

Original Research

Moderators of Treatment Outcomes from Family Caregiver Skills Training: Secondary Analysis of a Randomized Controlled Trial

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Abstract

Background: Moderator analyses may be helpful for evaluating intervention effects. The objective of this study was to evaluate whether the effect of a caregiver skills training intervention – Helping Invested Families Improve Veterans' Experience Study (HI-FIVES) – on care recipient outcome and caregiver outcome is moderated by the veteran's risk for hospitalization or level of functional impairment.

Methods: Secondary data analysis of HI-FIVES. Outcomes included veteran days in the community (cumulative days in the community at 12 months alive and not in the emergency department, hospital, or post-acute facility) and caregiver burden (Zarit Burden Interview at baseline, 3, 6, and 12 months). Moderators, risk for hospitalization and functional impairment, was assessed using their Care Assessment Need (CAN) score and the Older



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Americans Resources and Services (OARS) Questionnaire, respectively. Negative binomial and linear mixed models were used to assess intervention effects on community days and caregiver burden, respectively.

Results: Of 241 dyads, veteran (caregiver) mean age was 73 (61) years, 53% (54%) were Black, and 4% (89%) were female. Medium hospitalization-risk (91-98 CAN score) participants who received HI-FIVES had 3.75 times *more community days* vs. medium risk participants in the control group. By contrast, the high hospitalization-risk (99+ CAN score) participants who received HI-FIVES had 4.39 times *fewer community days* vs. high-risk participants in the control group. The CAN score did not have a significant moderating effect on caregiver burden. OARS did not have a significant moderating effect on community days or caregiver burden.

Conclusions: Targeting the HI-FIVES based on hospitalization risk may be an effective strategy for keeping veterans in the community longer.

Keywords

Disability; functional limitations; caregivers; veterans

1. Introduction

Nearly 8 million dependent older adults reside in the community and rely on informal caregivers for assistance [1]. Caregiving tasks include helping with activities of daily living (ADLs) such as personal hygiene, dressing and undressing, or instrumental activities of daily living (IADLs) such as taking prescribed medications, shopping for groceries, and transportation. Caregiving can be a satisfying experience if caregivers are adequately prepared and confident in their abilities [2]. However, to the degree that caregiving requires physical, psychological, social and economic resources, it can also be perceived as “burdensome,” especially for the primary caregiver [3]. The primary caregiver, or person designated to assume most of the responsibility for the older adults’ well-being, is more susceptible to burden [4], which can lead to depression, compromised physical health, hospitalization, and/or work interference [5, 6]. Caregiver burden is a powerful predictor of whether disabled older adults will stop receiving care “at home” or in the community, where they prefer to be, and whether they will be permanently placed into nursing homes [7-9]. Furthermore, many older adults have limited access to formal home and community-based services, and most caregivers report a lack of essential training needed to care for their loved ones, which suggests the need for enhanced support for caregivers [10].

1.1 Significant Gaps in Caregiver Research

Research on the effectiveness of interventions to support caregivers is limited in five ways. First, most studies focused on one disease of interest (i.e., Alzheimer’s disease), which precludes conclusions about a large swath of the at-risk primary care population – patients with multiple, clinically complex conditions. Second, most caregiver trials have focused on caregiver outcomes and less frequently on outcomes of the care recipient [11]. Care recipient outcomes reflect a

comprehensive dyadic experience, and are more indicative of the care recipient's quality of life (e.g. how the care recipient experiences healthcare and his/her independence). Given that care recipients would rather be at home than in healthcare facilities [12], "days in the community" represents a useful recipient-centered outcome of interest. Third, the sparse work on care recipient outcomes have neglected the large population of "military caregivers" who care for wounded, ill, and injured military personnel and veterans [13-15]. Finally, the majority of caregiver trials developed to reduce emergency department visits, hospitalizations, and nursing home placements have focused on efficacy and effectiveness of the intervention itself, which Guralnick [16] refers to as *first-generation research*; with one exception [17], all have failed to show significant reductions in either hospitalization or nursing home placement [18, 19]. One explanation of non-significant findings, aside from concerns about inadequate power, is that caregiver supports have yet to appropriately target individuals at risk for institutionalization during a vulnerable time in the care continuum. There is an urgent need for *second-generation research* [16] to focus on targeting scarce resources and caregiver supports for individuals at highest-risk of exiting their homes through an emergency department, acute or post-acute facility.

