

Increasing Social Connection
Through Crisis Caring Contacts: A
Pragmatic Trial

NCT05484297

November 29, 2022

INFORMATION SHEET FOR THE *Buddy Check Postcard Project*

You are being invited to take part in a study that is funded by VA Health Services Research and Development (HSR&D). For the study, we are enrolling Veterans over age 60 who have not been seen in primary care or mental health at their local VA recently. We're doing this study to learn if receiving postcards from the VA can help Veterans feel more connected. *Basically, it is like doing a quick Buddy Check.*

Joining this study is a great way to help other Veterans in your age group and people you may have served with. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

WHY IS THIS STUDY BEING DONE?

The main purpose is to learn if *Buddy Check Postcards* reduce loneliness and improve mental health. We want to understand if these messages are effective in Veterans aged 60 and above who have health issues but have not had recent appointments at the VA.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, you will receive a series of postcards with messages from your local VA. You will receive up to 10 postcards in envelopes over 10 months.

Half of the Veterans in this study will receive 3 postcards over 10 months with resource information from the VA. The other half will receive 10 postcards containing brief messages signed by a fellow Veteran. Each postcard will be sent to you privately in an envelope.

This is a randomized study which means you cannot choose which type of postcard you will receive. Instead, it will be decided by chance (like flipping a coin). You have a 50/50 chance of receiving the 10 postcards or the 3 postcards. *No matter which type of postcards you receive, your participation in this project is very helpful and important.*

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY? WHAT INFORMATION WILL YOU COLLECT?

You will be asked to fill out a survey at four different times (at the beginning of the study, and around 3 months, 6 months, and 12 months after beginning the study). Surveys will be given to you online, with the option to complete them by paper through the mail.

All four surveys will ask questions about you, your connections, your social situation, and your health. Each survey may take 15 – 30 minutes to complete. You can skip any survey questions you do not want to answer or skip the surveys altogether.

Study staff will reach out to you using the contact information you provide to remind you about the surveys. If you give us permission, we may contact up to two of your friends or family members to help us find you and update your contact information if we can't reach you.

As part of the study, the research team will also review your VA medical records for three years (the year that you are actively participating in the study, and for an additional two years after that). This will include information about the treatment you receive at the VA, such as a record of your appointments and diagnoses linked to those appointments. We will also look for reports of major health events, such as suicide attempts, drug overdoses, and death.

DO I HAVE TO TAKE PART IN THE STUDY?

No. Participation in this study is voluntary. Refusal to take part in this study will not result in penalty or loss of services, benefits, or rights to which you are entitled. You may leave at any time without any penalty or loss of services, benefits, or rights. If you want to withdraw from the study, contact the study team at [local study site phone number]. If you withdraw from the study entirely, we will not collect any more information from you or about you, but we may review data that we already collected.

ARE THERE ANY RISKS OR DISCOMFORTS?

Yes. All studies have possible risks and discomforts. However, the risks of participating in this study are minimal, and they are rare. The most important reason why a participant may not want to join this study is a small but real risk to your privacy and confidentiality. We take your privacy and security very seriously.

RISKS RELATED TO DATA COLLECTION

We will ask you to provide some of your personal information as a part of this study. A breach in confidentiality and a loss of privacy is always possible, but the research team will take every step to protect your private information. For the survey, answering questions takes time and you may find this inconvenient. Some of the questions may seem very personal or embarrassing, or they may upset you. You may refuse to answer any of the questions. All of your answers to the survey questions will remain confidential.

RISKS RELATED TO RECEIVING THE BUDDY CHECK POSTCARDS

It is possible someone other than yourself (like a family member) may see a *Buddy Check Postcard*. There is also a chance of being bothered by receiving the postcards, either due to the messages themselves or receiving the postcards in the mail.

There is a chance that *any* procedure can harm you and this study is no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

ARE THERE ANY BENEFITS?

The most important reason a person may want to join this study is to increase connection and support. You may experience reduced loneliness and increased connection with VA healthcare services, but there is no guarantee that your health will improve if you take part in this study. Another reason is to receive information about VA mental health and resources for health care.

Your participation may benefit other Veterans by helping us determine if sending messages from the VA (the *Buddy Check Postcards*) reduces loneliness and improves mental health.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential. Because this study is done at three VA locations, we will share information across these VA organizations, but only approved study staff will have access to this information. We will store your responses to survey questions and information from your medical record in a data file.

To protect you:

- These data files will NOT contain any identifying information about you, such as your name, mailing address or phone number. This kind of contact information will only be available to the study team and will be stored separately.
- A study ID number will be created for you, which will help to separate your survey responses from any identifying information.
- The electronic data will be stored on a secure, password-protected computer server at the VA. Any paper documents related to the study will be stored in a locked file cabinet in a locked office at a secure VA facility.

Information you provide on the study surveys will also be stored in a database called Qualtrics. By agreeing to join this study, you give permission for this data to be stored in Qualtrics, which will maintain security and confidentiality of the transferred data. The VA will have ownership of your research data for this study.

The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. All VA research records will be held in accordance with the VA records control schedule. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the Office of the Inspector

General, the VA Central Institutional Review Board (IRB), the local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

If we learn that you intend to harm others, we must report that to the authorities. If you report that you intend to harm yourself, we will connect you with professionals trained in suicide prevention.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will receive a \$20 gift card for completing each survey for your time and participation. You will receive an additional bonus \$20 gift card if you complete all four surveys, for a maximum total possible payment of \$100. The gift cards will be sent from the Ann Arbor VA in Michigan.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is caused by not following study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you believe you have been injured as a result of participating in this study, you can contact: [Local site PI] by email: [Local site PI email] or phone: [Local site PI phone]

If you have any other questions, comments, or concerns about the research, please contact the Principal Investigator:

Dr. [Name], [Degree]
[Location Name]
[Street address]
[City, State, Zip]

Email: [Local site PI email]
Phone: [Local site PI phone]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB).