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BRIEF REPORT OPEN ACCESS

Comparison of Two Dementia Care Interventions and Usual Care on Days Spent at Home: The D-CARE Randomized Clinical Trial

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Keywords: days spent at home | dementia care | older persons | pragmatic trials

ABSTRACT

Background: Days spent at home (DSAH) is a clinically meaningful patient-centered outcome among persons living with dementia (PLWD).

Objective: To evaluate whether either of two dementia care interventions increased the number of DSAH compared with each other and with usual care.

Design: Pragmatic 18-month 3-arm randomized clinical trial conducted from June 2019 through August 2023.

Setting: Four clinical trial sites in North Carolina, Texas, and Pennsylvania.

Participants: Total of 1968 (90.4% of 2176) community-living PLWD with complete Medicare data.

Interventions: Health-system dementia care (HSDC) co-management by advance practice providers, community-based dementia care (CBDC) provided telephonically by a social worker, nurse, or licensed therapist, and usual care (UC), each lasting up to 18 months.

Main Outcome: The number of DSAH was calculated as 546 (i.e., 18 months) minus the number of overnight days in a health care facility and days not alive, using data from Medicare.

Results: The percentages of DSAH were 83.5, 84.9, and 83.6 for the HSDC, CBDC, and UC groups, respectively. For each pairwise comparison among the three groups, incidence rate ratios for DSAH approximated 1.0, denoting no differences, and the corresponding mean differences in DSAH were small and not statistically significant: −7.2 (98.3% CI: −31.4 to 17.0) for HSDC versus CBDC; −0.3 (−48.4 to 47.7) for HSDC versus UC; and 6.9 (−41.3 to 55.5) for CBDC versus UC. There were no substantive differences in mean values across the three groups for days in any of the health care facilities. Mean [SD] days not alive were greatest for UC (68.3 [134.4]), followed by HSDC (65.3 [133.3]) and CBDC (60.0 [129.8]).

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Conclusions: In this pragmatic randomized clinical trial of dementia care programs, health system–based and community-based interventions did not differ from each other or from usual care in the number of DSAH for PLWD over the 18-month intervention period.
Trial Registration: Clinicaltrials.gov identifier: NCT03786471

Summary

- Key points
  - This pragmatic randomized clinical trial of dementia care programs found no significant differences between the health system–based and community-based interventions, or between either intervention and usual care, with respect to the number of days spent at home among persons living with dementia (PLWD) over the 18-month intervention period.
  - Each of the three treatment groups spent more than 83% of the follow-up period living at home.
  - For each of the groups, days not spent at home were primarily due to deaths and stays in a nursing home.
- Why does this matter
  - Days spent at home is considered an important patient-centered outcome among PLWD given an uncertain prognosis and, commonly, a diminished life expectancy. Whether different dementia care interventions increase time spent at home has not been previously evaluated.

1 | Introduction

Days spent at home (DSAH) is an important patient-centered outcome [1], especially among older persons who highly value quality of life in addition to survival [2]. For persons living with dementia (PLWD), DSAH can be considered as an integrative measure of control of dementia symptoms (e.g., problem behaviors), the ability of caregivers to cope with the disease, and the success of the health system in providing services that avoid days spent in health care facilities, such as a hospital or nursing home.

The Dementia Care (D-CARE) Study was a large multisite pragmatic clinical trial that compared two well-established interventions—health-system dementia care (HSDC) and community-based dementia care (CBDC)—with each other and with Usual Care (UC) [3]. Except for caregiver self-efficacy and satisfaction with care, which significantly improved in both intervention groups compared with UC [4, 5], there were no significant differences among the three groups in multiple pre-specified patient- and caregiver-reported primary, secondary, and tertiary outcomes [4, 5].

Whether different dementia care interventions increase time spent at home, an outcome that doesn't rely on PLWD or caregiver report, is uncertain. The objective of this manuscript was to evaluate whether either HSDC or CBDC increased the number of DSAH, a pre-specified D-CARE tertiary outcome, compared with each other and with usual care. Payers and health systems may be more likely to support dementia care interventions if they reduce time spent by PLWD in costly health care facilities and, in turn, increase time spent at home.

2 | Methods

The study's protocol, recruitment strategies, interventions, and many other pre-specified outcome results have been reported [3–6]. A single IRB approved the D-CARE protocol and amendments. All study materials and interviews were available in English and Spanish.