In this study, we evaluate how two care recipient factors (hospitalization risk and level of functional impairment) moderate the effects of a caregiver skills training intervention – Helping Invested Families Improve Veterans' Experience Study (HI-FIVES) – on a care recipient outcome (cumulative days alive and not in the emergency department, hospital, or post-acute facility at 12 months) and caregiver outcome (perceived burden).

2. Materials and Methods

2.1 Overview of HI-FIVES Program

The HI-FIVES training program was designed to support caregivers of cognitively and/or functionally impaired, community-dwelling veterans who have been referred to receive formal home care services. Eligible participants completed a baseline assessment and were randomized to an information-only usual care group or intervention group (HI-FIVES). For caregivers in the HI-FIVES group, three weekly individual phone training sessions occurred, followed by four weekly group-training sessions, and two additional phone-training sessions. All participants received information about the VA Caregiver Support Services Program services, including a hotline number. See Van Houtven et al [20], for further description of the study design, methodology, and protocol.

Authors report no personal or financial conflicts. This study was approved by the Durham VAMC Institutional Review Board.

2.2 Setting and Participants

HI-FIVES participants were eligible based on receiving a referral to Home and Community-based Services (HCBS) – qualifying HCBS included skilled home nursing care, homemaker home health aide care, home-based primary care, respite care, or adult day healthcare. We also targeted veterans referred to a VA geriatrics clinic, as they face similar deficits in function and cognition as HCBS-referred veterans. In the electronic health record, we identified all veterans who received a referral to HCBS or VA geriatrics clinic in the prior 6 months. Veterans were excluded if (1) they had a nursing home or hospice referral in the prior 6 months or (2) there was no veteran

telephone number or primary care provider listed in their chart. During telephone screening, we further excluded veterans if they (1) had no caregiver or did not permit us to contact the caregiver, (2) were fully independent, (3) unable to communicate in English, or (4) were in an institution or hospital. Caregivers were excluded by phone if (1) they could not attend four weekly group sessions, (2) could not communicate via telephone, (3) were <18 years, (4) were participating in another caregiver study, (5) had 5 or more errors on the short portable mental status questionnaire (SPMSQ), or (6) indicated that the veteran was in the hospital, an institution or terminally ill. Both the veteran and caregiver had to qualify for the study, and informed consent was obtained during an in-person enrollment visit with the dyad. The final sample included 241 veteran/caregiver dyads.

2.3 Outcome Variables

We examined two outcomes: (1) veteran days in the community and (2) caregiver burden. The first outcome was cumulative number of days the care recipient spends in the community (not in emergency department (ED), hospital or post-acute facility) during the 12 months following enrollment and is a measure of quality of life. For veterans who died or entered a residential nursing home or residential psychiatric inpatient unit ("residential" is defined as a stay >60 days), we only examined the location of the veteran up until their transition to a more permanent change in residence or until death occurred. The second outcome was caregiver burden, measured using Zarit Burden Interview scale. The Zarit scale was developed to measure subjective burden among caregivers of adults with dementia [21]. We used the 12-item short version of the Zarit scale, which consists of two domains, personal strain and role strain. Each question was scored in five-point Likert scale from 0 to 4 (never to almost always). Scores range from 0 (low burden) to 48 (high burden). Detailed psychometric information regarding the Zarit scale has been previously reported [22]. The Zarit scale was collected in-person at baseline and by telephone from caregivers at 3, 6, and 12 months post-randomization.

2.4 Moderating Variables

The Care Assessment Need (CAN) is a risk score, which reflects the estimated probability of hospital admission or death [23, 24]. Computer algorithms scan the electronic health record of each veteran and generate a CAN score (0 = lowest risk, 99 = highest risk). Predicting veterans at risk for hospital admission or death within a specified time period (90 days or 1 year) can inform coordination efforts of health care professionals working together to ensure veterans get the right care at the appropriate time, resulting in lower veteran distress, fewer hospitalizations, and reduced medical costs [25]. The CAN score consists of 36 data elements including veteran demographics, vital signs, clinic visits, inpatient and outpatient utilization, medications, labs, and coexisting conditions. To address the study's objective, we first divided the veteran cohort into three subgroups: 0 to 90 (n=131), 91 to 98 (n=72), and 99+ (n=38) representing low, medium, and high-risk veterans. CAN score risk groups were determined using a pooled distribution.

