Research Informed Consent / HIPAA Authorization
IRB # 2024-0862

Study Name: PEERS Pilot Study

Full Title: Pilot evaluation of a peer recovery support program adapted to target retention in clinic-based medication for opioid use disorder treatment

Lead Researcher: Melissa Poulsen, PhD

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, Option 3

Funded by: National Institutes of Health

In this consent form, “you” always refers to the person taking part in the research study.

Study Summary

We are asking you to join this study because you recently started medication treatment for opioid use disorder at a Geisinger clinic. We are doing this study to try out a new program for people beginning treatment for opioid use disorder that includes working with a **certified recovery specialist (CRS)**. A CRS is a person who is in recovery from a substance use disorder and who is trained to support others in their recovery journey. Through this study, we hope to learn how to improve the CRS program. If you choose to enroll in this research study, you will be offered support from a CRS. You will be able to meet with a CRS on a regular basis to receive support in your recovery from opioid use disorder.

You will be in the study for about 6 months. You will be asked to complete questionnaires and an interview as part of the study. You will receive gift cards as a thank you for your time.

This study might or might not help you. You might benefit from the support you receive from the CRS. There are risks related to the study. You could feel uncomfortable answering some questions in the questionnaires, but you can skip any questions you do not want to answer. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

For this study, we will share some information about you with our study collaborators at the University of Connecticut Health Center (UConn Health).

The rest of this form will describe the study in more detail.

We are asking you to be in a health research study.

You do not have to be in this study. If you join this study, you can stop at any time by contacting the study team listed in the box above. Your usual care or access to care at Geisinger will not change if you say no. You will not lose any benefits to which you are otherwise entitled if you decide not to join the study or if you decide to stop taking part after you join.

This form tells you about the study and how your health information will be used.

What should I do?

- Read this form or have it read to you.

- Make sure you understand the study and what you are being asked to do.
- Ask any questions you have about the study.
- Take the time you need to think about this.

Why is this study being done?

We want to learn more about whether adding a **certified recovery specialist** (CRS) to provide peer support helps individuals stay in medication treatment for opioid use disorder longer and have better success in their recovery. Through this study, we hope to learn how to improve the CRS program.

Why am I being asked to be in the study?

We are asking you to join this study because you are a patient at a Geisinger clinic receiving medication for the treatment of opioid use disorder.

How long will I be in the study?

You will be in the research study for about 6 months.

What will I be asked to do?

You will be invited to meet with a CRS on a regular basis who will provide additional support during your treatment journey. You will be able to choose when and if you meet with a CRS.

You will be asked to complete a questionnaire when you enroll in the study and again in about 3 months from now. You can complete these questionnaires online, on a secure-password-protected database, or by phone with one of the study staff members. Each questionnaire will take about 35-40 minutes to complete. The questionnaires will ask you about aspects of your recovery from opioid use disorder.

You will be asked to participate in an interview over the phone or video-conference with a study staff member in about 2-3 months from now. The interview will take 30-60 minutes. You will be asked questions about your experience in the CRS program. This interview will be audio recorded to ensure that your thoughts are accurately represented. The audio recording will be transcribed and de-identified. We will not share the audio recording with anyone outside of the Geisinger study team.

Researchers will also look at your medical record information in Geisinger's electronic health record system, Epic. We will combine this information with the answers on the questionnaires.

If you do not want to actively participate in the study, you have the option to just share your medical record information. If you choose this option, you will not be invited to meet with the CRS for this study and will not be asked to complete questionnaires or participate in an interview.

Will my data be used for future research?

Your information will be securely stored and shared for future research. For example, your information might be used for future research about how to improve treatment for opioid use disorder. To keep your information private, it will not contain your name or other information that could directly identify you. You will not be asked to provide consent when your information is shared for future research. We will not give you any results from these studies.

We may share your information with academic and medical institutions and other researchers.

You will likely not directly benefit from future research with your information. What is learned may help develop new scientific knowledge to help improve health care.

Can being in this study help me?

