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Brief Title
Community-based Education, Navigation, and Support Intervention for Military Veterans to Help Reduce Opioid-Related Harms

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NCT05343169
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Cover page – Informed Consent

Informed Consent Form for IRB-FY2022-5794

- **About volunteering for this research study**

  - You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.
  - The project is focused on helping military veterans who use opioids reduce opioid related harms through education into opioid safety, navigation of health and legal systems, and social support.

- **What is the purpose of this study?**
  - The purpose of this research is to evaluate the effectiveness of an experimental peer-delivered, community-based education, navigation and support (CENS) intervention which aims to help veterans who use opioids reduce opioid-related harm including HIV/HCV infection and overdose, and to increase connection to health and social services.

- **What will happen if I agree to participate in this study?**

  - You will be asked to answer a series of survey questions about your background, substance use, mental health, and social life in five separate sessions over fifteen months. The first will be in-person and the rest will involve electronic data collection with surveys sent to you via text and email.
  - This study will educate you in overdose prevention and response and the use of naloxone and best ways to prevent and reverse an overdose.
  - After you complete the initial questionnaires, you will be randomly assigned (by chance, similar to the flip of a coin) to either the CENS group or the Control group. Both groups will receive an overdose education and naloxone training at the first in-person study visit. The CENS intervention group participants will be assigned to a veteran health outreach worker and meet with them on a monthly basis over 9 months and will focus on risk-reduction for people who use opioids. The Control group participants will receive 9 months of telephone access to project staff who can provide customized referrals to healthcare, treatment, and supportive social services of interest. If your partner/significant other or roommate (family member or friend that you live with) is also participating in the study, you will be assigned to the same group.

    Each intervention is described in more detail below.

CENS Intervention.

  - If you are randomly assigned to the CENS group, you will be asked to participate in monthly meeting sessions with your veteran health outreach worker (VHOW) to discuss any navigation or support needs you may have. These may last up to

3 hours scheduled on one day, or spread over several days, with at least one meeting per month (and an average of 3 hours of contact with your VHOW per month). In addition, you will be provided with internet links to one short video every month about a topic related to veteran health, opioid use, and/or safer drug use. You will also receive free naloxone, the overdose reversal medication.

Control Intervention

- If you are randomly assigned to the Control group, you also will receive training in how to prevent and respond to an opioid overdose and free naloxone. You will also be given an extensive list of referrals for mental health and social services at the end of the in-person survey.
- To enroll in the study, we will ask that you meet a project staff member at New York University (NYU), if possible, and answer a series of survey questions about your background, substance use, mental health, and social life.
- Control participants will then receive monthly phone calls offering additional referrals. We ask that you participate by taking phone calls from your peer navigator and consider any way that a navigator could help you link to services or care.
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More Detail about Questionnaires.

- You will be asked to participate in a series of questionnaires when you begin the study and again at 3, 6, 9 and 15 months. These questionnaires will ask you about your: background; living situation; mental health and drug treatment history; experiences using opioids and other drugs, including experiences injecting drugs (opioids and others); knowledge of and attitudes about overdose; and social relationships with other people who use opioids.
- If you feel uncomfortable when our study requests information about topics that are sensitive to you, you can skip to the next question.
- When due for 3-, 6-, 9-, and 15- month follow-up, participants will be sent email and SMS notifications and links to online questionnaires that can be accessed and completed on all Android and Apple/iOS based mobile phones as well as tablets, computers, or any other web-enabled device with web browser functionality.
- If you do not have a phone or computer that allows you to take these online surveys, you can call the project phone number, (646) 820-4778, to get assistance with completing them.

How long will I participate in this study and how long will each study procedure take?

- Your participation in this research study is expected to last for a total of 15 months. You can choose to withdraw from this study at any time before completing it.
- For all participants, the VHOW or navigation component of the intervention will last 9 months, but there is a final internet survey at 15 months that will be sent electronically to all participants.

Keeping in Touch with the study and Updating Contact Information

- **Because phone numbers and other contact information can change**

often, we provide you an additional $10 incentive for just checking in with us each month via phone or in person to update us with any new phone numbers or to confirm that your contact information has not changed. We are providing a wallet size card with your date of enrollment and the dates for the next 14 months of study participation.

What are the possible risks or discomforts of the study?

- The risks from participating in this study are minimal. The questionnaires will ask about your drug use which may make you feel uncomfortable. If you are in the CENS intervention, the ongoing discussions you may have with your veteran health outreach worker may raise some distress or complex emotions. It is important that you understand that your outreach worker is not a trained clinician and will not be able to provide you with any form of treatment or professional support for such concerns as posttraumatic stress or other mental health experiences. What they are trained to do, however, is to direct you to the right healthcare providers who are experts in whatever concern you may have.