Functional status of veterans was measured using the Older Americans Resources and Services (OARS) Questionnaire [26]. The variable was operationalized using a composite of seven activities of daily living (ADLs): eating, dressing, grooming, walking, bathing, using the toilet, and transferring in and out of bed; and seven instrumental activities of activities of daily living (IADLs):

meal preparation, transportation, laundry, housekeeping, shopping, management of finances, and telephone use. Each item was rated as: 0 = No, never need help, 1= Yes, I have difficulty but can do without help, 2=Yes, I have difficulty and need help, and 3 = Never do the activity. Functional status (0 = without total functional impairment, 1 = total functional impairment) was coded as a dichotomous variable. The assessment of function may assist in the identification of high-risk veterans [27]. Veterans with total functional impairment (n=150) were defined as requiring assistance in performing 8 or more ADLs or IADLs out of a total of 14. Veterans without total impairment (n=91) were defined as requiring assistance with less than 8 of 14 ADL and IADLs. Measure cut points are determined using a Rasch analysis [28].

2.5 Stratification Variables

There were two mean-centered stratification variables used in randomization and included in the model – veteran cognitive status and super utilization. During the screening call, veteran’s cognitive status was measured using Pfeiffer’s 10-item Short Portable Mental Status Questionnaire (SPMSQ) [29]. This cognitive screening instrument consists of 10 questions which explore short- and long-term memory, orientation, current event information, and math calculation skills. Veterans are categorized based on the number of errors committed. In this study, based on SPMSQ scoring recommendations, veterans with ≥ 5 errors were considered to have moderate/severe cognitive deterioration and a failed screening. Health care super-utilizers were defined as those who were VA hospitalized ≥ 2 times in the 12 months prior to screening.

2.6 Analysis

Four models were examined to assess whether the effect of HI-FIVES on each of the two outcomes was moderated by the veteran’s risk for hospitalization or level of functional impairment.

The days in the community outcome was analyzed using generalized linear models with a negative binomial distribution with a log link and offset to account for number of days observed (i.e., days prior to death or permanent move into residential facility). Models with a Poisson and negative binomial distribution were compared, and the negative binomial model provided significantly better fit as determined by the Akaike Information Criterion [30]. Negative binomial regression is commonly used in the econometric literature and recommended for use with over-dispersed count data [31].

The caregiver burden outcome was analyzed using linear mixed models incorporating individual-level random effects to account for repeated measures. To assess whether a differential intervention effect was observed by the moderating variables, a three-way interaction (e.g., Total Impairment \times Randomization Group \times Time) and corresponding main effects and two-way interactions (e.g., Total Impairment \times Randomization Group) were entered into the model. Time was dummy coded to represent each follow-up point and allow for non-linear trends. Functional status (0 = without total functional impairment, 1 = total functional impairment) was included as a dichotomous variable, while the CAN score categories were entered as a three-level categorical variable. Within each level of the moderating variables, treatment arms were constrained to be equal at baseline and centered covariates used for randomization stratification, cognitive status (>

versus <5 errors on SPMSQ) and health care super use (>2 hospitalizations in prior 12 months), were included as baseline covariates.

Statistically significant results were defined as $p < 0.05$ with a two-tailed significance level. While not part of the original trial, all analyses presented herein were planned a priori, prior to analysis, as part of the current sub-analysis. All were conducted in SAS 9.4 (Cary, NC) using PROC MIXED and PROC GENMOD for the caregiver burden and days in the community outcomes, respectively.

3. Results

A total of 241 participants (123 usual care/118 intervention) were included in this study, and 89% of caregivers were females. Of all the participants, 54% of the caregivers and 53% of the veterans were African American (Table 1).

