ISRCTN60657985 https://doi.org/10.1186/ISRCTN60657985

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

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

Contact information

Type(s)
Public

Contact name
Ms Tanisha Dicks

Contact details
3900 Woodland Ave
Philadelphia
United States of America
19104
+1 2152222592
tanisha.dicks@va.gov

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

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 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(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, 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 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes