

Are Caring Letters from other Veterans or counselors more effective at preventing suicide attempts in US military Veterans who have contacted the Veterans Crisis Line?

Submission date 07/05/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2020	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

US Veterans are at higher risk of suicide than the rest of the US population, and the rates of suicide among callers to the Veteran Crisis Line are especially high. Therefore, suicide prevention efforts are a high priority for this group. Caring Letters (sometimes called Caring Contacts) is one intervention that has lowered rates of suicide in prior studies. With this approach, someone (usually the person's healthcare provider) sends them letters about once a month for about a year. These letters typically let them know that others are thinking of them and wishing them well. It may seem simple, but there is a theory behind how this can reduce suicide by making people feel less socially isolated and reminding them that help is available. The evaluation for this new program for the Veteran Crisis Line (VCL) will look at whether sending Caring Letters to Veterans who contact VCL will lower the incidence of suicide attempts (as a group) compared to before the program started. It will also examine hospitalizations for mental health reasons and their use of resources like mental health care. Since Caring Letters have not been used with people who contact a crisis line before, we will be evaluating the effects of letters sent from two different people: a counselor or a Veteran peer. Everyone enrolled will receive Caring Letters, but we will randomly assign participants to receive letters from one or the other (counselor or peer) and compare the results. We will evaluate the initial set up and operation of this project for the first few years to help understand program implementation. These results will help guide how the Caring Letters program for Veterans Crisis Line callers will continue.

Who can participate?

Anyone who is a Veteran and contacts the Veterans Crisis Line from the summer of 2020 to the summer of 2021 will be included in the program evaluation as long as they are calling about themselves, not about a loved one, they are enrolled in Veterans Health Administration (VHA) care, and there is no reason to think the program would be unhelpful in terms of their medical care. Since Veterans can contact the VCL in several ways (e.g., phone call, "warm transfer" from

another telephone hotline, text message communication with the VCL), Veterans from multiple forms of contact are included. Individuals who are enrolled will include all genders and all ages represented by Veterans who meet these criteria.

What does the study involve?

All individuals will receive a series of cards, sent in envelopes, wishing them well and letting them know that there are resources and people available to help them if they need anything. Half of the Veterans will receive cards that are written from a peer Veteran and the other half will receive letters from a counselor. The Veterans will receive a total of 9 cards in one year. For the first 4 months after calling the Veterans Crisis Line, the letters will be sent every month. Then they will be sent every other month. There will be an extra card for Veterans day. After the first year of the program we will reach out to some participants (about 30) to collect information about what it was like to receive the letters and whether they found them to be helpful or caring. This information will be used to help guide program continuation. In addition, because Veterans who contact the VCL again after completing the initial Caring Letters program are likely at increased risk of suicide, half of these Veterans will receive an additional three cards every other month.

What are the possible benefits and risks of participating?

The benefits are unknown. Prior research has shown that receiving Caring Letters can reduce rates of suicide behaviors. There are few risks. If someone had a negative experience with their military service, with the VA or with their contact to the Veteran Crisis Line, they may have negative feelings about receiving letters from a provider or peer from the Veterans Crisis Line. However, if they want to opt out of receiving the letters they can request to do so. It is illegal for someone to open mail that is not addressed to them, but it is possible this could happen; therefore, it is possible an unintended person could read the Caring Letters.

Where is the study run from?

The evaluation of the VCL Caring Letters program is a partnership between investigators at the VA Puget Sound Health Care System in Seattle, WA, USA, and the Veteran Crisis Line in Canandaigua, NY, USA. Other partner sites for the evaluation of this program include the Central Arkansas Veterans Health Care System in Little Rock, AR, USA and the VA Partnered Evidence-based Policy Resource Center (PEPReC) in Boston, MA, USA.

When is the study starting and how long is it expected to run for?

April 2019 to September 2025

Who is funding the study?