3.1 The Effects of HI-FIVES on Community Days Moderated by CAN Score

The model-estimated mean (and confidence intervals) number of days not spent in the community over a year were 11.94 (CI: 8.01, 17.81), 5.28 (CI: 3.03, 9.21), and 19.78 (CI: 9.34, 41.91) among Veterans in the low (0 to 90), medium (91 to 98), and high (99 +) CAN score groups who received HI-FIVES, respectively. The model-estimated mean (and confidence intervals) number of days not spent in the community were 9.96 (CI: 6.66, 14.90), 19.80 (CI: 12.15, 32.27), and 4.50 (CI: 1.93, 10.49) among veterans in the low, medium, and high groups who did not receive the HI-FIVES intervention, respectively. While there was no treatment effect in the low risk for hospitalization group, statistically significant treatment effects were found in the medium ($p=0.0004$) and high ($p=0.0048$) groups. In other words, there was a significant moderating effect of CAN score in the relationship between HI-FIVES and community days however the effects were in opposite directions. Participants in the medium group (91 to 98) who received the HI-FIVES intervention had 3.75 times *more* community days (or a 275% increase) compared to those in the control group, while those in the high (99+) group who received the HI-FIVES intervention had 4.39 times *fewer* days in the community (or a 339% decrease) compared to those in the control group. The comparison between groups are displayed in Figure 1.

3.2 The Effects of HI-FIVES on Days in the Community Moderated by Functional Impairment

Level of functional impairment did not moderate the effects of the HI-FIVES on days in the community. Among those who received HI-FIVES, the model-estimated mean (and confidence intervals) number of days not spent in the community over a year were 9.46 (CI: 5.84, 15.31) among veterans without total functional impairment group and 12.40 (CI: 8.52, 18.05) among veterans with total impairment. Among the usual care group, the model-estimated mean (and confidence intervals) number of days not spent in the community over a year were 10.99 (CI: 6.71, 17.99) among veterans without total functional impairment group and 12.90 (CI: 8.97, 18.55) among veterans with total impairment. The comparison between groups are displayed in Figure 2.

Table 1 Sample characteristics of caregivers and recipients.

| | Caregiver | | Recipient | |
|--|--------------|--------------|--------------|--------------|
| | 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, 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) |
| American Indian | 14 (11.4) | 9 (7.6) | 12 (9.8) | 8 (6.8) |
| Asian/Pacific Islander | 2 (1.6) | 2 (1.7) | 1 (0.8) | 0 (0.0) |
| Missing | 0 (0.0) | 0 (0.0) | 1 (0.8) | 0 (0.0) |
| Ethnicity (Hispanic or Latino), n (%) | 4 (3.3) | 2 (1.7) | 4 (3.3) | 1 (0.8) |
| Marital Status, n (%) | | | | |
| Married/Living together | 100 (81.3) | 89 (75.4) | 88 (71.5) | 78 (66.1) |
| Divorced/Separated | 11 (8.9) | 13 (11.0) | 13 (10.6) | 19 (16.1) |
| Widowed | 3 (2.4) | 4 (3.4) | 19 (15.4) | 18 (15.3) |
| Single, never married | 9 (7.3) | 12 (10.2) | 3 (2.4) | 3 (2.5) |
| Education, High School or Less, n (%) | 38 (30.9) | 29 (24.6) | 50 (40.7) | 55 (46.6) |
| Insurance, n (%) | | | | |
| Private Insurance | 60 (48.8) | 67 (56.8) | 28 (22.8) | 36 (30.5) |
| Public Insurance - Medicare, Medicaid | 67 (54.5) | 50 (42.4) | 81 (65.9) | 75 (63.6) |
| Military/VA Insurance | 37 (30.1) | 20 (16.9) | 121 (98.4) | 111 (94.1) |
| Other Insurance | 0 (0.0) | 0 (0.0) | 1 (0.8) | 1 (0.8) |
| Patient Comorbidities*, n (%) | | | | |
| Diabetes | . | . | 63 (51.2) | 58 (49.2) |
| Stroke/Neurologic Disorder | . | . | 50 (40.7) | 54 (45.8) |
| Heart Disease | . | . | 46 (37.4) | 44 (37.3) |
| Chronic Kidney Disease | . | . | 35 (28.5) | 40 (33.9) |
| Dementia | . | . | 33 (26.8) | 42 (35.6) |
| Lung Disease | . | . | 26 (21.1) | 32 (27.1) |
| Cancer | . | . | 26 (21.1) | 25 (21.2) |
| Amputation / Complications | . | . | 17 (13.8) | 22 (18.6) |
| Caregiver is the Veteran's..., n (%) | | | | |
| Spouse/Significant Other | 82 (66.7) | 72 (61.0) | . | . |
| Child | 24 (19.5) | 30 (25.4) | . | . |
| Parent | 3 (2.4) | 1 (0.8) | . | . |
| Sibling | 4 (3.3) | 7 (5.9) | . | . |
| Other | 10 (8.1) | 8 (6.8) | . | . |

