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CLINICAL INVESTIGATIONS

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

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BACKGROUND/OBJECTIVES: Although several approaches have been developed to provide comprehensive care for persons living with dementia (PWD) and their family or friend caregivers, the relative effectiveness and cost effectiveness of community-based dementia care (CBDC) versus health system–based dementia care (CBDC) and the effectiveness of both approaches compared with usual care (UC) are unknown.

DESIGN: Pragmatic randomized three-arm superiority trial. The unit of randomization is the PWD/caregiver dyad.

SETTING: Four clinical trial sites (CTSs) based in academic and clinical health systems.

PARTICIPANTS: A total of 2,150 English- or Spanish-speaking PWD who are not receiving hospice or residing in a nursing home and their caregivers.

INTERVENTIONS: Eighteen months of (1) HSDC provided by a nurse practitioner or physician's assistant dementia care specialist who works within the health system, or (2) CBDC provided by a social worker or nurse care consultant who works at a community-based organization, or (3) UC with as needed referral to the Alzheimer's Association Helpline.

MEASUREMENTS: Primary outcomes: PWD behavioral symptoms and caregiver distress as measured by the Neuropsychiatric Inventory Questionnaire (NPI-Q) Severity and Modified Caregiver Strain Index scales. Secondary outcomes: NPI-Q Distress, caregiver unmet needs and confidence, and caregiver depressive symptoms. Tertiary outcomes: PWD long-term nursing home placement rates, caregiver-reported PWD functional status, cognition, goal attainment, "time spent at home," Dementia Burden Scale-Caregiver, a

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composite measure of clinical benefit, Quality of Life of persons with dementia, Positive Aspects of Caregiving, and cost effectiveness using intervention costs and Medicare claims.

RESULTS: The results will be reported in the spring of 2024.

CONCLUSION: D-CARE will address whether emphasis on clinical support and tighter integration with other medical services has greater benefit than emphasis on social support that is tied more closely to community resources. It will also assess the effectiveness of both interventions compared with UC and will evaluate the cost effectiveness of each intervention. **J Am Geriatr Soc 68:2492-2499, 2020.**

Keywords: Alzheimer's disease; dementia; care coordination; pragmatic trials

In the United States, an estimated 5.8 million persons are affected by Alzheimer's disease, the most common type of dementia.[1] The clinical manifestations of dementia are devastating including progressive cognitive impairment, behavioral changes, functional decline, immobility and falls, swallowing problems, and aspiration pneumonia. These sequelae often lead to caregiver burden, emotional stress, and negative impacts on health indicators and outcomes.

In response, several comprehensive dementia care programs have been developed to meet the needs of persons living with dementia (PWD), caregivers, and other family members. These programs provide care coordination, high-quality dementia care, and caregiver support. Some have been based within healthcare systems and reach out to the communities, whereas others are based in the community and reach in to the healthcare system.[2] Despite demonstrated effectiveness of various models,[2] the comparative effectiveness on meaningful clinical outcomes and cost effectiveness of different approaches are unknown. In 2018, the Patient-Centered Outcomes Research Institute and the National Institute on Aging funded D-CARE, the Dementia Care Study (hence referred to as D-CARE), to compare clinical outcomes and healthcare utilization of a health system–based dementia care (HSDC) program, a community-based dementia care (CBDC) program, and usual care (UC).

METHODS

D-CARE is a pragmatic randomized trial of 2,150 PWD and their family or friend caregivers (referred to as "caregivers" throughout this article) at four clinical trial sites (CTSs) to compare the effectiveness and cost effectiveness of three approaches over 18 months: (1) HSDC (based on the University of California, Los Angeles [UCLA] Alzheimer's and Dementia Care program)[3] provided by an advanced practice provider (nurse practitioner or physician assistant) dementia care specialist (DCS) working within the heath system; (2) CBDC (using the Benjamin Rose Institute [BRI] Care Consultation model)[4] provided by a social worker or nurse care consultant working within a community-based organization (CBO); and (3) UC. The design of the trial is highly pragmatic according to the Pragmatic Explanatory Continuum Indicator Summary (PRECIS)-2 criteria (average score of 4.2 of possible 5 across nine domains).[5]