This study is funded by two groups from the United States Department of Veterans Affairs (VA): The VA Office of Mental Health and Suicide Prevention – Veterans Crisis Line and VA Quality Enhancement Research Initiative (QUERI).

Who is the main contact?

Dr Mark Reger, mark.reger@va.gov

Study website

<https://www.queri.research.va.gov/centers/Caring-Letters-VCL.pdf>

Contact information

Type(s)

Public

Contact name

Dr Mark Reger

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Randomized evaluation of a caring letters suicide prevention campaign

Study objectives

Current study hypothesis as of 09/02/2022:

Aim 1: To evaluate the effects of Caring Letters on clinical outcomes and VA clinical utilization rates.

Among Veteran contacts to the VCL who engage in VHA care, those who receive Caring Letters will have:

- 1.1. A lower incidence of VA-documented suicide attempts
- 1.2. Lower incidence and frequency of VA psychiatric hospitalization compared to Veterans who contacted VCL in the 2 years that preceded the launch of the Caring Letters campaign
- 1.3. Veterans who receive Caring Letters will have higher outpatient mental health utilization rates compared to the service members who contacted VCL in the 2 years that preceded the program.
- 1.4. After completing one year of Caring Letters, Veterans who contact the VCL again and

receive additional Caring Letters will have a higher proportion of VA mental health outpatient visits compared to Veterans who contact the VCL again and do not receive the additional Caring Letters (see Caring Letters Extension Analysis Plan for more details).

Exploratory Aim: To examine rates of all-cause mortality and suicide for Veterans who receive Caring Letters compared to the comparison cohort of Veterans from the 2 years prior to the launch of the Caring Letters campaign.

Aim 2: To study the effects of the two different Caring Letter signatories (peer and provider) on the clinical effectiveness of the intervention.

Among Veterans who contact the VCL and engage in VHA care, those who receive Caring Letters from a Peer Veteran will have:

- 2.1. A lower incidence and frequency of VA psychiatric hospitalization
- 2.2. Higher outpatient mental health utilization rates compared to Veterans who receive Caring Letters from a VA Provider. When compared to the comparison cohort, the effects will be greater for those who receive Peer letters relative to VA Provider letters.

Exploratory Aim 2: To compare two types of Caring Letter signatories on rates of all-cause mortality, suicide and suicide attempts.

Previous study hypothesis:

Aim 1: To evaluate the effects of Caring Letters on clinical outcomes and VA clinical utilization rates.

Among veteran callers to the VCL who engage in VHA care, those who receive Caring Letters will have:

- 1.1. A lower incidence of VA documented suicide attempts
- 1.2. Lower incidence and frequency of VA psychiatric hospitalization compared to veterans who called VCL in the 2 years that preceded the launch of the Caring Letters campaign
- 1.3. Veterans who receive Caring Letters will have higher outpatient mental health utilization rates compared to the service members who called VCL in the 2 years that preceded the program.

Exploratory Aim: To examine rates of all-cause mortality and suicide for veterans who receive Caring Letters compared to the comparison cohort of veterans from the 2 years prior to the launch of the Caring Letters campaign.

Aim 2: To study the effects of the two different Caring Letter signatories (peer and provider) on the clinical effectiveness of the intervention.

Among Veteran callers to the VCL who engage in VHA care, those who receive Caring Letters from a Peer Veteran will have:

- 2.1. A lower incidence and frequency of VA psychiatric hospitalization
- 2.2. Higher outpatient mental health utilization rates compared to veterans who receive Caring Letters from a VA Provider. When compared to the comparison cohort, the effects will be greater for those who receive Peer letters relative to VA Provider letters.