* Comorbidity categories are based on Hierarchical Condition Categories (HCCs)

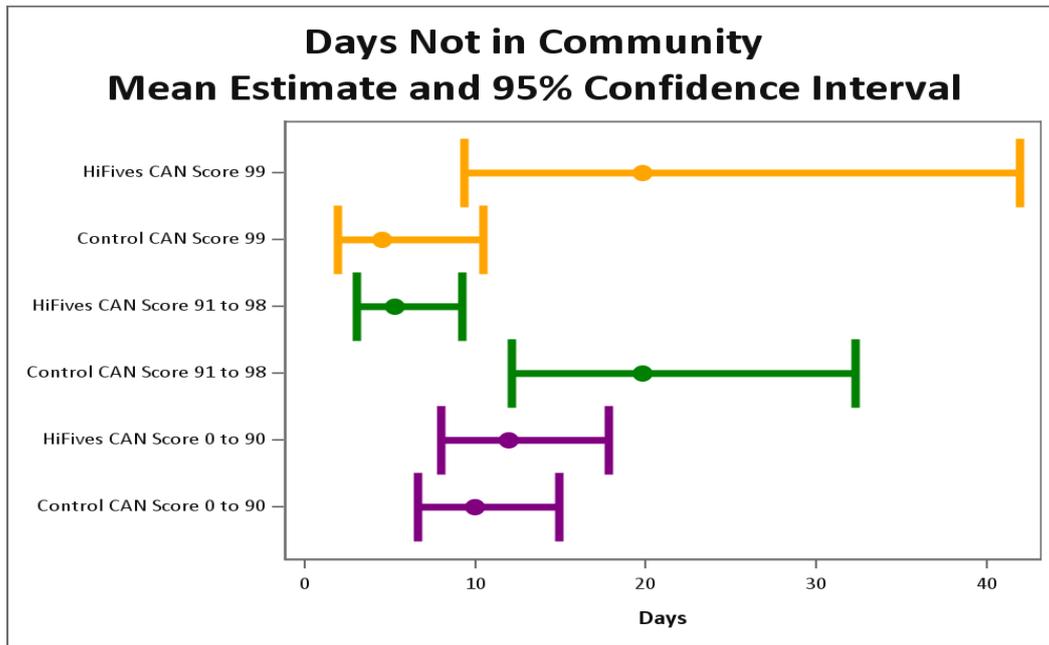


Figure 1 Days not in the community at 12 months for veterans by CAN score groups.

