

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

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| <b>Submission date</b><br>08/03/2021   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>21/05/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>13/03/2025       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## 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

## Contact information

**Type(s)**  
Public

**Contact name**  
Ms Tanisha Dicks

**Contact details**  
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United States of America  
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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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 assess 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Lower age limit**

65 years

**Sex**

All

**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

**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, Veterans' Administration, VA, USDVA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United States of America

## Results and Publications

### 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.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

| Output type                        | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>   |               | 25/05/2023   | 26/05/2023 | Yes            | No              |
| <a href="#">Other publications</a> |               | 12/03/2025   | 13/03/2025 | Yes            | No              |
| <a href="#">Study website</a>      | Study website | 11/11/2025   | 11/11/2025 | No             | Yes             |