Exploratory Aim 2: To compare two types of Caring Letter signatories on rates of all-cause mortality, suicide, and suicide attempts.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This project has been reviewed and meets the criteria for classification as non-research. The purpose of this project is to support internal implementation and evaluation efforts to evaluate the effects of the Caring Letters suicide prevention intervention on clinical outcomes and VA clinical utilization rates for contacts to the Veterans Crisis Line. Since this is a new population for the use of the intervention, the project will also evaluate the effects of two different Caring Letter signatories (VA Counselor and a Peer Veteran) by randomizing each Veteran to one of two conditions. Furthermore, the project assesses facilitators and barriers to implementing the Caring Letters program and will include budget impact analyses. The project will involve use of secondary VA data that are collected as a part of routine care and/or clinical management. This project will be collecting information that is designed for quality improvement initiatives, as described in the Department of Veterans Affairs, Office of Research and Development Program Guide (1200.21), "VHA Operations Activities That May Constitute Research."

These activities are designed and implemented for internal VA purposes and findings are intended to be used to better inform care in the VA. This project is not designed to inform activities beyond VA, produce information that expands the knowledge base of a scientific discipline or other scholarly field, and does not involve collecting additional data or performing analyses that are not needed for the purposes of this internal implementation. This determination was confirmed by Matthew Miller, PhD, MPH, Acting Director for the Suicide Prevention Program, VHA Office of Mental Health and Suicide Prevention on February 6, 2020. Therefore, consistent with VA policy, no other review is required.

Study design

Randomized parallel trial, combined with pre-post comparison of treatment vs no treatment; Hybrid Type 1 effectiveness-implementation trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Suicide prevention in US Veterans

Interventions

Current interventions as of 09/02/2022:

Caring Letters is a suicide prevention intervention that is well-suited for a public health approach delivered to a high-risk population. Caring Letters consist of simple expressions of care and support sent through the mail. Caring Letters directly work at the level of social support to enhance feelings of belongingness, but this model also has the potential to impact other factors by providing resources and promoting links to medical and mental health care and other services

available to Veterans. This approach continues to be one of few interventions that has reduced rates of suicide in a randomized controlled trial. The Veterans Crisis Line has adopted this intervention for continued outreach to Veterans, and the planned evaluation will provide actionable program guidance.

A traditional approach to Caring Letters (in which a provider with an established relationship with a patient sends Caring Letters) is not feasible for this target group. Therefore, the study team will assess two different approaches. In one, letters are sent from a mental health provider that the participant has not met. The second approach will send letters from a peer Veteran signatory; thus inclusion of peer signed notes is based on prior research highlighting the important role of peer support for Veterans.

Each letter will be based on a template with unique messages for each mailing. Letters will be mailed out on a schedule that has been used in several successful trials, with letters mailed monthly for the first 4 months and then bi-monthly (Months 1, 2, 3, 4, 6, 8, 10, 12) with an additional card on Veterans Day. After the initial Caring Letters intervention, Veterans with repeat contact with the VCL will receive letters on months 1, 3, 5 after re-engaging with VCL. The letters and envelopes will be designed as personalized cards (colorful envelopes distinguishable from other VA correspondence or bills). A mental health resource card will be included with each letter containing information about how to access VA resources (including the Veteran Crisis Line) and free online mental health and coping resources.

Eligible Veterans will be identified weekly and randomized at the individual level. Veterans will be randomly assigned to one of the two conditions (peer signatory, counselor signatory). Repeat contacts to the VCL will be randomized to one of two conditions (additional Caring Letters, no additional Caring Letters). Because there are fewer female than male Veterans, we will stratify on gender. Within strata, we will use permuted block randomization with fixed block size to allocate participants to conditions. The random allocation sequence will be based on a random number generator in Stata. Allocation of participants to conditions will be balanced (equal sample size in each treatment group). Letters will be mailed according to the randomized allocation and pre-determined templates.

