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# SAGE: Safer ageing through geriatrics-informed evidence-based practices

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|---|---|---|
| **Submission date**<br>08/03/2021 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>21/05/2021 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>13/03/2025 | **Condition category**<br>Other | |

**Plain English summary of protocol**

Background and study aims

Currently, there are more than 4 million Veterans in the United States aged 65 and older, yet the healthcare systems most widely used by this population are not optimized to provide them with the most consistent, highest quality care. A large body of research shows that inappropriate care and unmet care needs among older adults can lead to reduced quality of life, more frequent hospital visitation, and premature nursing home admission.

To address these gaps in care, we seek to create an ageing friendly healthcare system that incorporates four high-quality health care factors known as the "four M's": 1) what Matters (i.e., attending to each person's goals and preferences); 2) avoiding harms related to Medication; 3) preventing, identifying, treating, and managing dementia, depression, and delirium across settings of care (Mentation); and 4) promoting safe movement to maintain function and independence (Mobility).

Who can participate?

Veterans age 65 or older, attending a VA Medical Center or clinic within the Veterans Integrated System Network (VISN-4) can participate. Additional project-specific requirements apply.

What does the study involve?

Depending on project eligibility, participation might include consultation of goals prior to an elected surgery, receiving a mailed pamphlet on reducing medication harms, activities to increase mental acuity, or home visits to increase mobility and address safety concerns within the home.

What are the possible benefits and risks of participating?

There are no direct benefits of participating. Possible risks are dependent on specific study participation but could include withdrawal symptoms from reducing medication. Consultation with your primary care physician prior to reducing or stopping medication is recommended.

Where is the study being run from?

Self-electing clinics and medical centers within the VISN-4 area (https://www.visn4.va.gov/VISN4/locations/directions.asp)

When is the study starting and how long is it expected to run for?
October 2020 to September 2025

Who is funding the study?
The Department of Veteran Affairs (USA)

Who is the main contact?
Tanisha Dicks, tanisha.dicks@va.gov

### Study website
https://www.visn4.va.gov/VISN4/SAGE/index.asp

## Contact information

### Type(s)
Public

### Contact name
Ms Tanisha Dicks

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
eRA# 1 I50 HX003201-01

## Study information

### Scientific Title
Implementing the age-friendly health system in VHA: using evidence- based practice to improve outcomes in older adults

### Acronym
SAGE

## Study objectives
Currently, there are more than 4 million Veterans in the United States aged 65 and older, yet the healthcare systems most widely used by this population are not optimized to provide them with the most consistent, highest quality care. A large body of research shows that inappropriate care and unmet care needs among older adults accelerates cognitive and functional decline and increases medical harms, leading to poorer quality of life, more frequent hospital utilization, and premature nursing home admission.
To address these gaps in care, we seek to create an aging friendly healthcare system which incorporates four overarching dimensions of high-quality health care factors known as the "four M's": 1) what Matters (i.e., attending to each person's goals and preferences); 2) avoiding harms related to Medication; 3) preventing, identifying, treating, and managing dementia, depression, and delirium across settings of care (Mentation); and 4) promoting safe movement to maintain function and independence (Mobility).
This project will support internal implementation and evaluation efforts in implementing these four evidence-based practices (EBP), and will involve use of secondary and primary VA data collected using assessments that are part of routine care and/or clinical management. The information gathered from these initiatives will be used to design additional quality improvement initiatives to further improve clinical outcomes for older adults.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
This project has been approved as non-research, 25/11/2019, by the Chief Medical Officer and Associate Chief of Staff for Research and Development, VISN-4 Pittsburgh, PA

## Study design
Multicenter randomized type 3 hybrid effectiveness-implementation study with a stepped wedge design

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Implementation of age-friendly health systems within the Veterans Affairs healthcare system for veterans 65 or older

## Interventions

To improve clinical outcomes for older adult veterans, four evidence-based practices will be implemented across the Veterans' Integrated Service Network (VISN-4) in a type 3 hybrid effectiveness-implementation trial using a stepped-wedge design. The four evidence-based practices are aligned with each of the "4Ms" of the Age-Friendly Health System model: what Matters, Medications, Mobility, and Mentation. They include:
1. Initiate a preoperative frailty screening program, triggering referral of frail patients for a structured goal clarification conversation to ensure surgical treatment aligns with patient goals and values, ("Surgical Pause")
2. Implement a direct-to-consumer intervention that has been shown to more than triple the rate of discontinuation of high-risk medications among older adults ("Empower")
3. Conduct a home-based intervention to improve the function of Veterans with dementia and reduces caregiver burden ("TAP")
4. Conduct a home-based intervention to improve the ability of functionally impaired older Veterans to age in place ("CAPABLE"). There are two implementation strategies being compared in the trial: implementation as usual (using usual dissemination channels), and facilitation

We will conduct a randomized type III hybrid effectiveness- implementation study with a stepped wedge design consisting of 5 consecutive phases: Implementation as usual (IU), pre-implementation (Pre-I), active implementation (active I), consolidation (Consol) and evaluation.