- There is always a small risk of a breach of confidentiality in a study like this. We take extreme precautions to prevent this, however, which are noted below in the section called, "How will my intervention be protected?"

What are the possible benefits of the study?

- You may benefit from this experience by sharing information about your real experiences and behaviors that will help us to understand the experiences and challenges of veterans who use opioids.
- You may benefit from this study's training and the provided naloxone kit by being in a position to reverse an overdose being experienced by someone around you. Similarly, if the kit is available to someone in your immediate vicinity when you should happen to overdose, the kit could potentially be used to reverse your own overdose.

What other choices do I have if I do not participate?

- If you decide not to participate in the study, the study team will still offer you referrals and will provide you with an overdose education training and naloxone.

Will I be compensated for being in this study?

- The initial training and survey assessments last roughly 90 minutes. All participants enrolled in either "arm" of the study will complete this and will be compensated $60. Thereafter, follow-up assessment (about 30 minutes each to complete) will compensate $30, $40, $50, and $60 at 3-, 6-, 9-, and 15-month intervals post-enrollment. Thus, you will receive $240 for completing the study assessments.
- CENS participants will receive an additional $10 for each training video they watch and discuss briefly with their VHOW, for a total of an additional $90.
- CENS and Control group participants will receive an additional $10 each month for checking in with the study by phone or in person to let us know your contact

information has not changed or to update us on your new contact information. These check-in payments are available every month you are in the study except for the month in which you are enrolled (this visit). If you miss a month checking in, you will not receive that money the following month.

- In addition to the financial compensation, all participants will receive naloxone, a medication that reverses an overdose. Naloxone also known as Narcan is an opioid antagonist meaning it binds to the opioid receptors to block the effects of an opiate.

  As is required by the laws that apply to NYU, in order for you to receive payments, including those on your CTPayer card, you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you receive more than $600 from NYU in a calendar year, then NYU will report it to the US Internal Revenue Service and issue you a Form 1099. If you do not have either of these numbers or are not willing to complete the IRS form, you may be in the study but will not receive any payment.

When is the study over? Can I leave the study before it ends?

- Participation in the study includes 9 months of VHOW support and/or referrals as usual and also involves one final survey 15 months after you enter the study. While we ask that you stay in the study until it is completed, you are free to leave the study at any time without penalty.

What happens if I leave the study or am withdrawn from the study?

- There is no penalty for withdrawing from the study early, although you will not receive incentives for surveys or video viewings that you do not complete.
- If you choose to discontinue participation in the study or if the investigators withdraw you from the study, then you would no longer have access to the resources or materials that are available to you as a research participant in the study, depending on which group – CENS or control – that you're assigned to. Depending on when your participation stops, this may include no longer having access to the education in overdose prevention and response and the use of naloxone and best ways to prevent and reverse an overdose.

How will my information be protected?

- We will protect your confidentiality by coding your questionnaire responses with a study identification number only, not by your name. The only place we will store your name is on the consent form, the locator form and a master tracking log. All off this study information will be kept in locked file cabinets and computer networks accessible only to research staff. Code numbers will be locked up separately from all study data. Any publications and/or presentations that result from this study will not identify you by name or report information about you that could identify you.

<u>Certificate of Confidentiality.</u>

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use

information, documents or biospecimens that may identify you in any federal, state or local civil, criminal, administrative, legislative or other action, suit or proceeding, or be used as evidence – for example, if there is a court subpoena – unless you have consented to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except if there is a federal, state or local law that requires disclosure; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

- You should understand that a Certificate of Confidentiality does not protect you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person or entity not connected with the research, you must provide consent to allow the researchers to release it.

Will information collected about me in this study be shared with other researchers or used for future research?

- All data will be de-identified and the de-identified data will be preserved as-is and available to data users for a minimum of ten years. All specific identifies will be removed from final datasets prior to release for sharing. Study results will also be shared at scientific meetings, meetings with stakeholders including the Veteran Administration, Departments of Health, community-based organizations and Veteran Service Organizations.
- Information not containing identifiers may be used in future research, shared with other researchers, or placed in a data repository without your additional consent.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who should I contact if I have any questions about this study?

- You are encouraged to ask questions at any time during this study. For information about the study, contact If there is anything about the study or your participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact Alex S. Bennett at (212) 998-5290, asb19@nyu.edu, 708 Broadway 6th Fl. New York, NY.

- If you have questions about your rights as research participant or if you believe you've been harmed from the research, please contact the NYU Institutional Review Board at (212)998-4808 or ask.humansubjects@nyu.edu.

Agreement to Participate

When you sign your name, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Do not sign this form if you do not agree to participate in the study.

You will receive a copy of this consent document to keep.

Do you agree to participate in this research study?

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date