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Evaluation of veteran-directed home and community based services on older veterans' health care use and costs

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
21/03/2017

Overall study status
Completed

Last Edited
25/08/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
For the past 20 years, there has been a movement in the United States to move care out of nursing homes and other institutions and into the home or community for older adults with physical or cognitive (mental) limitations. One type of program that is designed to help individuals remain in their homes as long as possible is participant-directed services, where individuals are provided with monthly funds to purchase personal care services, medical equipment, or home modifications. The Department of Veterans Affairs' version of this program is called Veteran Directed Home and Community Based Services (VD-HCBS). This program has been implemented in some Veterans Affairs Medical Centers (VAMCs) and will be rolled out nationwide in the next three years. The aims of this study are to understand whether VD-HCBS reduces hospital admissions, emergency department admissions, nursing home admissions, and health care costs relative to usual care among veterans at risk for nursing home placement.

Who can participate?
VAMCs that have not started the VD-HCBS programs. The VD-HCBS program targets patients enrolled in the Veterans Health Administration who have physical or cognitive limitations and are at risk of a nursing home placement.

What does the study involve?
Medical centers are randomly allocated to when they begin enrolling patients in VD-HCBS. This program provides patients with more support for home care (provides modifications to their homes, provides medical equipment or supplies and allows them to choose a personal care worker). Sites that have VD-HCBS are compared to sites with the usual care, and by the end of the study period, all eligible VAMCs will have VD-HCBS programs. Healthcare use and costs for veterans with physical or cognitive limitations are also compared across VAMCs with and without the VD-HCBS programs.

What are the possible benefits and risks of participating?
Medical centers with VD-HCBS may have lower facility-wide rates of preventable hospital admissions, emergency department admissions, and nursing home admissions. There are no notable risks with participating.

Where is the study run from?
This study is being coordinated by the Partnered Evidence-based Policy Resource Center (PEPReC) at the VA Boston Healthcare System (USA) and takes place in many VAMCs across the USA.

When is the study starting and how long is it expected to run for?
October 2015 to September 2020

Who is funding the study?
U.S. Department of Veterans Affairs (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VA Boston Healthcare System IRB Protocol # 3069

Study information

Scientific Title
Evaluation of Veteran-Directed Home and Community Based Services on older veterans' health care use and costs: a stepped wedge cluster randomized trial

Acronym
VD-HCBS

Study objectives
The availability of Veteran Directed Home and Community Based Services (VD-HCBS) will be associated with a reduction in hospital admissions, emergency department visits, nursing home admissions, and health care costs among older veterans with functional limitations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
VA Boston Healthcare System IRB and R&D Committees, 02/02/2017, ref: Protocol # 3069

Study design
Retrospective observational trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Functional (needs assistance with 3 or more Activities of Daily Living) and/or cognitive limitations that place individuals at risk of nursing home placement

Interventions
The VD-HCBS program is a participant-directed program that enables veterans with functional or cognitive limitations to purchase care services in their homes. The goal of this program is to reduce these veterans' risk of placement in a nursing home or other long-term care facility. Clinicians within the VA can refer patients to the VD-HCBS program, wherein the VA pays for services coordinated by Aging and Disability Network Agencies (ADNAs). Veterans receive a monthly allotment to pay for personal care workers of their own choosing (including family members), medical equipment or supplies, or modifications to the home. ADNA representatives

work with veterans to identify and monitor care needs, facilitate purchasing of appropriate services or equipment, and to monitor spending.

As of December 2016, there are 78 Veterans Affairs Medical Centers (VAMCs) not yet participating in the VD-HCBS program. GEC plans to roll the VD-HCBS program out nationally over a period of 3 years. At the beginning of each six-month period, GEC identifies a list of 14 VAMCs (sites) that are ready to begin offering VD-HCBS to veterans within the next six months. These sites are in the process of creating contract agreements with local ADNAs who work directly with the patients. The subset of sites are randomized to begin enrolling patients in VD-HCBS at month one or month four. This process is repeated every six months until the remaining VAMCs have implemented VD-HCBS.

Simple randomization in a stepped wedge approach like this is likely to lead to imbalance across sites that enroll patients at month 1 vs month 4 in important characteristics that may be associated with the outcomes of interest. Examples of such characteristics include facility case-mix and facility engagement in providing other Geriatrics and Extended Care (GEC) services to older veterans. Imbalance could occur because GEC is constrained in each six-month period to randomize start times for only about 14 VAMCs — those that are capable of enrolling patients within the next six months. Therefore, just by chance, those that are randomized to start in month 1 could be different in important ways than those randomized to a month 4 start.

To address this concern, covariate constrained randomization (also known as restricted randomization) is used to assign start times. This allows for better baseline balance on more potential confounders than simple randomization, matching, or stratification. From the VAMCs ready for participation each six month period, the full set of all potential variations in start times among them is evaluated and these combinations are ranked according to site characteristic balance. Site characteristics used in covariate constrained randomization includes sites' percent of long-term services and supports (LTSS) expenditures going to HCBS, whether the site has a Community Living Center (CLC [nursing home]), market penetration of non-institutionalized care services among veterans 75 or older, urban/rural location, state participation in early participant-directed care initiatives, percent of state Medicaid LTSS expenditures going to HCBS, and case-mix for patients 75 and older (number of patients per site, mean Care Assessment Need (CAN) score (predicts 1-year mortality), mean Jen Frailty Index (based on VA data), and mean prospective VA data-based NOSOS score (measure of chronic disease burden). These characteristics are all likely to influence facility likelihood of referring patients to VD-HCBS and patient cost and utilization outcomes. For each combination, the difference between the month 1 facilities' mean values of standardized variables and month 4 facilities' mean values of standardized variables are calculated, squared, and summed to create a balancing score. Lower values of the balancing score indicate better covariate balance. From the combinations in the top 1% of covariate balance, one option is randomly selected.

The degree of follow up varies across different sites.

Intervention Type
Other

Primary outcome measure
1. Any hospitalization is measured using administrative data collected by the VA Corporate Data Warehouse at 60-day increments for six months
2. Any emergency department visit is measured using administration data collected by the VA Corporate Data Warehouse at 60-day increments for six months

3. Nursing home admissions (VA community living center and contracted nursing homes) is measured using administrative data collected by the VA Corporate Data Warehouse at 60-day increments for six months
4. Total health care costs (VA, Medicare, Medicaid) are assessed using administration data collected by VA Corporate Data Warehouse data, Medicare data, and Medicaid data at 60-day increments for six months

Secondary outcome measures
1. Frequency of hospitalisation is measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day increments for six months
2. Incidence and frequency of ambulatory care sensitive hospitalization is measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day incrementsfor six months
3. Costs attributed to HCBS measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day increments for six months
4. Costs attributed to nursing home stays are measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day increments for six months
5. Costs attributed to outpatient care are measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day increments for six months
6. Days at home (days not in an acute care setting or long-term care facility) are measured using administrative data collected by the VA, Medicare, and/or Medicaid at 60-day increments for six months

Overall study start date
15/10/2015

Completion date
01/09/2020

Eligibility

Key inclusion criteria
VAMC inclusion criteria (cluster level):
Site does not yet have an operational VD-HCBS program

VHA enrollee criteria (individual level)*:
1. Aged 75 and older
2. Jen Frailty Index (VA-data only) of 6 or higher
3. Had at least one inpatient or outpatient visit in the VHA system in the past year”
*Exact enrollee criteria will differ by site, as sites are allowed flexibility in choosing who to refer to the program

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1800

Total final enrolment
37407

Key exclusion criteria
VAMC criteria (cluster level)
1. Site has nearly completed readiness review and is unable to delay enrollment
2. Facility leadership not interested in implementing VD-HCBS program

VHA enrollee criteria (individual level)
There are no exclusion criteria for individual enrollment in VHA.

Date of first enrolment
22/03/2017

Date of final enrolment
29/02/2020

Locations

Countries of recruitment
United States of America

Study participating centre
Partnered Evidence-Based Policy Resource Center
Boston VA Healthcare System
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Sponsor type
Government

ROR
https://ror.org/05rsv9s98

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Veterans Affairs

Alternative Name(s)
Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer reviewed journal.

Intention to publish date
28/02/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons. Data will be stored on a secure server behind the Department of Veterans Affairs firewall.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	24/05/2020	Yes	No
Protocol article		21/08/2017	25/08/2022	Yes	No
Results article		13/01/2022	25/08/2022	Yes	No