Family Caregiver Skills Training to Improve Experiences of Care: a Randomized Clinical Trial

Courtney Harold Van Houtven, Ph.D., MSc.[1,2,3], *Valerie A. Smith, Dr.P.H.*[1,2,4], *Jennifer H. Lindquist, M.S., M.Stat.*[1], *Jennifer G. Chapman, BASW*[1], *Cristina Hendrix, DNS, RN*[5,6], *Susan Nicole Hastings, M.D., M.H.Sc.*[1,4,6,7], *Eugene Z. Oddone, M.D., M.H.Sc.*[1,4], *Heather A. King, Ph.D.*[1,2,4], *Megan Shepherd-Banigan, Ph.D., MPH*[1,2], *and Morris Weinberger, Ph.D.*[8]

[1]Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT), Durham Veterans Affairs Health Care System, Durham, NC, USA; [2]Department of Population Health Sciences, School of Medicine, Duke University Medical Center, Durham, NC, USA; [3]Duke-Margolis Center for Health Policy, Duke University, Durham, NC, USA; [4]Department of Medicine, Duke University Medical Center, Durham, NC, USA; [5]School of Nursing, Duke University Medical Center, Durham, NC, USA; [6]Geriatric Research, Education and Clinical Center, Durham VA Medical Center, Durham, NC, USA; [7]Center for the Study of Human Aging and Development, Duke University, Durham, NC, USA; [8]Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA.

OBJECTIVE: To evaluate the effectiveness of Helping Invested Families Improve Veterans' Experiences Study (HI-FIVES), a skills training program for caregivers of persons with functional or cognitive impairments.
DESIGN: A two-arm RCT.
SETTING: Single Veterans Affairs Medical Center.
PARTICIPANTS: Patients and their primary caregivers referred in the past 6 months to home and community-based services or geriatrics clinic.
INTERVENTION: All caregivers received usual care. Caregivers in HI-FIVES also received five training calls and four group training sessions.
MAIN MEASURES: Cumulative patient days at home 12 months post-randomization, defined as days not in an emergency department, inpatient hospital, or post-acute facility. Secondary outcomes included patients' total VA health care costs, caregiver and patient rating of the patient's experience of VA health care, and caregiver depressive symptoms.
RESULTS: Of 241 dyads, caregivers' (patients') mean age was 61 (73) years, 54% (53%) Black and 89% (4%) female. HI-FIVES was associated with a not statistically significant 9% increase in the rate of days at home (95% CI 0.72, 1.65; mean difference 1 day over 12 months). No significant differences were observed in health care costs or caregiver depressive symptoms. Model-estimated mean baseline patient experience of VA care (scale of 0–10) was 8.43 (95% CI 8.16, 8.70); the modeled mean difference between HI-FIVES and controls at 3 months was 0.29 ($p = .27$), 0.31 ($p = 0.26$) at 6 months, and 0.48 ($p = 0.03$) at 12 months. For caregivers, it was 8.34 (95% CI 8.10, 8.57); the modeled mean difference at 3 months was 0.28 ($p = .18$), 0.53 ($p < .01$) at 6 months, and 0.46 ($p = 0.054$) at 12 months.
CONCLUSIONS: HI-FIVES did not increase patients' days at home; it showed sustained improvements in caregivers' and patients' experience of VA care at clinically significant levels, nearly 0.5 points. The training holds promise in increasing an important metric of care quality—reported experience with care.

KEY WORDS: caregiving; aging; utilization; health care costs; patient satisfaction.

J Gen Intern Med 34(10):2114–22
DOI: 10.1007/s11606-019-05209-x

Prior Presentations *This work was presented in poster form at IAGG, San Francisco (July 2017), and AcademyHealth, Seattle (June 2018). Secondary outcomes were presented in poster form at AcademyHealth, New Orleans (June 2017).*

Received August 27, 2018
Revised April 3, 2019
Accepted June 14, 2019
Published online August 6, 2019

INTRODUCTION

For adults with cognitive or functional limitations, caregiving provided by family and friends is critical to their remaining at home. Nearly 87% of community-residing older adults needing assistance receive care exclusively from informal sources.[1, 2] While many older adults do not wish to burden family members or friends,[3, 4] formally provided home and community-based services (HCBS) are prohibitively costly for most Americans. Because few older adults have viable alternatives to informal care,[2] it is imperative to understand how best to support family caregivers.

Despite ad hoc training by individual health care providers and community agencies, systematic training for family caregivers is limited. Even within the Veterans Administration (VA), which has an extensive caregiver support system, half of caregivers reported inadequate training to perform their caregiving duties.[5] Lack of training raises significant concerns for caregivers, patients, and providers.[6] Training that addresses a broad range of skill gaps may allow caregivers to provide high-quality care without experiencing the negative health consequences of caregiving.[7–9]

