinical trial. *JAMA Intern Med*. 2019;179:1658-1667.
36. Bass DM, Judge KS, Lynn Snow A, et al. Caregiver outcomes of partners in dementia care: effect of a care coordination program for veterans with dementia and their family members and friends. *J Am Geriatr Soc*. 2013;61:1377-1386.
37. Bass DM, Judge KS, Snow AL, et al. A controlled trial of partners in dementia care: veteran outcomes after six and twelve months. *Alzheimers Res Ther*. 2014;6:1-12.
38. Callahan CM, Boustani MA, Unverzagt FW, et al. Effectiveness of collaborative care for older adults with Alzheimer disease in primary care. *JAMA*. 2006;295:2148.
39. Grill JD, Raman R, Ernstrom K, Aisen P, Karlawish J. Effect of study partner on the conduct of Alzheimer disease clinical trials. *Neurology*. 2013;80:282-288.

SUPPORTING INFORMATION

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

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