IU ranges 3-21 months, depending on site. This phase will include communication strategies (i.e. email blasts, website development) implemented at all 54 sites, and will serve as the baseline for outcome data. Pre-I will last 6 months, and will include site visits, interviews with stakeholders to identify barriers and facilitators to implementation, and relationship building. Active-I will last 6 months, and include focusing on facilitation of the 4 evidence based practices at sites. We will use the implementation strategy RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) to guide activities. Consolidation expands over 6 months, and include promoting maintenance of the 4 EBPs. This phase includes ongoing audit and feedback, as well as providing technical assistance. Evaluation will follow the remaining 12 months to asses nationally available VHA specific datapoints, with a focus on comparing IU to Active-I efforts.

Randomization of sites: Unlike typical cluster trials that assign clusters of sites to a control /comparison condition or an active treatment condition, all sites in the stepped wedge design receive both the comparison condition and the active treatment condition at some point during the study. Clusters are randomized to start time for Active Implementation.

## Intervention Type
Behavioural

## Primary outcome measure
Data collected from the following nationally available datasets: VA administrative health records stored in the VA Corporate Data Warehouse, and Medicare claims records
1. The proportion of all eligible Veterans who received one (or more) of our interventions per clinical site, data collected monthly
2. The proportion of all eligible Veterans who are referred to the interventions, data collected monthly
3. The number of "facility-free days," or the number of days older Veterans remain alive and outside the hospital or nursing home, data collected annually

## Secondary outcome measures

Measured monthly using the VA administrative health records stored in the VA Corporate Data Warehouse, and Medicare claims records:
1. Postoperative mortality
2. Length of stay (at hospital and ICU)
3. Index hospital discharge disposition
Intervention specific outcome measures:
4. "Surgical Pause": Readmission rates
5. "EMPOWER":
5.1. Number of cessation prescription fills for target medication reduction
5.2. Number of mailed brochures to eligible Veterans
6. TAP and CAPABLE:
6.1. Hospitalization and nursing home placement rates
6.2. Percentage of trained occupational therapists and registered nurses delivering the program

### Overall study start date
01/10/2020

### Completion date
30/09/2025

## Eligibility

### Key inclusion criteria
1. Community-dwelling veteran
2. Age 65 or older
either receiving a treatment targeted by one of our EBPs (for example, are referred for a surgical procedure or prescribed a high-risk medication), or have risk factors targeted by one of our EBPs ( for example, carrying a diagnosis of dementia or with functional impairments that prevent completion of activities of daily living)
3. Each EBP has additional eligibility criteria specific to its purpose:
3.1. Surgical Pause, will include anyone with a score indicating frailty who is also considering an elective surgery
3.2. EMPOWER, Veterans must have been receiving a high-risk medication for at least 90 of the 120 days prior to implementation
3.3. TAP, Veterans must have a diagnosis of dementia
3.4. CAPABLE, Veterans must have 1 Activity of Daily Living or 2 Instrumental Activities of Daily Living deficiencies

### Participant type(s)
Patient

### Age group
Senior

### Lower age limit
65 Years

### Sex
Both

### Target number of participants
We aim to implement these initiatives within 9 of the Veteran Affairs Medical Centers and 45 affiliated clinics within the VISN-4 district. There is no target recruitment number of participants. The sites will be randomized in three clusters.

### Key exclusion criteria
1. Receipt of hospice care or being in long-term nursing home care
2. Veterans with severe mental illness will be excluded from EMPOWER
3. Veterans without a caregiver will be excluded from TAP

### Date of first enrolment
21/07/2021

### Date of final enrolment
01/04/2025

## Locations

### Countries of recruitment
United States of America

### Study participating centre
**James E. Van Zandt VA Medical Center**
2907 Pleasant Valley Boulevard
Altoona
United States of America
16602

### Study participating centre
**VA Butler Healthcare**
353 North Duffy Road
Butler
United States of America
16001

### Study participating centre
**Coatesville VA Medical Center**
1400 Black Horse Hill Road
Coatesville
United States of America
19320

### Study participating centre

**Erie VA Medical Center**
135 East 38th Street
Erie
United States of America
16504

**Study participating centre**
**Lebanon. VA Medical Center**
1700 South Lincoln Avenue
Lebanon
United States of America
17042

**Study participating centre**
**Corporal Michael J. Crescenz VA Medical Center**
3900 Woodland Avenue
Philadelphia
United States of America
19104

**Study participating centre**
**Wilkes Barre VA Medical Center**
1111 East End Blvd.
Wilkes-Barre
United States of America
18711

**Study participating centre**
**Wilmington VA Medical Center**
1601 Kirkwood Highway
Wilmington
United States of America
19805

**Study participating centre**
**Pittsburgh VA Medical Center**
University Drive C
Pittsburgh
United States of America
15240

# Sponsor information

### Organisation
Department of Veterans Affairs

### Sponsor details
HSR&D Central Office (14RDH) 810 Vermont Avenue, NW
Washington
United States of America
20402
2024435726
vacoqueri@va.gov

### Sponsor type
Government

### Website
http://www.dva.gov.au/

### ROR
https://ror.org/05dbx6743

# 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
We plan to disseminate through the Institute for Healthcare Improvement, the Hartford Foundation, the Leonard Davis Institute of Health Economics, and the VA in addition to traditional academic channels (presentations and publications). VA personally identifiable data is not shareable but de-identified datasets will be maintained.

## Intention to publish date
30/09/2026

## 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 confidentality.

## IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 25/05/2023 | 26/05/2023 | Yes | No |
| Other publications | | 12/03/2025 | 13/03/2025 | Yes | No |