Building on previous literature,[10–12] a survey of training needs,[13] and a pilot-test of the intervention, we developed and refined the Helping Invested Families Improve Veterans Experiences Study (HI-FIVES), a skills training program to support family caregivers of persons with cognitive or functional impairment. We targeted patients referred to HCBS or geriatrics clinic because such referrals signal an increase in needs and a change in the type of care required in the home, which could contribute to increased caregiver time demands, uncertainty about tasks, and commensurate increased risk for caregiver burden and depressive symptoms. In addition, time of referral presents a teachable moment for caregivers to learn new skills to safely maintain the patient in the home. We hypothesized that HI-FIVES would significantly increase the number of days a patient spent at home at 12 months compared to caregivers in usual care. Older adults with disability overwhelmingly prefer to remain at home; thus, this primary outcome was selected to reflect a high quality of life day from the patient perspective,[3, 14] making it person- and caregiver-centered.[15–17] More days at home is associated with higher self-rated health, lower mobility impairment, lower rates of depression, and less difficulty in self-care.[18] If increased, this primary outcome will also reflect cost-savings. Secondary outcomes are patients' total VA health care costs at 12 months; perceived quality of VA health care for patients and caregivers at 3, 6, and 12 months; and caregiver depressive symptoms at 3, 6, and 12 months.

METHODS

Setting and Participants

Data pulls identified all Durham VA Health Care System patients who received a referral to HCBS or geriatrics clinic in the prior 6 months. A referral to HCBS requires that a Veteran has 2 or more functional limitations or has a family caregiver experiencing strain. Qualifying HCBS included skilled home nursing care, homemaker home health aide care, home-based primary care, respite care, or adult day health care. Patients were excluded if they had a nursing home referral in the prior 6 months, or if, during chart review, there was no patient telephone number, no primary care provider, resided in an institution, or were hospice-eligible. Telephone screening excluded patients if they had no caregiver or did not permit us to contact the caregiver, were fully independent, unable to communicate in English, or were in an institution or hospital. For eligible patients, we called the family member or friend identified by the patient as most helping the patient at home. Caregivers were excluded if they could not attend four weekly group sessions or communicate via telephone, < 18 years, a professional caregiver, in another caregiver study, had 5 or more errors on the short portable mental status questionnaire (SPMSQ),[19] or indicated the patient was in a hospital, institution, or terminally ill. Both the caregiver and patient had to qualify for the study. Informed consent was obtained during an in-person enrollment visit. The IRB of record approved this study.

Randomization

Dyads were randomized to HI-FIVES or usual care via a computer-generated randomization sequence. Randomization was stratified by patients' cognitive status (≥ 5 errors on SPMSQ) and health care use (≥ 2 hospitalizations in past 12 months) with a block size of 4. Within 1 week of enrollment, the project director called the caregiver, initiated the tracking database to retrieve arm assignment, and informed the caregiver of their assignment.

Intervention

Caregivers in the HI-FIVES group chose four topics from a list of 12 that they wished to learn (e.g., "how to ask for more help"; details appear in Van Houtven et al., [20]). Each caregiver received a nine-session intervention: three weekly individual protocolized telephone training calls conducted by the interventionist; four weekly group sessions; and two individual booster calls at 1 and 2 months post-group training.

The first phone session focused on medication reconciliation, with the caregiver gathering the patient's medications for the call. To activate caregivers in their caregiving role, the interventionist used motivational interviewing techniques to solicit an action item the caregiver would be willing to complete. The interventionist asked, "What is the one thing that you think you could do better for the patient in helping him/her with his/her medications?" In the next call, the interventionist revisited the action item. Thereafter, the discussion focused on topics that caregivers selected to learn and ended by eliciting a new action item, saying: "What one thing would you be willing to do to make a positive change in your situation?" The three phone calls occurred weekly and some overlapped with group training.

Each group training lasted 1.25 hours with the interventionist in a private conference room. The group training related directly to supporting caregiving activities in the clinical, psychological, and support seeking skill domains (see[21]). The clinical topics focused on common care issues that arise in persons with limitations in activities of daily living (ADLs) or instrumental activities of daily living (IADLs). Examples include safe transferring, protecting one's back, and checking the home for safety (locks, firearms, tripping hazards). The psychological topics focused on self-care. The support seeking topics focused on navigating the health care system and requests for help. A VA Caregiver Support Coordinator helped teach class 4 and focused on planning for the future and VA Caregiver Support Program services and supports.

One and 2 months after group training ended, the interventionist conducted booster training calls. In the first, the interventionist revisited the action item from the third training call and asked if there was anything from the group training that required discussion. If so, they discussed that topic and created one final action item. If not, the interventionist probed about other possible issues based on recorded notes from previous calls. In the second booster call, the interventionist asked about the action item from the prior call and checked in on how the caregiver and patient were doing generally. In all, the nine-session intervention occurred over about 12 weeks.

Usual care dyads received information about the VA Caregiver Support Program. Study staff were not involved in care of patients and obtained study assessments at baseline and 3, 6, and 12 months per protocol, blinded to treatment assignment. Caregivers randomized to HI-FIVES were paid $55 per class, reflecting the replacement cost of the caregiver's time, transportation, and parking. Caregivers received $10 for each phone call and each survey. The maximum received was $310 for treatment and $40 for control caregivers.

