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VA breath check quit program

Submission date
17/06/2026

Recruitment status
Not yet recruiting

Registration date
30/07/2026

Overall study status
Ongoing

Last Edited
30/07/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tobacco use remains the leading cause of preventable death and disproportionately affects Veterans compared to the general population. Veterans Affairs (VA) spends billions on smoking-related care and was estimated to cost the Veterans Health Administration (VHA) $2.7 billion in 2010, representing 7.6% of all healthcare expenditures. Approximately half of all Veterans who smoke attempt to stop each year, yet despite the interest in cessation, treatment utilization remains low. Financial incentives (FI) or contingency management (CM) in combination with behavioral counseling and pharmacotherapy are recommended by the 2026 VA/DoD Tobacco Use Treatment Guidelines to treat tobacco and nicotine use. These use external rewards to encourage desired behaviors (e.g., abstinence) by providing incremental and direct reinforcement, while incentive-based reward programs attempt to induce abstinence by the provision of much larger rewards that are offered less often (e.g., a single occasion or at defined endpoints). CM and FI have high-certainty evidence.

The overarching goals of this program are to reduce combustible tobacco use among Veterans by enhancing existing VA cessation treatments with FIs, to improve long-term Veteran health outcomes, including cardiovascular and respiratory health, and to reduce suicide risk associated with tobacco use. The study also comprises evaluation objectives, including the assessment of abstinence, impact, intermediate and long-term effects and cost-effectiveness of FI on tobacco abstinence and quality of life. Additionally, the study has implementation objectives to assess maintenance, feasibility, patient, provider and staff (including program/clinical managers) experiences and attitudes with the FI tobacco cessation program.

Who can participate?
Veterans aged ≥18 who are enrolled in VA health care, currently smoke cigarettes and are willing to set a quit date within 2–60 days of the first pharmacist visit.

What does the study involve?
Participants will be randomly assigned to one of two intervention groups:
1. Enhanced Usual Care
2. Enhanced Usual Care + FI
Both intervention groups will receive pharmacotherapy and behavioral counseling delivered by VISN Clinical Research Hub (CRH) pharmacists through VA Video Connect (VVC) visits. This will include an initial consultation to set a quit date and visits occurring on their quit date as well as

at 1-, 2-, 4-, 8-weeks, and 6-months post quit date. Veterans assigned to the Enhanced Usual Care + FI group can receive up to $800 for sustained cessation throughout the 6-month program. FI is based on biologic confirmation of cessation at weeks 2 ($200), 8 ($200)and 6 ($200+$200 bonus) months. Carbon monoxide (CO) breath tests will be used at specific visits to confirm smoking cessation status for both intervention groups and to justify incentive release for those in the FI group. Participants will be asked to complete a baseline survey to capture demographic information, smoking history, and current health status. They will also be asked to complete follow-up surveys 6 and 12 months post-quit date to assess outcomes. Semi-structured interviews will be used to evaluate patient, provider, and staff experiences with the program after 12 months. This work has been deemed non-research and will not have Institutional Review Board (IRB) and Research and Development Committee (RDC) oversight.

What are the possible benefits and risks of participating?
Benefits:
• Tobacco cessation treatment, including pharmacotherapy and behavioral counseling via telehealth visits with a clinical pharmacist
• Potential to receive financial incentives for participation and for achieving/sustaining smoking cessation
• Potential health benefits associated with smoking cessation (improved cardiovascular and respiratory health over time)
• Continued primary care support (via handoff to PCP/PACT team) regardless of whether the Veteran completes the program or achieves abstinence

Risks:
• Time burden of multiple required visits over a 6–12-month period
• Standard side effects associated with smoking cessation medications
• Minor burden/discomfort associated with completing breath tests (iCO) at scheduled visits
• Standard privacy risks associated with use of electronic health record data for recruitment and use of direct deposit/EFT for payment processing.

Where is the study run from?
VA Center for Care and Payment Innovation, USA.

When is the study starting and how long is it expected to run for?
September 2026 to December 2030.

Who is funding the study?
VHA Office of Healthcare Innovation and Learning, USA.