2.1 | Participants

D-CARE enrolled 2176 community-living PLWD-caregiver dyads from June 2019 to January 2022. PLWD needed a clinician's diagnosis of dementia and a primary care or referring provider who was willing to partner with the study. Caregivers needed to be family or friends who had a phone. PLWD were excluded if they resided in a nursing home, were enrolled in hospice, planned to move out of the area within a year, or had a primary caregiver who was paid or had cognitive impairment [4]. A complete list of the inclusion and exclusion criteria has been reported [4].

2.2 | Procedures Through Randomization

Screening and recruitment were facilitated by common strategies used across the four clinical trial sites: Atrium Health Wake Forest Baptist, Baylor Scott & White Health, Geisinger Health, and University of Texas Medical Branch [3, 6]. At the time of enrollment, all caregivers and PLWD who scored ≥ 17 on the Montreal Cognitive Assessment (MoCA) provided informed consent, and PLWD who scored <8 on a shortened or <17 on the full MoCA provided verbal assent, with proxy consent provided by a designated caregiver or Legally Authorized Representative [7]. Dyads were enrolled after completion of the baseline assessment and randomized to HSDC, CBDC, or UC in a 7:7:1 ratio. Of the 2176 PLWD-caregiver dyads, 1016 were randomized to each intervention group and 144 to UC.

2.3 | Interventions

All participants were given information on local community and health care services, including the phone number of the Alzheimer's Association Helpline (1-800-272-3900), which caregivers and PLWD could call as needed to speak with master's

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level consultants for decision-making support, crisis assistance, and education.

2.3.1 | HSDC

Based on a well-established program [8], a nurse practitioner or physician assistant Dementia Care Specialist (DCS) worked within the health system to tailor and provide coordinated dementia care in collaboration with the partnering clinician (co-management). The DCS could write orders, communicate directly through the electronic health record, and facilitate clinical care. HSDC was provided primarily in-person until the COVID-19 pandemic and primarily virtually after March 2020.

2.3.2 | CBDC

Using the Benjamin Rose Institute (BRI) Care Consultation model [9], dementia care was delivered by a social worker, nurse, or licensed therapist certified as a BRI Care Consultant who worked within a community-based organization in partnership with a D-CARE clinical site. Throughout the study, all interactions between the BRI Care Consultant and the PLWD and caregiver were telephonic.

2.3.3 | UC

Participants were given no personalized dementia care treatments.

2.4 | Outcome

DSAH were calculated, starting with the day after randomization, as 546 days (i.e., 18 months) minus the number of overnight days in a health care facility, including hospital, nursing home (post-acute and long-term), and hospice, and days not alive; home hospice counted as time spent at home. Consistent with prior literature [7, 10], death was not treated as a censoring event; rather, days following death were counted as zero DSAH. This approach preserves the interpretation of DSAH as an integrated, patient-centered outcome that jointly reflects survival and not residing in a health care facility [1]. The primary sources for data on health care utilization, obtained from the NIA Data LINKAGE Program [11], were Medicare claims (fee-for-service patients), Medicare encounters (Medicare Advantage patients), Minimum Data Set (MDS), which is available for all residents in a Medicare- or Medicaid-certified nursing home, and the Master Beneficiary Summary File, which provides date of death [12, 13]. The Medicare claims and encounters are organized into files based on claim type and care setting, including hospital (acute care and rehabilitation) and hospice facility [14]. Claims for inpatient hospice care were available for all participants regardless of Medicare coverage type. As per other studies that have used MDS data [15–18], it was not possible to accurately distinguish post-acute and long-term nursing home days.

2.5 | Analytic Sample

Complete Medicare data were not available for 208 participants, leaving 1968 (90.4%) in the analytic sample (Supplementary Figure S1). LINKAGE restrictions precluded comparison of characteristics between excluded and included participants.

2.6 | Statistical Analysis

The pre-specified statistical analysis plan was followed [19]. For the three treatment groups, characteristics at baseline were calculated as mean and standard deviation for continuous variables and frequency and percentage for dichotomous variables. For each group, frequency distributions were generated for the number of DSAH during the 18-month follow-up period.

DSAH were treated as count data and analyzed using a negative binomial regression model, with treatment group as a categorical predictor and clinical trial site included as a fixed effect. Since the distribution was left-skewed, we also analyzed the complementary outcome, total days not at home, in the same manner. Treatment effects were expressed as incidence rate ratios (IRR) and mean differences, with 98.3% confidence intervals to account for the three pairwise treatment comparisons.

For descriptive purposes, the distribution of days not at home, including days in the three types of health care facilities and days not alive, was also calculated.

All analyses were "intent-to-treat" and assumed that data were missing at random. Analyses were performed using SAS/STAT software version 15.3.

3 | Results

The baseline characteristics of participants in the analytic sample are provided in Table 1. Substantive differences between the three groups were not noted, although the UC group included a lower proportion of females than the other two groups. Mortality over 18 months was a bit lower for CBDC (23.8%) than for HSDC (27.1%) and UC (27.5%), although the differences were not statistically significant.

Figure 1 shows the distribution of DSAH for the three treatment groups over the 18-month study period. For each group, the median value approximated the maximum possible value of 546. For the CBDC group, the mean value (463.3) was slightly higher than those for the HSDC (456.0) and UC (456.3) groups, and the interquartile range was tighter due to the higher 25th percentile value. The percentages of DSAH were 84.9, 83.5, and 83.6 for the CBDC, HSDC, and UC groups, respectively.

Pairwise comparisons among the three treatment groups for DSAH are provided in Figure 2. For each comparison, the IRR approximated 1.0, denoting no differences, and the corresponding mean differences were small and not statistically significant, ranging from −0.3 for the comparison between HSDC and UC

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TABLE 1 | Baseline characteristics of study participants.

Characteristic	Health system-based dementia care, $n = 924$	Community-based dementia dare, $n = 913$	Usual care[a], $n = 131$
		No. (%)	
Age, mean (SD), y	81.2 (7.6)	81.3 (8.0)	81.5 (8.2)
Female	552 (59.7)	521 (57.1)	70 (53.4)
Race[b]			
White	773 (83.7)	784 (86.0)	108 (82.4)
Black	109 (11.8)	106 (11.6)	> 12 (> 9.2)
Other	41 (4.4)	22 (2.4)	< 11 (< 8.4)
Hispanic/Latino ethnicity	79 (8.6)	78 (8.6)	13 (9.9)
Currently married	494 (53.5)	482 (52.8)	69 (52.7)
Living arrangement			
At home with caregiver	647 (70.0)	672 (73.6)	94 (71.8)
At home alone without caregiver	132 (14.3)	114 (12.5)	20 (15.3)
At home with someone else	92 (10.0)	80 (8.8)	< 11 (< 8.4)
Assisted living facility	53 (5.7)	47 (5.1)	< 11 (< 8.4)
Primary caregiver			
Spouse	394 (42.6)	410 (44.9)	> 59 (> 45.0)
Child or child-in-law	472 (51.1)	451 (49.4)	61 (46.6)
Other	58 (6.3)	52 (5.7)	< 11 (< 8.4)
Education			
High school graduate or less	395 (42.8)	424 (46.4)	59 (45.7)
Some college or equivalent	213 (23.1)	212 (23.2)	33 (25.6)
College graduate	188 (20.4)	147 (16.1)	18 (14.0)
Post-graduate	126 (13.7)	130 (14.2)	19 (14.7)
Chronic conditions, mean (SD)	2.4 (1.6)	2.5 (1.6)	2.5 (1.6)
Hypertension	603 (65.3)	641 (70.2)	92 (70.2)
Depression	369 (39.9)	386 (42.3)	61 (46.6)
Diabetes	218 (23.6)	212 (23.2)	39 (29.8)
Cancer	184 (19.9)	208 (22.8)	33 (25.2)
Stroke	195 (21.1)	164 (18.0)	22 (16.8)
Chronic lung disease	143 (15.5)	139 (15.2)	20 (15.3)
Myocardial infarction	133 (14.4)	133 (14.6)	17 (13.0)
Chronic kidney disease	133 (14.4)	121 (13.3)	21 (16.0)
Congestive heart failure	117 (12.7)	108 (11.8)	12 (9.2)
Hip fracture	73 (7.9)	72 (7.9)	< 11 (< 8.4)
Parkinson's disease	78 (8.4)	64 (7.0)	< 11 (< 8.4)
MoCA[c]			
Total, no	681	664	97
Median (IQR)	3 (2–6)	3 (2–6)	4 (2–6)

(Continues)

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TABLE 1 | (Continued)

Characteristic	Health system-based dementia care, $n = 924$	Community-based dementia dare, $n = 913$	Usual care[a], $n = 131$
Functional assessment questionnaire[d]			
Total, no	907	895	130
Median (IQR)	24 (17–28)	23 (17–27)	22 (15–28)

Abbreviation: MoCA, Montreal Cognitive Assessment.
[a]Data representing fewer than 11 participants have been suppressed in compliance with the CMS Cell Size Suppression Policy, with complementary suppression as needed to prevent calculation of small cell counts.
[b]Race was reported by participants from a list of options.
[c]The shortened 3-item version of the MoCA has a range of 0 to 12, with higher scores indicating less cognitive impairment.
[d]The 10-item Functional Activities Questionnaire has a range of 0 to 30, with a higher score indicating worse function.

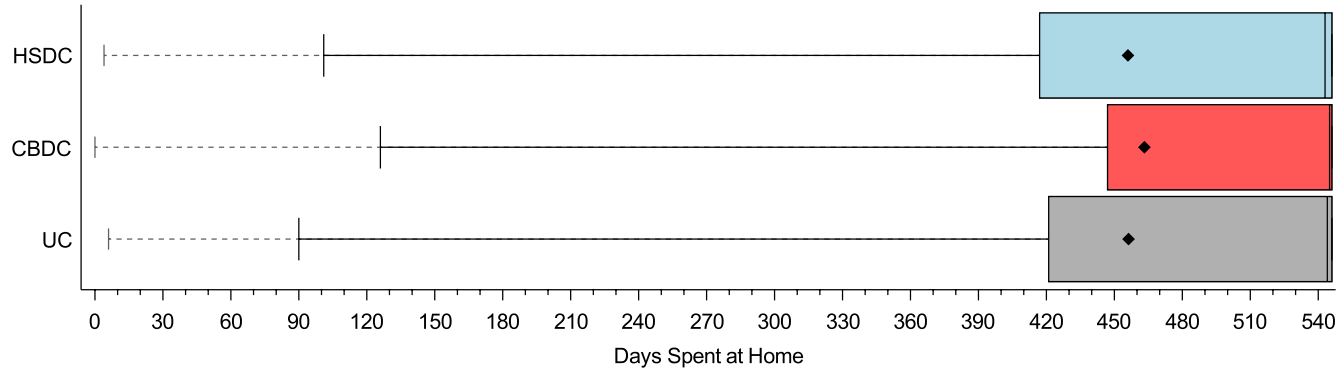


FIGURE 1 | Distribution of days spent at Home for the three treatment groups over the 18-month study period. For each box plot, the left border, midline, and right border represent the 25th percentile, median, and 75th percentile values, respectively, while the black diamond represents the mean value. The solid lines from the boxes extend to the 5th percentile. The dashed lines extend to the minimum values. The 75th percentile, 95th percentile, and maximum values were all 546. HSDC, Health-system dementia care, CBDC, Community-based dementia care, and UC, Usual Care.

to −7.2 for the comparison between HSDC and CBDC to 6.9 for the comparison between CBDC and UC. The results for comparisons using total days not at home were consistent with these estimates.

The distribution of days not at home for each treatment group is provided in Supplementary Figure S2. For all three groups, the largest number was days not alive, followed by days in a nursing home, hospital, and hospice facility, respectively. There were no substantive differences in the mean values across the three treatment groups for days in any of the health care facilities. Mean [SD] days not alive were greatest for UC (68.3 [134.4]), followed by HSDC (65.3 [133.3]) and CBDC (60.0 [129.8]), largely explaining the small differences among the three treatment groups in DSAH (Figure 2).

4 | Discussion

In this pragmatic randomized trial conducted in four health care systems in the US, we evaluated whether either of two dementia care interventions increased the number of DSAH for PLWD, relative to each other and to usual care, over 18 months. We found that each of the three treatment groups spent more than 83% of the follow-up period living at home and that absolute differences in DSAH among the three groups were small. Furthermore, in three pair-wise comparisons, we found no statistically significant differences in DSAH. For each of the groups, days not spent at home were primarily due to deaths and stays in a nursing home.

DSAH is considered an important patient-centered outcome among PLWD given an uncertain prognosis and, commonly, a diminished life expectancy. In theory, either or both of the HSDC and CBDC interventions could have increased the number of DSAH among PLWD relative to UC by providing care coordination, furnishing caregivers with education and support on how to manage dementia symptoms and cope with the disease, and working with caregivers to identify and prioritize goals. In practice, however, we found no differences among the three groups. There are several potential explanations for these findings. First, for each of the three groups, most of the days over the 18-month follow-up period were spent at home, diminishing the opportunity to detect significant differences. Mean percentages of DSAH were much higher (83.5–84.9) than 2021 estimates from a national sample of dually eligible Medicare beneficiaries with dementia (65.2), including those receiving home- and community-based services (75.3) [20]. D-CARE occurred in the midst of the COVID-19 pandemic when discretionary hospitalizations and nursing home admissions were delayed or discouraged, which could have contributed to the higher DSAH values and the trial's null findings [4]. The COVID-19 pandemic may have also impeded the ability to fully deliver health system- and community-based care as designed [4]. Although the HSDC and CBDC interventions formally ended at 18 months, it is possible that their benefits

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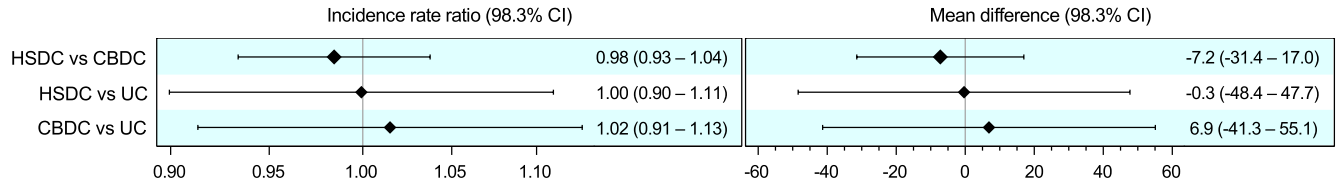


FIGURE 2 | Pairwise comparisons in days spent at home among the three treatment Groups. The left panel provides rate ratios, while the right panel provides mean differences. Both sets of values are accompanied by 98.3% confidence intervals to account for the three pairwise comparisons. The confidence intervals for the mean differences were obtained using the delta method. Clinical trial site was included as a fixed effect in the statistical models. HSDC, Health-system dementia care, CBDC, Community-based dementia care, and UC, Usual Care.

might accrue over a longer period, increasing the power to detect significant differences in DSAH. Second, given the high burden of other chronic conditions, which did not differ among the three groups, days not spent at home may not have been readily amenable to reduction by the dementia care interventions. Third, reducing days not spent at home and, hence increasing time at home, was not an explicit target for either of the interventions. For some PLWD, the value of greater DSAH may depend on whether remaining at home is goal-concordant and adequately supported. Fourth, the modest size of the UC group reduced the power to detect small differences between UC and HSDC and between UC and CBDC.

The DSAH outcome was based on a definition provided in a highly cited report [1], which excluded days not alive and days in a hospital, nursing home, and hospice facility, but not days spent in assisted living. Hence, new moves to assistive living were not captured. Given the small absolute differences, our null findings cannot be explained by the exclusion of days not alive, which may have been less amenable to the HSDC and CBDC interventions than the health facility components. In addition, DSAH was a pre-specified tertiary outcome that was objectively ascertained using Medicare data, avoiding potential bias from self-reported information. The exclusion of participants without complete Medicare data, however, led to some minor baseline imbalances among the three treatment groups.

In summary, this pragmatic randomized clinical trial of dementia care programs found no significant differences between the health system–based and community-based interventions, or between either intervention and usual care, in DSAH among PLWD over the 18-month intervention period.

Author Contributions

Drs. Greene and Gill had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors meet the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Study concept and design: Gill, Reuben. Acquisition of data: Araujo, Stevens, Williamson, Yang, Galloway, Volpi, Lichtenstein. Analysis and interpretation of data: Gill, Xu, Peduzzi, Greene. Preparation of manuscript: Gill, Greene. Critical revision of the manuscript for important intellectual content: Reuben, Araujo, Liu, Stevens, Williamson, Yang, Galloway, Volpi, Lichtenstein, Jennings, Summapund, Peduzzi.

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Disclosure

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Conflicts of Interest

The authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Supplementary Figure S1:** Assembly of Analytic Sample. The original sample size was 2176, but complete Medicare data were not available for 208 participants, including 92, 103, and 13 in the Health-system dementia care (HSDC), Community-based dementia care (CBDC), and Usual Care (UC) groups, respectively. Part B files were needed to identify overnight hospital observation stays billed in outpatient claims and encounters among participants with fee-for-service Medicare (Part A), in contrast to Medicare Advantage (Part C). **Supplementary Figure S2:** Distribution of Days Not at Home for the Three Treatment Groups over the 18-Month Study Period. Days not at home include days at health care facilities and days not alive. Because the numbers were very small, days in an acute rehabilitation facility were included under hospital. For each box plot, the left border, midline, and right border represent the 25th percentile, median, and 75th percentile values, respectively, while the black diamond represents the mean value. The solid lines from the boxes extend to the 95th percentile. The dashed lines extend to the maximum values. HSDC, Health-system dementia care, CBDC, Community-based dementia care, and UC, Usual Care.

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