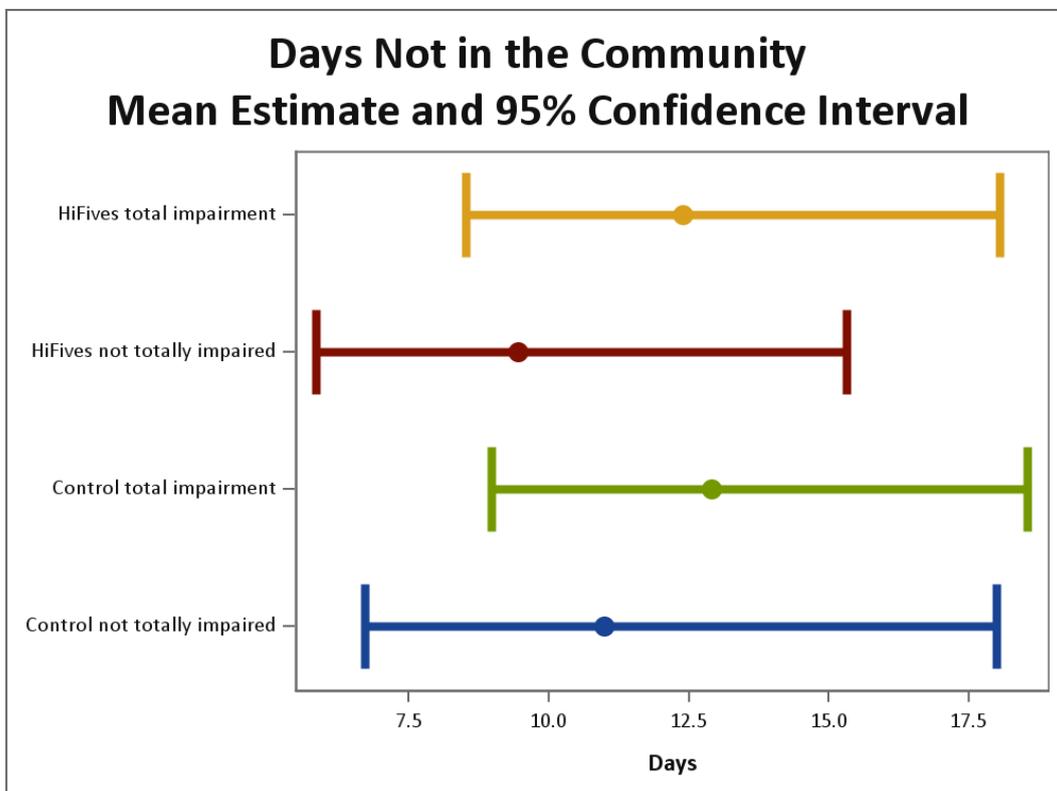


Figure 2 Days not in the community at 12 months for veterans with and without total impairment.

3.3 The Effects of HI-FIVES on Caregiver Burden Moderated by CAN Score

Across all CAN score groups, there were no statistically significant differences in burden between caregivers who received HI-FIVES compared those who did not. Comparing those who received the HI-FIVES intervention to those who did not, the mean difference (and confidence

intervals) in burden at 3 months, 6 months, and 12 months, respectively, was -0.62 (CI: -2.81, 1.57), -0.99 (CI:-3.49, 1.52), and -0.81 (CI: -3.61, 1.98) among caregivers providing care to veterans in the 0 to 90 (low) group. The mean difference (and confidence intervals) in burden at 3 months, 6 months, and 12 months, respectively, was -2.04 (CI: -5.04, 0.96), -0.47 (CI: -3.97, 3.03), and -0.04 (CI: -3.87, 3.79) among caregivers providing care to veterans in the 91 to 99 (medium) group. The mean difference (and confidence intervals) in burden at 3 months, 6 months, and 12 months, respectively, was 0.10 (CI: -4.05, 4.25), -0.51 (CI: -5.39, 4.37), and -3.24 (CI: -8.65, 2.18) among caregivers providing care to veterans in the +99 (high) group.

3.4 The Effects of HI-FIVES on Caregiver Burden Moderated by Functional Impairment

While no statistically significant differences between groups were reached, the model-estimated mean Zarit score for those with total impairment after receiving HI-FIVES was 13.88 (CI: 10.99-16.77) compared to those in the control group 15.37 (CI: 12.53-18.22) at 12 months, resulting in a non-significant 1.5-point reduction in burden among caregivers providing care to veterans with total impairment. No difference was observed among those without total impairment. The comparison between each group is displayed in Figure 3.

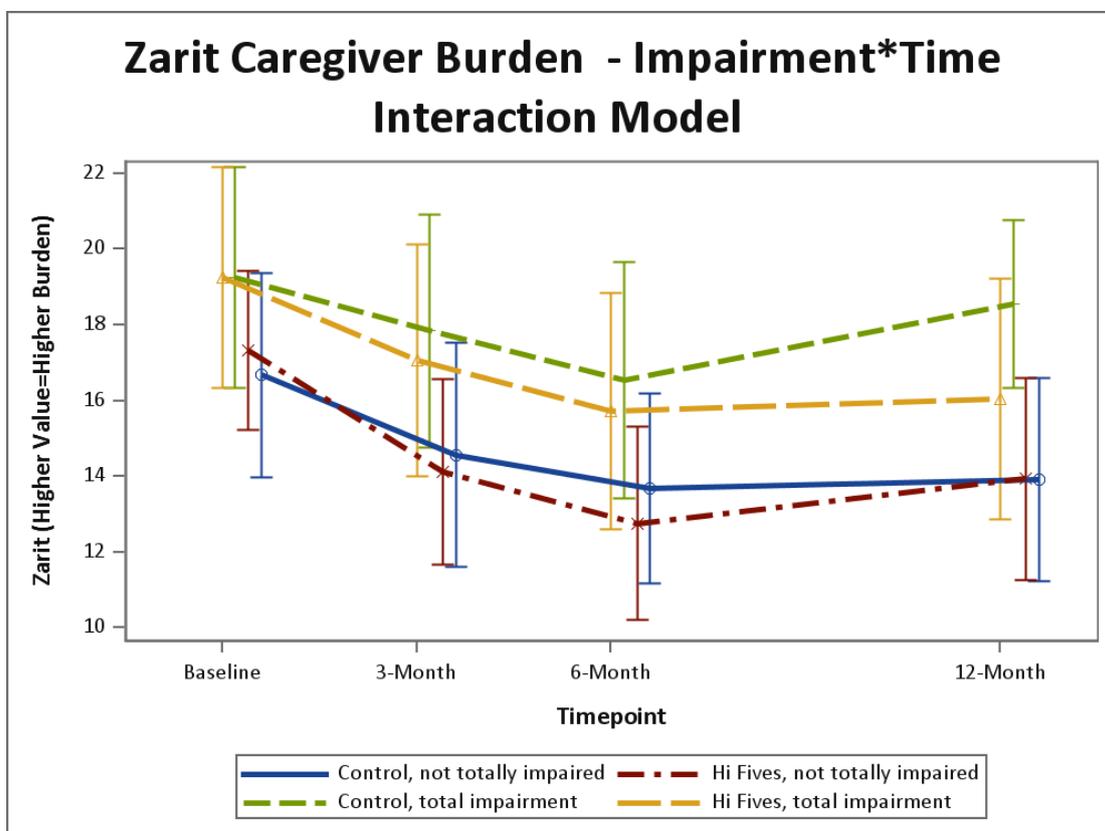


Figure 3 Zarit Burden over 12 months for Caregivers providing care to veterans with and without total impairment.

4. Discussion

HI-FIVES is a multi-modal caregiver skills training intervention targeting caregivers of veterans with cognitive and/or functional impairment residing in the community. We conducted a subgroup

analysis to assess whether the effect of HI-FIVES on days in the community and caregiver burden was moderated by the veteran's risk for hospitalization or level of functional impairment. We observed a significant moderating effect of hospitalization risk groups (91 to 98 [medium] and 99 + [high]) in the relationship between HI-FIVES and days in the community at 12 months. As such, findings from this study have important implications for the assessment and management of community-residing veterans as well as targeting interventions for those at risk for hospitalization or death. However, we did not find that the intervention effect was moderated by functional status.

While the average effect of HI-FIVES on days in the community showed a promising trend toward an increase, these effects were not significant at the 5% level (Van Houtven et al, under review). Nichols and colleagues [32] indicated effective VA caregiver interventions such as the Resources for Enhancing All Caregivers Health (REACH), should be based on risk areas or categories. As such, in the current study, considering the CAN score as a means of distinguishing different risk categories of leaving the community (through the emergency department, hospital and post-acute care path), revealed significant effects of the HI-FIVES program. In light of these findings, we offer the following interpretation, with the caveat that our findings were exploratory and post-hoc. The HI-FIVES program appears to be an effective mechanism to bolster community-residence among those in the medium risk group (91 to 98). Future efforts involving veterans in this risk category should explore whether targeting this group a priori and referring them to HCBS or geriatric care would further reduce health transitions and burdensome care for veterans and their caregivers. Caregivers of veterans in the high-risk group (99+), who received HI-FIVES and experienced higher rates of veterans leaving the community, could have been prompted by goals of care communication during training sessions as it offered opportunities for them to identify personal care needs and facilitated goal attainment. Alternatively, caregivers of veterans in the high-risk group may need a different type of training than what HI-FIVES offered. In future efforts, our intervention could be modified for high risk groups by bundling it with intensive formal care services (e.g., home health/hospice) or case management, to allow persons with functional and cognitive impairment to remain in the community. Our findings contribute to the field by extending previous research and informing future program efforts.

Examining differential moderation effects of HI-FIVES for veterans with and without total functional impairment revealed non-significant results. This finding was surprising, particularly among veterans with total functional impairment, given many reports indicate function as a strong predictor of hospitalization, nursing home admission, and death [33-35]. One potential strategy for future study is to establish sufficient power to examine differential effects by subgroups. Another potential strategy would be to use a performance-based measure of physical functioning (e.g., mobility, gait speed, grip strength) as the moderator. Our definition of total impairment uses the OARS count of ADL and IADL limitations, and therefore gives equal weight to IADLs and ADLs. It may be that different types of functional impairment would have led to differential associations with the outcomes of interest.

4.1 Limitations

There were several limitations noted in this study. First, this is an exploratory, hypothesis-generating secondary analysis of a family caregiver training trial. Second, veterans and their

caregivers were recruited from one VA facility, which may not be generalizable to other VA facilities or other more heterogeneous civilian older adults and their caregivers. Third, it is not clear from current results which components of the training program contributed to the increase in community days among the medium risk group. Despite the aforementioned limitations, the study also had several important strengths. These included the use of a rigorous design and a sample with equal proportion of both veterans and their caregivers. By intervening jointly with caregiving dyad, clinicians can help both individuals obtain needed support, targeted to meet their specific care needs.

4.2 Implications for Practice and Program Development

There are several implications for practice and program development to consider. Focusing care coordination efforts on veterans most likely to benefit requires appropriately targeting interventions according to their risk levels. Use of the CAN score to stratify veterans is a promising method to provide this support. For example, low risk veterans could be referred to educational programs while high risk veterans could be automatically enrolled in more intense community-based programs. Hospitalizations and other undesirable utilization can be reduced, but a clear picture of veterans at higher risk is needed to guide program development, foster aging-in-place initiatives, and improve quality of life.

Caregivers play an important role in the health and well-being of veterans. The VA MISSION Act of 2018 will greatly expand the Program of Comprehensive Assistance for Family Caregivers, providing training, education and resources to qualifying family caregivers [36]. This expanded role for caregiver training in VA may find the HI-FIVES curriculum useful as a model to expand training for caregivers of veterans. Additionally, to ease the roll out of this training, it may be useful to prioritize training to caregivers whose Veteran care recipients have high-risk CAN scores. Our study also suggests more attention is needed to address the needs of veterans without total impairment in extending days in the community. Specifically, formal home and community-based support services that benefit both members of the dyad and facilitate remaining in the community need to be expanded.

5. Conclusions

Integrating moderator analyses in the research design of caregiver trials holds the promise of generating practical information about interventions that are more or less effective for subgroups of caregivers and their recipients. The HI-FIVES intervention had significant moderating effects by CAN score (medium and high-risk groups) in the relationship between HI-FIVES and community days. As such, this study advances the science of caregiving. Caregiver services should be appropriately targeted and intensified for veterans accordingly to their levels of risk for hospitalization, although additional strategies are needed to better address high caregiver burden.

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Author Contributions

Study concept and design: Cary, Smith, and Van Houtven. Acquisition of data, statistical analysis, and interpretation of data: Cary, Smith Van Houtven, Shepherd-Banigan, Lindquist, and Chapman. Drafting/revising of the manuscript: Cary, Smith Van Houtven, Shepherd-Banigan, Lingquist, Chapman, and Hastings.

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Competing Interests

The primary author and co-authors report no financial or personal conflicts of interest. Also, each author meets each of the authorship requirements as stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.

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