MEASURES

Primary Outcome

Our primary outcome was number of days at home, i.e., not in emergency department (ED), hospital or post-acute facility, during the 12 months following randomization. The funded grant definition included any nursing home facility days. Prior to analysis, we refined the definition and analysis to be limited to post-acute care facility days, because a residential nursing home care transition (> 60 days) may be consistent with patient and caregiver preferences.[15, 16] As such, for patients who died or entered a residential nursing home or residential psychiatric inpatient unit, we censored days after the event. We examined days at home incorporating such residential stays in sensitivity analyses. Hospice days in a facility were not included because hospice care also may be consistent with patient preferences.

We used VA administrative data and non-VA medical records. Non-VA medical records were needed because, as Medicare beneficiaries, most Veterans qualified for non-VA services. Caregiver assessments ascertained dates and names of non-VA emergency department, hospital, and nursing home use. The team confirmed this utilization through a medical record request. Each day with an ED encounter was 1 day not at home. Inpatient days were calculated using admission and discharge dates. A post-acute facility stay was any nursing facility stay of $\leq$ 60 days immediately following hospital discharge. In a previous trial of patients with heart failure considering inpatient use, an increase in 1 day at home over 12 months was clinically important.[22] Because we include both post-acute care and ED visits, we defined a priori a 2.5-day increase in the number of days at home over 12 months as clinically meaningful.

Secondary Outcomes

VA total health care costs included VA and non-VA contracted care. Total costs of utilization were aggregated across inpatient and outpatient fields from randomization to 12 months later.[23]

Patient and caregiver experience of VA care (CAHPS) is used by the VA Office of Performance and Quality as a key measure for operational initiatives to assess and improve quality of care. "Using any number from 0 to 10, where 0 is the worst health care possible and 10 is the best health care possible, what number would you use to rate all your [the Veteran's] health care in the VA in the last 3 months?" The primary time point was post-treatment (~3 months), but we also modeled 6- and 12-month time points simultaneously in a longitudinal model.

Caregiver Depressive Symptoms. The widely used and validated CESD-10 was the depressive symptoms measure.[24] The primary time point was post-treatment (~3 months) but we also modeled 6- and 12-month time points simultaneously in a longitudinal model.

Demographics and Clinical Measures. Caregiver. Self-reported demographic characteristics included relationship to the patient, age, gender, race/ethnicity, education, working status, and marital status. Subjective burden came from the Zarit burden measure,[25] and relationship satisfaction came from the caregiver relationship subscale of the Caregiver Appraisal Scale.[26, 27]

Patient. Caregivers reported patient demographics. A list of selected comorbidities highly prevalent in older adults was pulled from Hierarchical Condition Categories.[28]

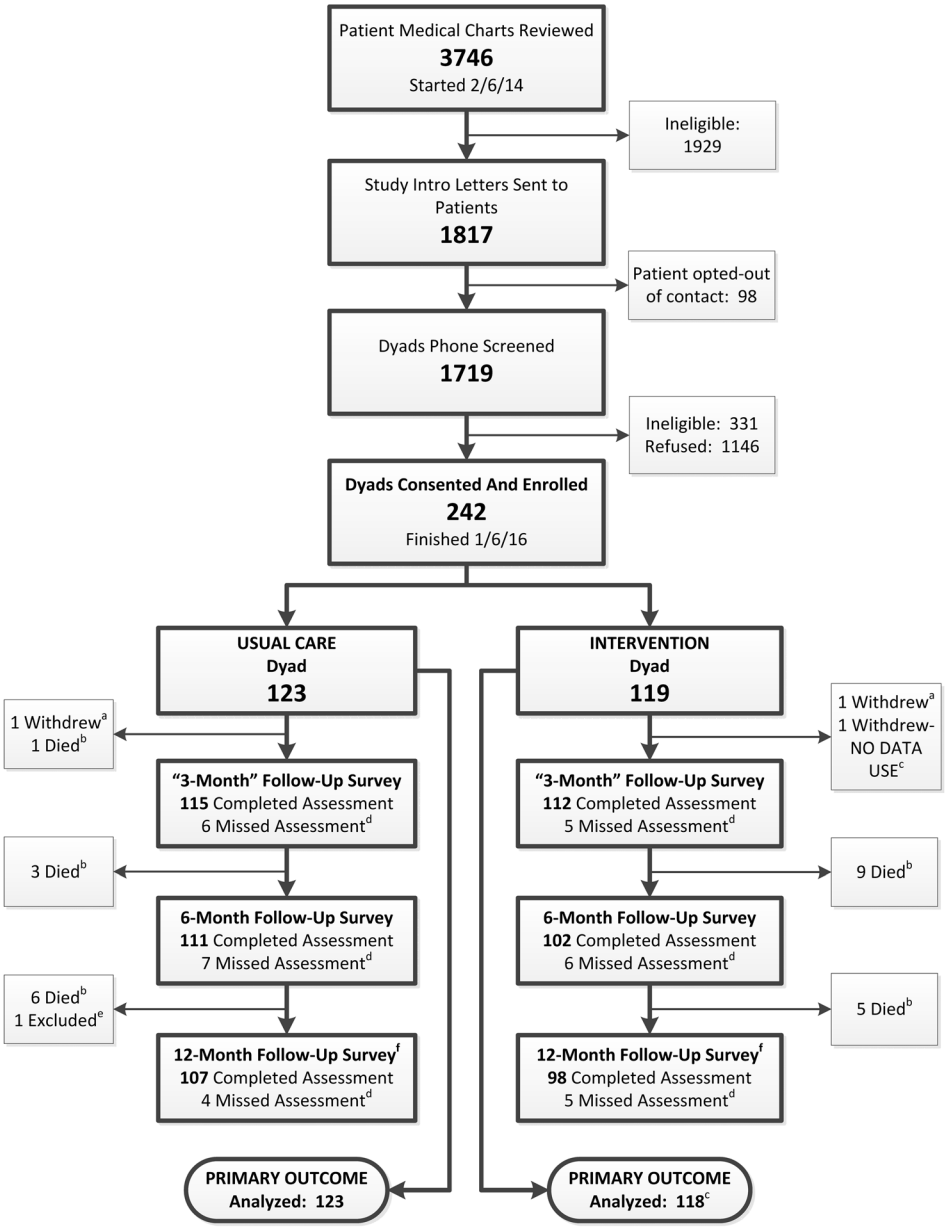
Treatment Fidelity. One study team member attended all group sessions to assess fidelity to a checklist of topics. We also audiotaped all calls in which written consent was granted. Two investigators reviewed 2 calls from each training module to compare against the semi-structured script and to assess general quality. Feedback was provided to the interventionist, as needed.