The organizational structure of the study including diversity of trial sites (Baylor, Scott, & White; Geisinger Health; University of Texas Medical Branch; Wake Forest University), the Data Coordinating Center, and Central Project Management is provided in the online Supplementary Material S1. The trial is overseen by a Study Advisory Committee and includes Local Patient and Stakeholder Committees and a National Patient and Stakeholder Committee[6] (Supplementary Material S1) to ensure that patient and other stakeholder views are continually integrated into the trial. The central institutional review board (IRB) at UCLA has approved the study. The trial is registered on clinicaltrials.gov (Identifier: NCT03786471), and a four-member Data Safety Monitoring Board monitors the study.

Inclusion and Exclusion Criteria, Screening, Recruitment, and Enrollment

Table 1 summarizes inclusion and exclusion criteria. To facilitate recruitment, each site generates a list of patients at participating practices who have a diagnosis of dementia established by International Classification of Diseases-9 or -10 billing diagnosis, the patient's problem list, and/or past medical history codes. Lists of potential eligible PWDs are then forwarded to the primary care providers (PCPs), practice nurses, or likely partnering physicians to review, remove patients who should not be contacted, give permission to contact the patient/caregiver, and confirm

Table 1. Inclusion and Exclusion Criteria for D-CARE Trial

Inclusion criteria
• Have a diagnosis of dementia established by a physician or other primary care provider
• Have a caregiver who speaks English or Spanish and has a phone
• Have a primary care provider who is willing to partner with the program
Exclusion criteria
• Resides in a nursing home
• Enrolled in hospice
• Plans to move out of the area within the coming year
• Caregiver is unwilling or anticipates being incapable of providing self-reported outcome measures for 18 months
• Caregiver is paid and is not a relative or close friend of the participant
• Caregiver has cognitive impairment
• Baseline measures refused or not completed
• Patient or caregiver is participating in another dementia intervention study
• Patient or caregiver is a member of a site's Local Patient & Stakeholder Committee
• A member of the same household is already participating in the study
• The site has already enrolled 25% of participants from assisted living facilities

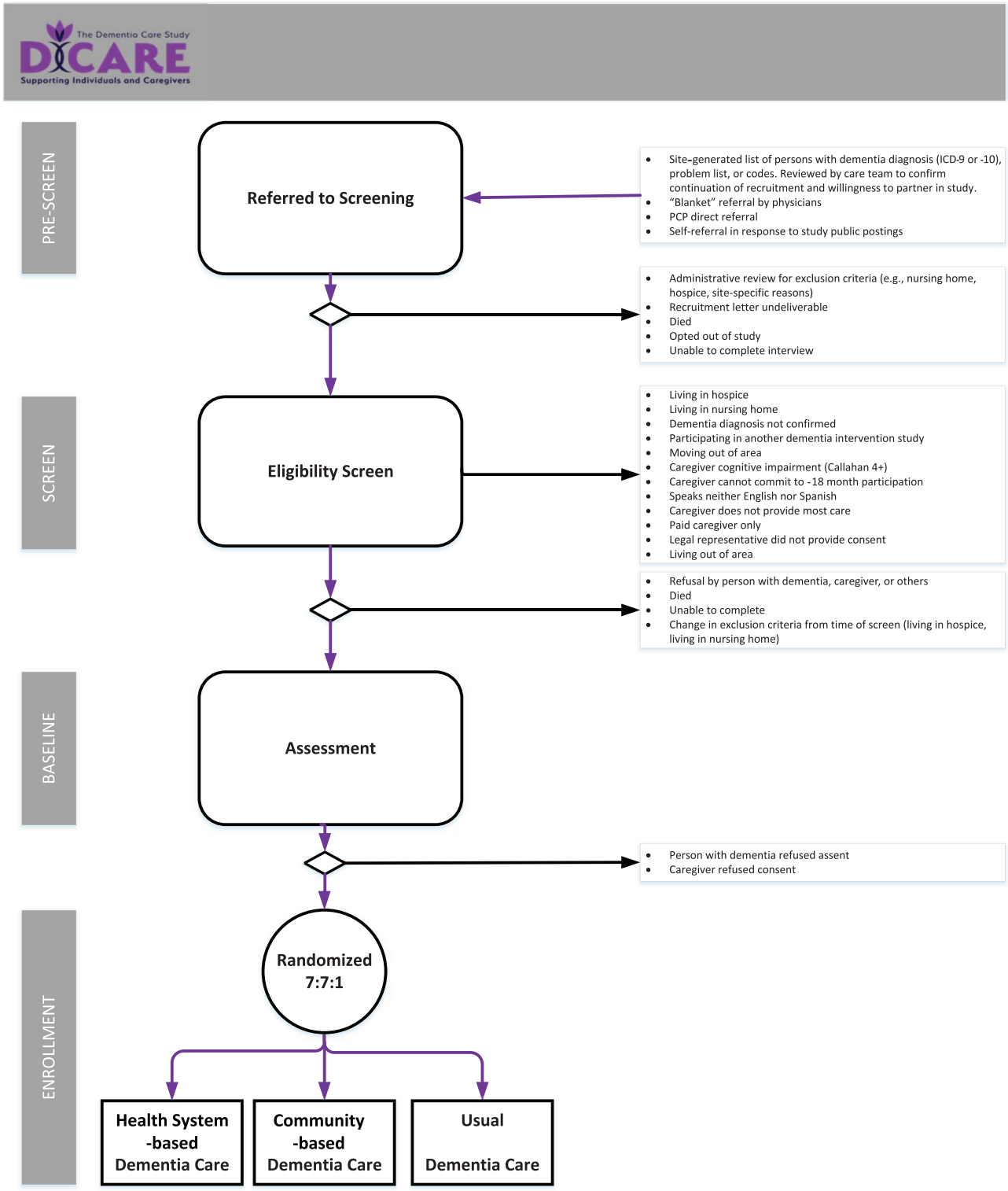

Figure 1. D-CARE Recruitment and Enrollment. ICD, International Classification of Diseases; PCP, primary care provider.

willingness to serve as the physician partner. Some practices give a blanket referral, allowing research staff to recruit participants directly. Partnering physicians may also make referrals directly to the study. Self-referrals may originate through several mechanisms including public postings in collaborating clinics and CBOs, social media, and traditional media coverage of D-CARE (Figure 1).

PWD who score 17 or above on the 22-item telephone-administered Montreal Cognitive Assessment (MoCA)[7] (or proxy consent by caregivers or legally authorized representative if score <17) and caregivers consent to be enrolled in the study, and they are randomized after baseline assessment to HSDC, CBDC, or UC in a 7:7:1 ratio. Randomization is computer generated and stratified by site using a

permuted block design; the allocation sequence is concealed.

Interventions

Each intervention has access to existing community services.

Health Systems–Based Dementia Care

Comprehensive dementia care is delivered by a DCS who works within the heath system to tailor and provide coordinated dementia care in collaboration with the partnering physician (co-management) and reaches out to CBOs for additional services as needed. DCSs can write orders, communicate directly through the electronic health record, and facilitate clinical care.

Community-Based Dementia Care

Comprehensive dementia care is delivered by social worker, nurse, or licensed therapist certified as a BRI Care Consultant who works within a CBO that is partnered with a D-CARE clinical site.[8] BRI Care Consultation has three main components: (1) action plan, (2) initial and reassessment, and (3) ongoing monitoring.

Usual Care

UC consists of referral to the Alzheimer's Association Helpline (1-800-272-3800), which caregivers and PWD can call, as needed, to speak with master's-level consultants for decision-making support, crisis assistance, education on issues families face every day, and referral to local programs and services.