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Veteran Health Incentive Pilot: Financial Incentives for Tobacco Cessation (VHIP-FITC)

Acronym
VHIP-FITC

Study objectives
1. Primary:
a. To reduce combustible tobacco use among Veterans by enhancing existing VA cessation treatments with financial incentives (FI).
b. To improve long-term Veteran health outcomes, including cardiovascular and respiratory health, and reduce suicide risk associated with tobacco use.
2. Secondary:
a. To assess the return on investment (ROI) of FI for tobacco cessation.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Using a pragmatic, patient-level, randomized design, Veterans who smoke cigarettes will be randomized in a 1:1 ratio to one of two intervention groups: Enhanced Usual Care or Enhanced Usual Care + Financial Incentives (FI). To ensure unbiased data collection, allocation to the intervention group will occur following completion of the baseline surveys. The study will use a blocked randomization scheme, stratified by CRH pharmacist and participant sex, using randomly permuted blocks of size 2, 4, and 8 generated by the project statistician, in a sequential manner unknown to project staff or the participants prior to randomization. Outcomes assessment and processing will be conducted by project staff blinded to intervention assignment.

Enhanced Usual Care Group (700 Veterans):
• Participants will receive Clinical Resource Hub (CRH) counseling, pharmacotherapy as recommended by pharmacist, and periodic carbon monoxide (iCO) testing to determine smoking cessation status.
• Participants will be asked to complete baseline, 6-month, and 12-month surveys to collect data not otherwise specified in the EHR.
• Participants will receive $25 for each iCO test and $25 for each survey completed.

Enhanced Usual Care + FI Group (700 Veterans):
• Participants will receive CRH counseling, pharmacotherapy as recommended by pharmacist, and periodic iCO testing to determine smoking cessation status.
• Participants will be asked to complete baseline, 6-month, and 12-month surveys to collect data not otherwise specified in the EHR.
• Participants will receive $25 for each iCO test and $25 for each survey completed.
• Participants will receive up to $800 for quitting and remaining quit. Assessment time points will be 2 and 8 weeks, and 6 months post-quit date. Each iCO test result that indicates sustained smoking cessation (<6 PPM) will result in a $200 FI payment (up to $600 total). If participants quit at 2 weeks and remain quit at 8 weeks and 6 months post-quit date, they will receive an additional $200 bonus FI payment.
This work has been deemed non-research and will not have IRB/RDC oversight.

Intervention Type
Behavioural

Primary outcome(s)
1. 7-day point abstinence measured using CO verified at 6-month follow up

Key secondary outcome(s)
1. 7-day, CO verified abstinence at 12-month follow-up measured using PPM at 12-month follow up

2. 6-month prolonged abstinence at 6 and 12 month follow-up measured using self reporting at 6 and 12 month follow ups

3. Quality of life measured using the EUROQOL EQ-5D instrument at 12 month follow up

4. Cost-effectiveness measured using Incremental Cost-Effectiveness Ratio (ICER) at 6 month follow up

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Age ≥18
2. Enrolled in VA health care
3. Assigned to a primary care provider in a participating VISN (currently 4, 12, 17, 20)
4. Has a valid mailing and/or email address on file
5. Currently smokes cigarettes:
5.1. Reported as a current tobacco user per clinical data in the EHR
5.2. Self-reported having smoked ≥5 cigarettes per day at the time of recruitment call
5.3. CO pre-enrollment verification of smoking status (≥8 PPM)
6. Willing to set a quit date within 2–60 days of the first pharmacist visit
7. Device/internet capable (assessed via digital divide consult if needed)
8. Able to receive payment via direct deposit and enrolled in EFT prior to randomization

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Enrolled in hospice care or diagnosed with a condition where there is less than 12 months of expected survival
2. Diagnosis of cognitive impairment
3. No phone contact on file
4. Unwilling or unable to participate in telemedicine visits

Date of first enrolment
01/08/2026

Date of final enrolment

17/08/2029

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
Center for Innovation

ROR
https://ror.org/04c1v2b17

Funder(s)

Funder type

Funder Name
VHA Office of Healthcare Innovation and Learning (OHIL)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	09/06/2026	07/07/2026	No	No