Statistical Analysis

The sample size calculation was based on the primary hypothesis that the HI-FIVES intervention would lead to an average of 2.5 more days at home over 12 months. To have 85% power to detect this difference using a zero-inflated Poisson model at a two-sided 0.05 significance level and an expected attrition of 15%, we planned to randomly assign 240 patient-caregiver dyads.

Primary Hypothesis

We analyzed days *not* at home so the larger stack of values would be at zero, allowing consideration of zero-inflated models, while providing inference on days at home. We compared the fit of marginalized zero-inflated Poisson and negative binomial models[29, 30] and standard Poisson and negative binomial models using Akaike Information Criterion (AIC). The standard negative binomial model, producing the best fit, was estimated in SAS PROC GENMOD. The model included an indicator for study arm as well as the centered stratification variables and an offset for the maximum number of days an individual



[a] A member of dyad chose to withdraw. Did not conduct follow-up survey assessments with either member of dyad. Included available data in analysis.
[b] A member of dyad died. Did not continue with assessments with other member of dyad. We included patients in analysis up until the time of death.
[c] One member of dyad withdrew permission to use their data. Data from this dyad removed from all analyses.
[d] Could not reach informal caregiver for assessment survey, tried again at next time point, if applicable.
[e] Caregiver no longer appropriate for study participation due to provider and family reported significant cognitive impairment.
[f] Last 12-month follow-up survey conducted on 12/22/2016

Fig. 1 CONSORT flow chart.

could have spent at home prior to censoring. The primary treatment effect was the incidence density ratio (IDR), or difference in rate between arms of days spent at home.

To assess sensitivity to changes to the definition of days at home, we explored a sensitivity analysis determined a priori. We re-analyzed days at home, using the same principles as followed for the primary outcome, but including nursing home stays as days not at home.

Secondary Hypotheses

Total VA Health Care Costs. We first examined the proportion of zeros and overall distribution. Because the proportion of zeros was low, we used a generalized linear model fit using quasi-likelihood; we conducted specification testing to identify the best link function and distribution following the guidelines in Manning and Mullahy.[31] Our final model incorporated

Table 1 Baseline Characteristics of HI-FIVES Participants

	Caregiver		Patient	
	Control	Intervention	Control	Intervention
Study participants, *n* (%)	123 (51.0)	118 (49.0)	123 (51.0)	118 (49.0)
Mean age, (SD)	61.8 (12.60)	59.9 (11.78)	72.9 (12.12)	73.7 (11.24)
Female, *n* (%)	111 (90.2)	103 (87.3)	5 (4.1)	4 (3.4)
Race—all that apply, *n* (%)				
Black	71 (57.7)	58 (49.2)	71 (57.7)	56 (47.5)
White	58 (47.2)	63 (53.4)	54 (43.9)	64 (54.2)
Other/missing	16 (13.0)	11 (9.3)	14 (11.4)	8 (6.8)
Ethnicity (Hispanic or Latino), *n* (%)	4 (3.3)	2 (1.7)	4 (3.3)	1 (0.8)
Married/living together, *n (%)*	100 (81.3)	89 (75.4)	88 (71.5)	78 (66.1)
High school or less, *n* (%)	38 (30.9)	29 (24.6)	50 (40.7)	55 (46.6)
Working full/part-time, *n* (%)	36 (29.3)	41 (34.7)		
Financially strained, *n* (%)*	49 (39.8)	61 (51.7)	43 (35.0)	61 (51.7)
SPMSQ, ≥ 5 errors, *n (%)*†			31 (25.2)	30 (25.4)
> 1 VA hospitalization in year prior to HCBS referral, *n (%)*			30 (24.4)	27 (22.9)
OARS, total ADL/IADL impairment, *n (%)*¥			76 (61.8)	74 (62.7)
Mean number of ADL + IADL limitations (SD)			9.07 (3.63)	9.63 (3.37)
≥ 2 ADL or IADL limitations (unable to do or need help to do), *n (%)*			120 (97.6)	117 (99.5)
Patient comorbidities‡				
Diabetes, *n* (%)			63 (51.2)	58 (49.2)
Stroke/neurologic disorder, *n* (%)			50 (40.7)	54 (45.8)
Cardiovascular disease, *n* (%)§			46 (37.4)	44 (37.3)
Dementia, *n* (%)			33 (26.8)	42 (35.6)
Kidney disease, *n* (%)‖			35 (28.5)	40 (33.9)
Chronic obstructive pulmonary disease/lung problems, *n* (%)			26 (21.1)	32 (27.1)
Cancer, *n* (%)			26 (21.1)	25 (21.2)
Amputation/complications, *n* (%)			17 (13.8)	22 (18.6)
Caregiver is the Veteran's …, *n* (%)				
Spouse/significant other	82 (66.7)	72 (61.0)		
Other relative	31 (25.2)	38 (32.1)		
Other	10 (8.1)	8 (6.8)		
Years caregiving, median (Q1–Q3)	3.0 (1.5–8.0)	4.0 (1.0–9.0)		