Details of the interventions can be found in Table 2 and in Supplementary Material S1.

Outcomes

Primary, secondary, and tertiary outcomes are summarized in Table 3 (details in Supplementary Material S1). PWD- and caregiver-reported outcomes are assessed at baseline and at 3, 6, 12, and 18 months. Baseline measures were collected in person until the 2020 COVID-19 pandemic and afterward by telephone; follow-up measures are collected by telephone. All baseline and follow-up data are collected by trial staff blinded to treatment group.

Because of the importance of both the PWD and caregiver in dementia care, the primary outcomes include both the PWD-focused Severity scale of the Neuropsychiatric Inventory Questionnaire (NPI-Q)[9] and the Modified Caregiver Strain Index (MCSI) that measure behavioral symptoms of the PWD and the effects of caregiving, respectively.[10] Secondary outcomes include caregiver unmet needs and confidence, distress in response to NPI-Q symptoms,[6] and depressive symptoms (Patient Health Questionnaire-8).[11] Tertiary outcomes include cognition using a shortened version of the MoCA,[12] functional status using the Functional Activities Questionnaire,[13] activities of daily living[14] and instrumental activities of daily living scales,[15] long-term nursing home placement, goal attainment,[16] mortality, PCP and proxy ratings of care and

Table 2. Comparison of HSDC, CBDC, and UC

	HSDC	CBDC	UC
Key personnel	Dementia care specialist (nurse practitioner or physician's assistant)	Care consultant (social worker, nurse, or therapist)	Care consultant (master's level)
Key personnel base	Health system	CBO	Alzheimer's Association
Face-to-face or telemedicine visits	At least annually	None	None
Structured assessments	√	√	None
Creation of individualized plans	Care plan	Action plan	None
Monitoring and revising plans	√	√	None
Access 24/7/365	√	No or Alzheimer's Association helpline	Alzheimer's Association helpline
Identification and prioritization of goals	√	√	No
Communication with physicians	Electronic health record/phone	Mail or fax	None
Order writing	√	No	No
Caregivers' support and education	√	√	Existing local resources
Access to existing community services	√	√	√
Helping caregivers access community services	√	√	Existing local resources
Geri's List (online directory of local resources)	√	√	√
Coaching to prepare for physician or other provider visits	No	√	No

Abbreviations: CBDC, community-based dementia care; CBO, community-based organization; HSDC, health systems–based dementia care; UC, usual care.

Table 3. Schedule of Outcomes Data Collection for D-Care Trial

Measure	Administration[a] All telephone interviews	Month				
		Baseline[b]	3	6	12	18
Primary outcomes						
NPI-Q Severity (patient behaviors)	Questionnaire	X	X	X	X	X
Caregiver strain (MCSI)	Questionnaire	X	X	X	X	X
Secondary outcomes						
NPI-Q Distress (caregiver)	Questionnaire	X	X	X	X	X
Caregiver depression (PHQ-8)	Questionnaire	X	X	X	X	X
Caregiver self-efficacy	Questionnaire	X		X		X
Tertiary outcomes						
Cognition (MoCA)	Interview[b]	X				X
Functional status (FAQ)	Interview	X				X
Goal attainment scaling[c]	Interview		X	X	X	X
Mortality	CMS interview					X
			X	X	X	X
Time spent at home	CMS					X
Inpatient hospital use[c]	CMS					X
Acute inpatient rehabilitation use[d]	CMS					X
Post-acute SNF use[d]	CMS					X
Hospice use[d]	CMS					X
Long-term nursing home use[d]	CMS					X
Caregiver rating of dementia care quality	Questionnaire				X	
Caregiver satisfaction with dementia care	Questionnaire		X		X	X
Dementia Burden Scale-Caregiver	Composite	X	X	X	X	X
Clinical Benefit	Composite	X	X	X	X	X
Quality of life in Alzheimer's disease	Questionnaire	X				X
Positive aspects of caregiving	Questionnaire	X		X		
Spouse caregiver utilization	CMS					X
Cost-effectiveness analysis	CMS					X

Abbreviations: CMS, Center for Medicare & Medicaid Services and site-obtained claims data; FAQ, Functional Assessment Questionnaire; MCSI, Modified Caregivers Strain Index; MoCA, Montreal Objective Cognitive Assessment; PHQ, Patient Health Questionnaire; NPI-Q, Neuropsychiatric Inventory Questionnaire; SNF, skilled nursing facility.