Previous interventions:

Caring Letters is a suicide prevention intervention that is well-suited for a public health approach delivered to a high-risk population. Caring Letters consist of simple expressions of care and support sent through the mail. Caring Letters directly work at the level of social support to enhance feelings of belongingness, but this model also has the potential to impact other factors by providing resources and promoting links to medical and mental health care and other services available to Veterans. This approach continues to be one of few interventions that has reduced rates of suicide in a randomized controlled trial. The Veterans Crisis Line has adopted this intervention for continued outreach to callers, and the planned evaluation will provide actionable program guidance.

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monthly for the first 4 months and then bi-monthly (Months 1, 2, 3, 4, 6, 8, 10, 12) with an additional card on Veterans Day. The letters and envelopes will be designed as personalized cards (colorful envelopes distinguishable from other VA correspondence or bills). A mental health resource card will be included with each letter containing information about how to access VA resources (including the Veteran Crisis Line) and free online mental health and coping resources.

Eligible callers to the Veterans Crisis Line will be identified weekly and randomized at the individual level. Callers will be randomly assigned to one of the two conditions (peer signatory, counselor signatory). Because there are fewer female than male veterans, we will stratify on sex. Within strata, we will use permuted block randomization with fixed block size to allocate participants to conditions. The random allocation sequence will be based on a random number generator in Stata. Allocation of participants to conditions will be balanced (equal sample size in each treatment group). Letters will be mailed according to the randomized allocation and pre-determined templates.

Intervention Type

Behavioural

Primary outcome measure

Suicide attempts, as measured by a record of a suicide attempts in VA suicide behavior surveillance data (reports submitted by VA providers) or ICD-10 codes during the 1-year receipt of Caring Letters. A record of a suicide attempt in either data source will indicate that the case is positive for a suicide attempt. ICD-10 codes that will be considered a suicide attempt include those associated with intentional poisoning and other intentional self-harm.

Secondary outcome measures

Current secondary outcome measures as of 09/02/2022:

1. Incidence and frequency of VA psychiatric hospitalization from analysis of VA health care records data obtained from the VA's Corporate data Warehouse (CDW) assessed for 1 year during Caring Letters and 2 years pre-intervention
2. Incidence and frequency of VA emergency department visits obtained from analysis of VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
3. Rates of outpatient VA mental health care utilization from analysis of VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
4. All-cause mortality, i.e., death rate from all causes of death obtained from VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
5. Rates of calls to the VCL and VA411 (help line included in the Caring Letters) assessed for 1 year during Caring Letters and 2 years pre-intervention
6. Rates of suicide: Suicide mortality rates will be obtained from the VA/DoD Mortality Data Repository which contains the National Death Index (state death records data) for all Veterans assessed for 1 year during Caring Letters and 2 years pre-intervention. Since these data are not available until about 2 years after the year of death, these results will be delayed compared to other analyses.
7. Measures described in 1-6 above will also be compared between Veterans who contact the VCL again and receive additional Caring Letters, and Veterans who contact the VCL again and do not receive the additional Caring Letters.

A secondary goal for this study is to collect data on the delivery of the intervention to inform

potential improvements for implementation. The project will assess facilitators and barriers to implementing the Caring Letters program and will include budget impact analyses. The RE-AIM analytic framework will be used to examine implementation and impact of the intervention.

Previous secondary outcome measures:

1. Incidence and frequency of VA psychiatric hospitalization from analysis of VA health care records data obtained from the VA's Corporate data Warehouse (CDW) assessed for 1 year during Caring Letters and 2 years pre-intervention
2. Incidence and frequency of VA emergency department visits obtained from analysis of VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
3. Rates of outpatient VA mental health care utilization from analysis of VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
4. All-cause mortality, i.e. death rate from all causes of death obtained from VA health care record data from the CDW assessed for 1 year during Caring Letters and 2 years pre-intervention
5. Rates of calls to the VCL and VA311 (help line included in the Caring Letters) assessed for 1 year during Caring Letters and 2 years pre-intervention
6. Rates of suicide: Suicide mortality rates will be obtained from the VA/DoD Mortality Data Repository which contains the National Death Index (state death records data) for all veterans assessed for 1 year during Caring Letters and 2 years pre-intervention. Since this data is not available until about 2 years after the year of death, these results will be delayed compared to other analyses.

A secondary goal for this study is to collect data on the delivery of the intervention to inform potential improvements for implementation. The project will assess facilitators and barriers to implementing the Caring Letters program and will include budget impact analyses. The RE-AIM analytic framework will be used to examine implementation and impact of the intervention.

Overall study start date

01/04/2019

Completion date

30/09/2025

Eligibility

Key inclusion criteria

Current inclusion criteria as of 09/02/2022:

Participants will be included if they call the Veterans Crisis Line during the recruitment period (11/06/2020 – 10/06/2021) and:

1. Are an identifiable VCL contact (i.e., not an anonymous contact)
 2. Have a valid mailing address on file with the VA
 3. Are contacting VCL about themselves (i.e., not contacting VCL about a loved one)
- All Veterans who complete the initial intervention and contact the VCL again will be considered for the additional Caring Letters.
- All Veteran age ranges and genders will be included.

Previous inclusion criteria:

Participants will be included if they call the Veterans Crisis Line during the recruitment period (estimated to be 6/1/2020 – 5/30/2022) and:

1. Are an identifiable VCL caller (i.e. not an anonymous caller)

2. Have a valid mailing address on file with the VA
 3. Are calling about themselves (i.e. not calling about a loved one)
- All veteran age ranges and genders will be included.

Participant type(s)

Other

Age group

Adult

Sex

Both

Target number of participants

100,000

Total final enrolment

102365

Key exclusion criteria

Current exclusion criteria as of 09/02/2022:

1. No fixed valid mailing address available in VA records
2. Not identifiable (e.g., full SSN not known; last 4 digits of the SSN and name not available)
3. Not a Veteran (e.g., someone calling on behalf of a Veteran)
4. Has not received Veterans Health Administration (VHA) care

Previous exclusion criteria:

1. No fixed valid mailing address available in VA records
2. Not identifiable (e.g. full SSN not known; last 4 digits of the SNN and name not available)
3. Not a veteran (e.g. someone calling on behalf of a veteran)
4. Has not received Veterans Health Administration (VHA) care
5. The intervention is thought to be counter-productive to clinical goals (e.g. poor boundaries with VCL staff)

Date of first enrolment

11/06/2020

Date of final enrolment

10/06/2021

Locations**Countries of recruitment**

United States of America

Study participating centre

VA Puget Sound Healthcare System

1660 S Columbian Way

Seattle

United States of America
98108

Study participating centre

**Partnered Evidence-Based Policy Resource Center (PEPReC) / VA Boston Healthcare System
Research & Development**
150 South Huntington Avenue
Boston
United States of America
02130

Study participating centre

Central Arkansas Veterans Healthcare System
2200 Fort Roots Drive
Little Rock
United States of America
72114

Study participating centre

Veterans Crisis Line
400 Fort Hill Avenue
Canandaigua
United States of America
14424

Sponsor information

Organisation

Veterans Crisis Line

Sponsor details

400 Fort Hill Avenue
Canandaigua
United States of America
14424
+1 352 240 2748
vhavclcaringlettersprogram@va.gov

Sponsor type

Government

Website

<https://www.veteranscrisisline.net/>

Organisation

Quality Enhancement Research Initiative (QUERI)

Sponsor details

1100 1st Street NE, Suite 6
Washington, DC
United States of America
20002
(202) 443-5818
vacoqueri@va.gov

Sponsor type

Government

Website

<https://www.queri.research.va.gov/>

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

Funder Name

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

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 confidentiality reasons. Data will be stored on a secure server behind the Department of Veterans Affairs firewall.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2024	01/05/2024	Yes	No
Statistical Analysis Plan			07/06/2024	No	No
Statistical Analysis Plan			07/06/2024	No	No