Blank cells represent data not collected for that participant type (caregiver or patient)
**Defined as "barely getting by", "falling behind", or "in serious financial trouble"*
†Caregivers not eligible to participate if they had ≥ 5 errors
¥Total impairment is defined as requiring assistance in performing 8 or more basic or instrumental activities of daily living out of a total of 14[33]
‡Comorbidity categories are based on hierarchical condition categories (HCCs) as identified in the VA computerized patient medical record system
§Coronary heart disease/heart attack/CAD/congestive heart failure
‖ Chronic kidney disease, dialysis, acute renal failure

a variance structure proportional to the mean with a log link. Terms in the model included study arm and the two centered stratification variables; empirical standard errors were utilized to accommodate potential over-dispersion or variance misspecification.

Perceived Quality of Care and Caregiver Depressive Symptoms. A linear mixed model was used to estimate changes in satisfaction and depressive symptoms over time.[32] Our model incorporated an indicator for the 3 follow-up time points and the interaction of study arm with each follow-up time interval. Baseline was constrained as equal across study arms and centered stratification variables were included. We assumed an unstructured covariance matrix to represent the correlation among caregivers' repeated measures and models were fit using SAS PROC MIXED (SAS Institute, Cary, NC). Model-estimated means and confidence intervals were obtained using ESTIMATE statements. Centered stratification variables were set to zero, thereby estimating the mean outcome values at the observed mean values of cognitive function and prior hospitalizations. This allows interpretation of mean trends by group over time, paired with confidence intervals to convey the level of precision with which the mean is estimated.

RESULTS

Of 3746 patients with qualifying referrals to HCBS or geriatrics over the study period (Fig. 1), 1817 were eligible by chart review and sent an introduction letter, 98 of whom opted out. An additional 331 screened ineligible and 1146 refused participation, leaving 242 dyads consented and enrolled (13.3% of contacted). One dyad withdrew requesting their data not be used, leaving 123 usual care and 118 HI-FIVES dyads. Because the primary outcome used administrative data, our primary analysis suffered no loss to follow up; completion rates of 3, 6, and 12-month assessment varied, with 205 survey assessments completed for secondary outcomes at 12 months. The demographic characteristics of

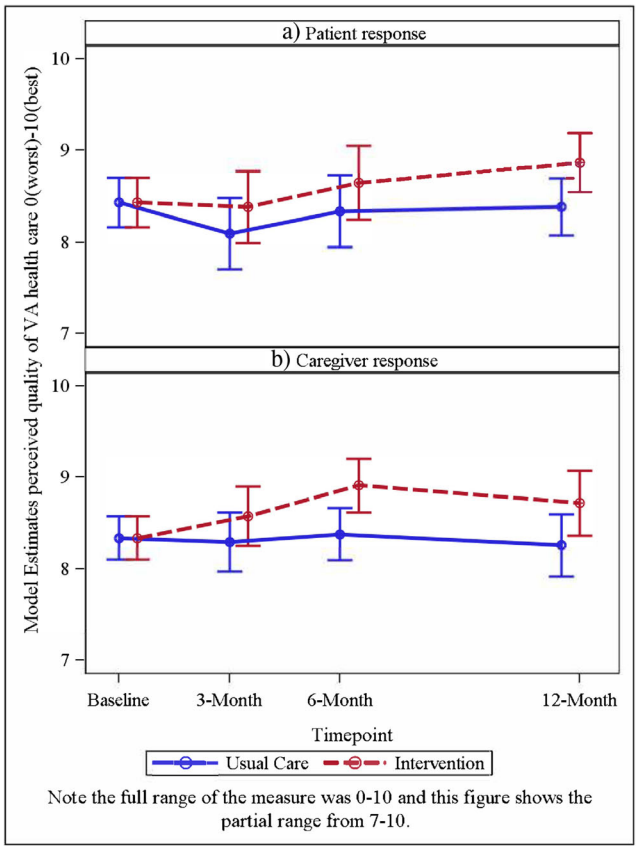


Fig. 2 Perceived quality of VA health care in the past 3 months, assessed at baseline and 3, 6, and 12 months post-randomization.

patients and caregivers appear in Table 1. The groups were balanced on mean number of IADL and ADL impairments (9 total).[33] Comorbid conditions at baseline appeared different by group, with intervention subjects having higher rates of stroke, dementia, amputations, and lung problems.

HI-FIVES Implementation

Intervention call completion rate was 96.9%, and mean phone call duration was 45 min. Group class attendance was 79.1%. Of 12 phone training topics caregivers could select, the most popular were "planning for the future" (48.8% of caregivers selected this); "coping with a frustrated or angry Veteran" (47.5%); "when and how to ask for more help" (46.7%); and "management of stress" (45.5%).

Patient Days at Home

Patients randomized to the intervention experienced a non-significant 9% increase (point estimate 1.09, 95% CI 0.72, 1.65) in their days at home, translating to a mean difference of 1.0 day over a year. Sensitivity analysis that included "any nursing home stays as days not at home" estimated HI-FIVES led to 5.8 more days at home (35% increase) over 12 months (95% CI −0.13, 2.09).

Secondary Outcomes

There were no significant differences in VA health care costs at 12 months. Model-estimated mean baseline caregiver experience of VA care quality (0–10 scale) was 8.34 (95% CI 8.10, 8.57); the modeled mean difference between HI-FIVES and controls at 3 months was 0.28 ($p = .18$), 0.53 ($p < .01$) at 6 months, and 0.46 ($p = 0.054$) at 12 months (Fig. 2). Model-estimated mean baseline patient experience of VA care quality was 8.43 (95% CI 8.16, 8.70); the modeled mean difference between HI-FIVES and controls at 3 months was

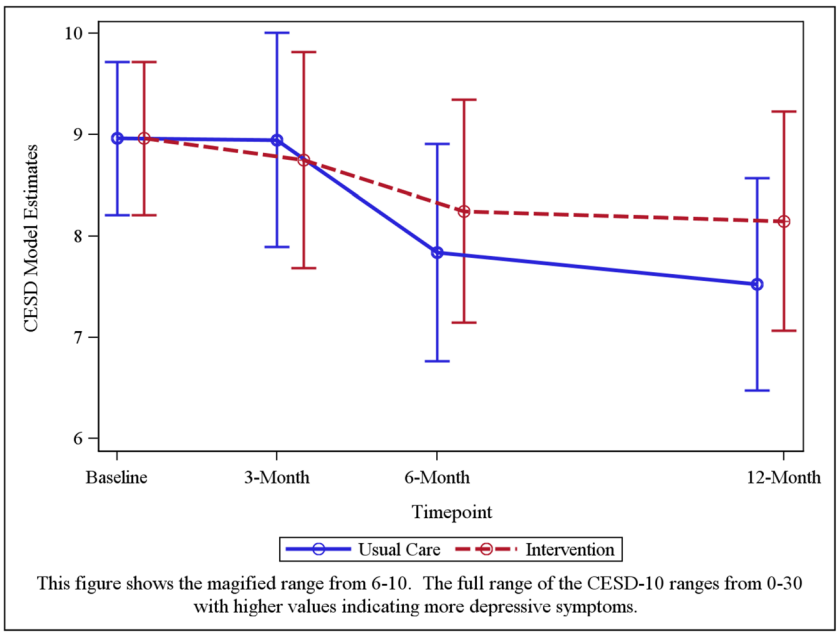


Fig. 3 Estimated effects of HI-FIVES on caregiver depressive symptoms (CESD-10) assessed at baseline and 3, 6, and 12 months post-randomization.

Table 2 Description of Other Caregiver Self-reported Measures of Well-being

Description of measure	Usual care	Intervention
Number of respondents		
Baseline	123	118
3 months	115	113
6 months	111	102
12 months	107	98
Subjective burden score	Mean (SD)	Mean (SD)
Baseline	18.3 (9.3)§	19.6 (10.0)
3 months	16.7 (9.1)‖	17.4 (9.5)
6 months	15.1 (9.1)	15.7 (9.1)
12 months	16.4 (9.1)	15.9 (9.0)
High subjective burden (%)*	%	%
Baseline	56.2§	60.2
3 months	53.5‖	52.2
6 months	47.7	43.1
12 months	45.8	49.0
Objective burden-average hours/week†	Median (Q1–Q3)	Median (Q1–Q3)
Baseline	59.5 (28.0–105.0)	71.75 (31.5–112.0)
3 months	64.0 (35.0–112.0)§	63.0 (31.5–112.0)§
6 months	52.5 (20.0–112.0)	59.5 (21.0–112.0)
12 months	70.0 (21.0–126.0)‖	66.5 (21.0–112.0)
Positive aspects of caregiving‡	Mean (SD)	Mean (SD)
Baseline	35.4 (7.5)	34.8 (7.9)
3 months	34.8 (8.5)	37.0 (7.3)
6 months	36.4 (7.2)	36.9 (7.3)
12 months	35.8 (8.1)	36.8 (7.4)
Current health is fair or poor	(%)	(%)
Baseline	35.8	35.6
3 months	29.6	33.9
6 months	32.4	31.4
12 months	35.5	35.7
Health worse than 3 months ago	(%)	(%)
Baseline	8.1	12.7
3 months	13.2‖	17.1
6 months	12.6	12.8
12 months	15.0	14.3

**Zarit score ≥ to 17*
†Caregiving hours in past week. Distribution was skewed so median, quartiles presented
‡Summary score where higher score means experiences more positive aspects of caregiving
§Two missing responses
‖ One missing response

Table 3 Descriptive Detail on Veteran Utilization During 12 Months Post-randomization

	Usual care	Intervention
Days not in the community, median (Q1–Q3)		
Days in the ED, median (Q1–Q3)	2 (0–3)	2 (0–3)
Days in the hospital, median (Q1–Q3)	0 (0–5)	0.5 (0–6)
Days in post-acute facility, median (Q1–Q3)	0 (0–0)	0 (0–0)
Any ED visit, *n* (%)	92 (74.8)	82 (69.5)
Any hospitalization, *n* (%)	64 (52.0)	59 (50.0)
Any facility-based long-term services and supports (LTSS), *n* (%)*	25 (20.3)	27 (22.9)
Any post-acute facility stay, *n* (%)†	17 (13.8)	15 (12.7)
Any short-term nursing home stay, *n* (%)‡	12 (9.8)	15 (12.7)
Any residential nursing home stay > 60 days, *n* (%)§	8 (6.5)	4 (3.4)
Any home and community-based LTSS, *n* (%)	61 (49.6)	61 (51.7)
Homemaker/home health aide services (H/HHA), *n* (%)	49 (39.8)	42 (35.6)
Home health nursing services, *n* (%)	10 (8.1)	4 (3.4)
Home-based primary care, *n* (%)	14 (11.4)	9 (7.6)
Adult day healthcare, *n* (%)	9 (7.3)	17 (14.4)
Respite care, *n* (%)	28 (22.8)	37 (31.4)
Any geriatric clinic visit, *n* (%)	33 (26.8)	39 (33.1)
Any home and community-based LTSS or geriatric clinic visit, *n* (%)‖	68 (55.3)	70 (59.3)
Number of observations	123	118

**Includes post-acute care, short-term, and residential care*
†Defined as a nursing home stay (1) within 1 day on an inpatient discharge and (2) with a length of stay (LOS) of 60 days or less
‡Defined as a nursing home stay (1) NOT within 1 day of an inpatient discharge and (2) with a LOS of 60 days or less. Not counted as a day not at home. Not censored
§Defined as a nursing home stay of 61 days or more. Nursing home type can be CLC, CNH, domiciliary, etc. Cases censored at first date of this type of stay and days spent in this setting not included in the primary outcome count of days not at home
‖ 100% of patients had a referral to home and community-based LTSS or geriatric clinic in the 6 months prior to consent (eligibility criteria)

0.29 ($p = .27$), 0.31 ($p = 0.26$) at 6 months, and 0.48 ($p = 0.03$) at 12 months (Fig. 2). Model-estimated mean baseline caregiver CESD-10 was 8.96 (95% CI 8.21, 9.72). No significant differences were observed, although both groups experienced declines in CESD-10 (Fig. 3).

For caregiver measures (Table 2), the proportion of caregivers with high subjective burden (Zarit score ≥17) fell by 11 percentage points at 12 months in both arms. Additionally, whereas the positive aspects of caregiving score did not change for usual care caregivers over time, caregivers in HI-FIVES gained 2 points, indicating a more positive rating. Table 3 illustrates health care utilization, showing over 70% of patients had an ED visit and 50% had an inpatient hospitalization in the 12-month follow-up. Whereas all subjects had received a referral to HCBS or geriatric clinic in the 6 months prior to enrollment, just over half used those services in the 12-month follow-up.

DISCUSSION

The HI-FIVES trial evaluates a strategy to improve caregivers' and patients' experiences with care during a difficult time, when a patient has received a referral to HCBS or geriatrics. Caregiver skills training statistically significantly increased the patient and the caregiver's perceived experience with care received by the patient up to 12 months following the intervention and showed potentially positive, yet non-statistically significant, trends towards increasing days at home.

A priori the team viewed a 2.5-day gain in days at home over a 12-month period to be clinically significant. The gain of 1.0 to 5.8 days at home, depending on the definition of nursing home use, approached clinical significance. This discrepancy in magnitude was in part driven by 8 individuals in the usual care arm experiencing long nursing home stays (> 60 days) compared to 4 in the HI-FIVES arm. Thus, a trial with more dyads may be necessary to obtain a more stable and accurate estimate. In addition, researchers should obtain data directly from caregivers and patients to learn what they consider to be a meaningful increase in days at home for their quality of life and whether setting of care affects quality of life differently.

The researchers testing the "days at home" construct have thus far considered different utilization types in its calculation.[16–18, 34] Therefore, work to arrive at a universal definition could facilitate cross-study comparisons.

The increase in patient and caregiver experiences of VA care, as measured by the global rating of quality of care the patient recently received, was about 0.5 points on a 0–10 scale. For context, mean VA scores nationally reported by patients over the past 10 years were remarkably stationary, changing by at most a 1/10th of a point from year to year.[35, 36] Therefore, that HI-FIVES increased scores by nearly half a point for patients and caregivers on average could be interpreted favorably by VA decision makers, who use these scores as health system performance metrics. Whether a 0.5-point increase in the score is universally viewed as a clinically meaningful change, however, is unknown. Future work could assess meaningful gain from the caregiver and care recipient perspective.

We note three main study limitations. First, we tested HI-FIVES in a single VA medical center limiting the generalizability of our findings, including in non-VA settings, which do not have as extensive geriatrics and extended care services. Second, the study was likely underpowered to detect statistically significant differences in our primary outcome. Power calculations based on pre-study VA utilization data of similar VA patients referred to HCBS led us to assume a Poisson distribution, thereby equating the variance to the mean days not at home. Our variance was instead approximately 22 times higher than the mean. Thus, a larger sample size may have been needed to detect true differences. Third, although functional limitations (Table 1) were identical across groups, the intervention group had higher rates of stroke, dementia, amputation, and lung problems compared to usual care; it is unclear how comorbidity differences may have affected study outcomes.

This study also has multiple strengths. We successfully delivered family caregiver skills training with high fidelity and measured the effects of caregiver skills training on meaningful measures of quality of life for caregivers and their care recipients. Many prior studies have focused exclusively on caregiver outcomes to establish effectiveness, which prevents measuring any positive spillover effects of training on care recipients.[21] Second, we enrolled caregivers of a heterogeneous patient population at high risk of "bad" outcomes, including inpatient hospitalization and subsequent post-acute care. The patients had functional and cognitive impairment in common that prompted referral to HCBS or geriatrics, but had no index health condition and different comorbidity profiles. This strategy was intentional so, if successful, we could disseminate the training to a broader population in need rather than focusing on persons with a single index condition such as Alzheimer's disease, stroke, or cancer. Third, we enrolled a group of racially diverse and financially strained study members, often underrepresented in research. Fourth, the intervention and its content were designed to link participants to existing caregiver support services.

Lastly, we make a significant methodological contribution. Medical record requests to confirm non-VA care uncovered 25% of ED visits, 28% of inpatient visits, and 64% of post-acute facility care that were otherwise uncaptured. Overall, 99.3% of non-VA facilities provided records requested. Typically, trials in VA are unable to include Medicare claims due to lags in their release. While time-consuming, obtaining non-VA utilization should be considered by investigators conducting RCTs where there is multi-system health care use, especially for outcomes intended to capture the full universe of a person's utilization. To increase generalizability within VA and to address the power concerns of the single site RCT, in 2018, we began delivering HI-FIVES at 8 VA medical centers nationally using a type III hybrid effectiveness-implementation stepped-wedge CRT design. Investigators interested in replicating and/or implementing HI-FIVES may contact our team for a toolkit.

CONCLUSION

Implementing HI-FIVES on a broader scale in VA could fill the observed training gap whereby 50% of caregivers report not receiving the training they need. The training holds promise in increasing an important metric of care quality—reported experience with care. Other strategies, however, may be needed to increase patient days at home and address high caregiver depressive symptoms. Future work should also examine whether subsets of patient and caregiver dyads (e.g., persons with high functional impairment), benefited differentially compared to the average treatment effects reported here.

Acknowledgments: *We thank the members of the study's advisory board, for excellent input and expertise on the study: Peggy Becker, Dayna Cooper, Darlene Davis, Thomas Edes, Margaret Kabat, Christy Knight, Jennifer Martindale-Adams, Linda Nichols, Kenneth Shay, Scott Trudeau, and Laura Wray. We are grateful to Maren Olsen and Brian Neelon who provided early statistical support of this project. We thank our interventionist, Shirley Barnhart, Josh D'Adolf who taught class 4 from the VA Caregiver Support Program, and our research assistant, Laurie Marbrey, and we sincerely thank the caregivers and veteran patients who participated in the study.*

Corresponding Author: *Courtney Harold Van Houtven, Ph.D., MSc.; Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT), Durham Veterans Affairs Health Care System, HSRD 152, 508 Fulton Street, Durham, NC 27705, USA (e-mail: courtney.vanhoutven@duke.edu).*

Funding *This study was supported by the U.S. Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Health Services Research and Development Service (IIR 11-345) and by the Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT) (CIN 13-410) and Geriatrics Research Education and Clinical Center. Megan Shepherd-Banigan was supported by a VA OAA HSR&D PhD Fellowship TPP 21-027. Dr. Weinberger, at the time of this research, was supported by the U.S. Department of Veterans Affairs, Veterans Health*

Administration, Office of Research and Development, Research Career Scientist Program (RCS 91-408).

Data Availability The datasets created and analyzed during the current study are available from the corresponding author upon reasonable request.

Compliance with Ethical Standards:

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

Disclaimer: *The contents of this manuscript are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Veterans Affairs.*

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