[a]Questionnaires are formal self-report instruments. Interviews include direct tests and open- ended responses.

[b]Switched from in person to telephone collected after beginning of COVID-19 pandemic.

[c]Goal Attainment Scaling will be obtained only on subset of participants (i.e., it will not be performed in participants in the UC group); this will be completed by an unblinded assessor (i.e., the dementia care specialist or care consultant).

[d]Also used to calculate time spent at home.

satisfaction. Quality of Life in Alzheimer's Disease,[17] Positive Aspects of Caregiving,[18] a composite measure of caregiver burden,[19] a composite measure of clinical benefit,[20] and time spent at home.[21]

Six months after study follow-up has been completed, Medicare claims and Medicare Advantage (MA) data will be requested to ascertain utilization (before and during the study), long-term nursing home placement, and calculate time (in days) spent at home. For participants in MA or commercial health plans, we will use internal records of utilization and compute costs using Medicare prices. Costs to consumers will include beneficiary cost-sharing payments for services as well as caregiving costs using questions from the Aging, Demographics, and Memory Study.[22] The cost of paid caregiving will be estimated based on average hourly rates from caregiver agencies, and the cost of family care will be estimated based on the market wage paid to formal caregivers or the cost of foregone wages by caregivers based on average market wages.[23]

Statistical Analysis

All analyses will be according to intent to treat. To evaluate the two primary outcomes, NPI-Q Severity and MCSI scores, we will use a longitudinal repeated measures analysis[24] adjusted for the baseline value of the outcome and stratified randomization by site. Treatment differences, averaged over all follow-up time points, will be summarized by least square means and multiplicity corrected confidence intervals (CIs).[25] Significance testing will be done by the Hochberg procedure[26] (5% type I error, two sided) to account for multiple hypothesis testing (i.e., two primary outcomes and three pairwise comparisons). Sensitivity analyses will consist of fitting joint longitudinal-survival models[27] and multiple imputation for missing data because of dropout other than death.

Heterogeneity of treatment effects (HTE) for the primary outcomes will be assessed in seven subgroups: high versus low patient function, high versus low cognition, high

Table 4. Power and Sample Size for the Two Primary Outcomes

Comparison	Difference to be detected	Power for MCSI[a]	Power for NPI-Q Severity[b]	Overall power	Adjusted sample sizes
HSDC vs CBDC	1.5	95%	95%	90%	1,000 per group
HSDC or CBDC vs UC	3.0	95%	95%	90%	1,000 HSDC and CBDC vs 150 UC

Abbreviations: CBDC, community-based dementia care; HSDC, health systems–based dementia care; MCSI, Modified Caregivers Strain Index; NPI-Q, Neuropsychiatric Inventory Questionnaire; UC, usual care.

[a]Range 0–26 (higher is worse).

[b]Range is 0–36 (higher is worse).

versus low NPI-Q Severity, high versus low MCSI, spouse caregiver versus other caregiver, White non-Latinx versus non-White or Latinx, and those residing in urban versus rural areas (based on participants' ZIP Codes). Evidence of HTE will be based on tests of interaction with multiplicity controlled by Hochberg as previously described; subgroup treatment differences will be reported using 99% CIs.

The analysis of the secondary outcomes (Table 3) will be analyzed like the primary outcomes. Multiplicity will be controlled by Hochberg (5% type I error, two sided); treatment differences will be reported using 99% CIs. The analysis of tertiary outcomes will be considered exploratory without control for multiplicity. Hospitalizations will be summarized by counts, frequency distributions, and event rates per person-year of follow-up and mortality by calculating Kaplan-Meier rates. A *P* value of .05 (two sided) will be used for the safety analyses.

