ISRCTN16316660 https://doi.org/10.1186/ISRCTN16316660

The impact of eScreening on AUDIT-C questionnaire completion rates

Submission date	**Recruitment status**	[X] Prospectively registered
26/01/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
08/02/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/12/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This is a cluster-randomized quality improvement project that is intended to evaluate the effectiveness of pre-visit screening for alcohol use disorder among patients in the Veterans Health Administration. The project will take place among patients due for screening, who will either receive a pre-visit electronic link to complete a standard alcohol use disorder identification test (AUDIT-C) survey or receive the screening in person during a visit, as is the usual practice. The project will be randomized by assigning primary care providers at each site to the intervention (electronic screening) or usual care (in-person) arms and will take place at two regional primary care clinics. The primary objective is to measure differences in AUDIT-C screening completion after an associated clinic visit.

Who can participate?
Primary care clinicians who are assigned to one of the two project conditions.
Patients who are assigned to a participating clinician and engaged in primary care at the Veterans Health Administration in two clinics, Seattle and American Lake, and are due for alcohol use disorder screening at an upcoming regular primary care appointment.

What does the study involve?
Completing routine health screenings either by the usual method of administration (in-person questions asked by a clinic staff member) or completing the screenings by a secure, approved system that sends an electronic survey link to a patient's home device (phone or computer). The project will run until the minimum number of patients to detect a difference is achieved, anticipated by 6-8 weeks, or until the health system determines one method of screening is preferable (which would occur independently from the project evaluation) and the conditions change that makes it possible to evaluate a difference in screening types.

What are the possible benefits and risks of participating?
Participating clinicians will be randomly allocated to one of the two conditions affecting the administration of screenings before their encounter. This will not affect follow-up protocols for positive screenings or other aspects of patient care. Patients may notice differences in privacy,

convenience, or comfort receiving a screening by electronic link compared to in-person screening, but will not otherwise experience a difference in clinical care workflows or usual practices.

Where is the study run from?
At two sites in the VA Puget Sound Health Care System, the Seattle VA, and the American Lake VA primary care clinics.

When is the study starting and how long is it expected to run for?
July 2023 to December 2024

Who is funding the study?
Evaluation of the difference in screening types will be supported by the Primary Care Analytics Team, funded by the VHA Office of Primary Care.

Who is the main contact?
Alaina Mori (Project Administrator), Alaina.Mori@va.gov

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PCIL-AUDIT-C

Study information

Scientific Title
The impact of eScreening on Alcohol Use Disorders Identification Test (AUDIT-C) questionnaire completion rates at VA Puget Sound among Veterans due to screening

Study objectives
AUDIT-C survey completion rate among Veterans who have been sent an eScreening differs compared to Veterans who did not receive eScreening

Ethics approval required
Ethics approval not required

Ethics approval(s)
This work was designated as non-research, quality improvement after review by the VHA Office of Primary Care under the national VHA Office of Research and Development policy of the U.S. Department of Veterans Affairs (VHA Office of Research & Development Program Guide 1200.21, “VHA Operations Activities That May Constitute Research,” issued Jan 9, 2019), consistent with the intent to resolve questions of operationally-relevant process optimization for the health system. This exempts the work from further VHA Institutional Review Board (IRB) review. Work under this designation is conducted following all methodologic, policy, and ethical guidelines and regulations governing the conduct of VHA Office of Primary Care non-research quality improvement activities.

Study design
Prospective clustered randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Completion of an eScreening AUDIT-C questionnaire to Veterans before an upcoming visit among Veterans who are due for an AUDIT-C screening at the VA Puget Sound

Interventions
This is a prospective, clustered randomized controlled trial that will evaluate the effectiveness of improving AUDIT-C survey completion rates by sending a Veteran with primary care providers at the Seattle and American Lake clinics an AUDIT-C eScreening (24-48 hours) before an

upcoming visit. Among the active arm, the eScreening will be sent to all Veterans on the provider's panel with an upcoming visit who are due for an AUDIT-C screening. The control arm (i. e., usual care) of primary care providers and associated encounter-specific nursing staff will continue to complete screening reminders as identified for patient care during visits.

Providers eligible for enrollment into the trial will be randomized in a 1:1 allocation using permuted block randomization (with random block sizes of 2 and 4) to the following interventions:
1. Active arm: eScreening
1.1. Intervention Type: Other
1.2. Intervention Description: Text message with AUDIT-C survey link sent via BHL Touch
2. Control arm: No eScreening
2.1. Intervention Type: No intervention
Randomization will be stratified within arms by site (Seattle vs. American Lake).

Intervention Type
Behavioural

Primary outcome(s)
Alcohol screenings (%) measured using AUDIT-C survey completion at 1 day post-visit, among patients due for screening with a virtual or telephone visit encounter

Key secondary outcome(s))
Proportion (%) patients screening positive (score >/= 5 on AUDIT-C survey) among patients with completed surveys at 1 day post-visit from virtual or telephone visit encounter

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. All Veterans assigned to a primary care provider at the VA Puget Sound as of November 1, 2023, with an upcoming visit (index trial visit)
2. Upcoming visits must be telephone, VVC, or face-to-face.
3. Eligible Veterans must have an AUDIT-C reminder due (no AUDIT-C completed in 12 months before the index trial visit).

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1731

Key exclusion criteria
Providers will be identified via an audited list of Primary Care providers from Seattle and American lake.
1. Providers will be excluded if they had a total FTE across all their teams less than 0.3 and are not on a team of type (GERI, *H*, SCI, ,VPACT or HBPC).
2. Providers will be excluded if they participated in a trial test of BHL rollout.
3. Providers will be excluded that had less than 1 patient visit during study timeframe.

Date of first enrolment
24/06/2024

Date of final enrolment
05/08/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Seattle VA Medical Center
1660 S Columbian Way
Seattle
United States of America
98108

Study participating centre
American Lake VA Medical Center
9600 Veterans Dr SW
Tacoma
United States of America
98493

Sponsor information

Organisation
VA Puget Sound Health Care System

Funder(s)

Funder type
Government

Funder Name
Health Services Research and Development

Alternative Name(s)
VA Health Services Research and Development Service, VA HSR&D, Veterans Health Administration HSR and D, HSR&D

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
No additional data for this project will be collected, outside routine data collected for patient care under the Veterans Health Administration Office of Primary Care. As such, no datasets will be available for dissemination or sharing outside the institution. Analytic plans and detailed methods, outside those shared through scientific publications and conference proceedings, can be made available upon reasonable request.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			08/02/2024	No	No