Sample Size

Sample size was calculated using PASS.[28] Assumptions for testing differences among the three treatment groups for the two primary outcomes were (1) type I error .05/6 = .008 Bonferroni adjusted for three treatment comparisons times two primary outcomes, (2) standard deviation (SD) of 6.5 units for NPI-Q Severity and 6.7 units for MCSI, (3) treatment difference of 1.5 units for HSDC versus CBDC, (4) treatment difference of 3 units for HSDC and CBDC versus UC, and (5) 18-month lost to follow-up of 25% from death and dropout. The intervention difference of 1.5 units for HSDC versus CBDC was based on data suggesting a minimally clinical important difference ranging from 2.8 to 4.0.[29] Because both groups will be receiving an intervention, we reduced the detectable difference in half to 1.5. Data from two studies[30,31] indicated an expected benefit between HSDC and UC of about 3 units for the NPI-Q Severity score. The estimates of SD and censoring rates were based on UCLA pilot data.

Sample size (adjusted for censoring) was first determined for HSDC versus CBDC because the effect size is expected to be smaller than comparisons with UC. Testing each outcome at 95% power with a sample size of 1,000 subjects per treatment group gave 90% overall power for testing both outcomes. Given these sample sizes, the sample size for UC was 150 for comparisons with the two interventions, yielding a total sample size (Table 4) of 2,150. For the three secondary outcomes, we determined detectable effect sizes for 90% power assuming a Bonferroni-adjusted type I error of $.05/(3 \times 3) = .006$ to account for multiplicity. The detectable effect sizes were .20 for testing HSDC versus CBDC and .40 for testing HSDC/CBDC versus UC. Power for the tertiary outcomes was not done.

Cost Effectiveness and Utilization Analysis

The cost effectiveness of the interventions compared with UC is the ratio of incremental net costs to incremental effects of the two primary outcomes. Thus the ratio will be the net costs per "x" point change in NPI-Q-Severity and "y" point change in MCSI. Costs will be taken from the perspective of Medicare. The net costs of the interventions are the costs of training and implementing the intervention minus the cost offsets of reduced medical care and caregiving. We will model the cost offsets using differences in differences and general estimating equations with a gamma family and log link, as was done in a prior Centers for Medicare & Medicaid Innovation analysis that showed significant cost savings.[32] The cost-effectiveness ratio can be transformed into the clinical benefit gained (patient, caregiver) per $1,000 investment per year. After calculating intervention costs and savings, we will compute return on investment = (cost savings minus intervention costs)/(intervention costs).

Secondary analyses will be from a societal perspective and include costs to Medicaid and consumers as well as Medicare. In tertiary analyses to understand where the cost savings arise, we will study changes in utilization by type of use. Additional details of cost effectiveness and utilization analysis can be found in Supplementary Material S1.

Changes as a Result of COVID-19

By March 16, 2020, all in-person recruitment visits and assessments for HSDC participants were suspended. In response, we switched the baseline assessment and informed consent to telephone with verbal consent as permitted by state and institutional regulations including mailed-in or electronic consents at two CTSs. To accommodate a telephone baseline assessment, we chose an abbreviated version of the MoCA[11] administered by telephone with a cutpoint of 8 or above to determine ability to receive the remainder of the 22-item telephone MoCA[6] to determine capacity of the PWD to consent (prorated to >16 of 22 items based on the original threshold of >22 of 30 items). After

central and approval of IRBs at CTSs, enrollment restarted on May 4, 2020.

DISCUSSION

D-CARE is designed to answer questions about how best to improve dementia care. Although it does not test all evidence-based models of dementia care, D-CARE does compare two prototypes, one based within the health system and the other based in the community. These prototypes also differ in the types of health professionals delivering care and how the care is delivered.

A fundamental question is whether emphasis on clinical support (through the HSDC intervention) and tighter integration with other medical services offers greater benefit than emphasis on social support that is more closely tied to community resources. The two interventions are likely to differ on costs needed to implement and maintain, with HSDC the more expensive. Hence the question of cost effectiveness also becomes important.

The study's outcomes are broad and reflect the impact of dementia on both PWDs and their caregivers including clinical symptoms, personal goals, and costs of care. Thus differential benefits of the different interventions can be assessed (e.g., one or the other intervention may be more efficacious for specific outcomes). Some subgroups (e.g., those with more behavioral symptoms or caregiver strain) may also benefit more from one of the interventions, which will be explored in prespecified subgroup analyses. The inclusion of a UC arm allows comparison of the HSDC and CBDC interventions with services that are currently available without the investment of additional resources. Potential threats to the validity of the study include inadequate fidelity in implementing the interventions and the effects of external events (e.g., COVID-19).

The study is designed to readily translate findings into practice if there are mechanisms to support the interventions financially. If HSDC proves to be superior, dissemination will be less of an issue for systems that serve high percentages of capitated patients because the program would achieve cost savings if it is as effective as the original UCLA demonstration ($2,404 per person per year cost savings).[33] In fee-for-service environments, under the current reimbursement structure, revenues from billings would likely not cover the entire costs of the HSDC intervention. Other obstacles to disseminating HSDC include the lack of a trained workforce including advanced practice providers who can fill the DCS role.

If CBDC proves to be superior, health systems that serve high percentages of capitated patients may opt to contract with CBOs to provide this service as a member benefit or provide these services in house. Systems that largely care for fee-for-service patients will likely face financial obstacles to implement this program because these services currently are not covered by Medicare. Nevertheless, if CBDC confers clinical advantages, other mechanisms through the Administration for Community Living or new Medicare mechanisms might be created to support this program.

If neither intervention is superior but both are more effective than UC, subgroup analyses to identify specific characteristics associated with benefit may be useful. For example, there may be no overall difference between the interventions, yet HSDC may be more effective for those with more advanced dementia. A large healthcare system might then implement both approaches and triage patients to the least expensive intervention that is effective.

D-CARE is expected to complete enrollment by September 2021 and report findings by spring 2024. We anticipate that these findings will guide the delivery and financing of care for PWD and their caregivers.

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Conflict of Interest: The D-CARE study is funded by the Patient-Centered Outcomes Research Institute, a nonprofit institution, and the National Institute on Aging. The award includes four clinical trial sites. The collaborative work on this manuscript was completed by study investigators and staff who receive salaries and benefits from these funders.

Author Contributions: Study concept and design: Araujo, Bass, Carnie, Dziura, Finney, Galloway, Gill, Jennings, Liu, Raji, Peduzzi, Reuben, Stevens, Tan, Volpi, Weitzman, Williamson, Wilson, and Yang. Aquisition of subjects and/or data: Abraham, Araujo, Borek, Carne, Charpentier, Currie, Finney, Galloway, Greene, Hirst, Ladd, Lenoir, Lichtenstein, Raji, Rahm, Samper-Ternent, Stevens, Unger, Vernon, Volpi, Williamson, Analysis and interpretation of data: Dziura, Evertson, Greene, Meng, Peduzzi, Reuben, Stevens, Volpi, and Williamson Tan. Preparation of manuscript: Peduzzi, Reuben, Stevens, Volpi, Williamson Tan, Abraham, Araujo, Bass, Borek, Carnie, Currie, Evertson, Galloway, Gill, Evertson, Greene, Jennings, Ladd, Lichtenstein, Raji, Peduzzi, Rahm, Reuben, Samper-Ternent, Stevens, Tan, Unger, Volpi, Weitzman, Williamson, Wilson, and Yang.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

Supplementary Material S1: Organizational Structure and Detailed Descriptions of Interventions, Outcome Measures, and Cost-effectiveness Analysis