This study might or might not help you. We hope you will benefit from the support you receive from the CRS. We also hope that what is learned from this study will help others in the future by improving the CRS program.

What are the risks?

There are no physical risks expected with this study. You could feel uncomfortable answering some questions in the questionnaires. You have the option to skip any question you do not wish to answer. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information. Your name and identifying information will be stored separately from your questionnaire answers and from your medical information. All study information will be stored on a secure computer database that only study staff can access.

What are the costs?

There are no costs for meeting with the CRS or to participate in the study.

Will I be paid?

You will receive a $15 gift card for the use of your medical record information, $40 gift card for completing a baseline questionnaire, a $75 gift card for completing a follow-up questionnaire, and a $50 gift card for participating in an interview. The total payment for this study will be $180. This is taxable income and reportable to the IRS. If your total payments from Geisinger are $600 or more in a calendar year, Geisinger, will send you a 1099 form for your taxes.

How will my information be used?

Your information will be collected and used by Geisinger study staff to help improve the CRS program.

Geisinger study staff will view and collect information about you during this study. The information collected about you for the study will include:

- Your answers to the questionnaires and interview. Some of the questions in the online questionnaires are about your past and current use of illicit drugs.
- Information from your Geisinger medical record. This will include information about substance use disorders and mental health conditions that you have been diagnosed with and any medication treatment for opioid use disorder that you have received.
- Information from your medical record may also include:
    - Demographics
    - Clinical Notes
    - Dates
    - Encounter Data
- The study will also collection information from your medical record of the frequency of meetings with the CRS, the amount of time each CRS meeting took, and the overall focus of each meeting.

Study information will be stored securely in a research record at Geisinger**.** These records will be kept indefinitely.

How will my information be shared?

Some of your information will be shared outside of Geisinger for this study. Information about you will be shared with researchers at the University of Connecticut Health Center (UConn Health) who are helping with this study. We will <u>not</u> share information that directly identifies you, like your name or medical record number. They may keep and use the information from the study without end for the research purposes described in this form.

Information shared with the University of Connecticut Health Center will include:

- De-identified demographic information such as age and sex

- Responses to the study questionnaire
- De-identified interview transcripts

We will not share your questionnaire answers with your medical providers.

How will my information be protected?

This study has a Certificate of Confidentiality (COC).
For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the NIH. This means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law in the United States.

There are some limits to this protection, including:
- If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
- If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
- The FDA and other government agencies who audit the research.

Information about you can be released when you say it is okay. For example:
- You may give us permission to release information to insurers, medical providers or any other persons not connected with the research.
- You and your family can share information about your part in this research, if you wish.

How might my information be reviewed for quality?

Your research record could be reviewed for quality and to make sure research rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Department of Health and Human Services (DHHS)

- Office for Human Research Protections (OHRP)

What if I have questions or problems?

If you have questions, concerns, or complaints about the study, call or study team at: 1-866-910-6486, Option 3.

Call the Geisinger Institutional Review Board (IRB) at 844-542-3299 or 570-271-8663 (Danville, PA) if you:

- Have questions about your rights as a research participant.
- Have questions, concerns, or complaints about the research.

A description of this study will be available on 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.

Signature

By signing this form, you are giving Geisinger permission to use and share your health information. It can be shared indefinitely for purposes of this study and for future research as explained in this form. If you change your mind, tell us in writing to stop sharing your information. Write to: PEERS, 44-00, 100 N. Academy Ave, Danville, PA 17822.

Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow the law.

If you do not sign this form, you cannot join this study.

_____

Electronic Signature Page: Adult Research Participant

I agree to take part in this research study and allow my health information to be used and shared as stated in this form. My questions have been answered.

_____
Research Participant's Printed Name

_____ _____
Research Participant's Signature Date

Thank you for agreeing to let us use your medical record information. We will send you a $15 electronic gift card.

What type of gift card would you like?
[ ] Amazon (if you do not already have one, you will need set up a free Amazon account to use this gift card)
[ ] Walmart

Where should we send your electronic gift card?
[ ] Email
[ ] Mail

We will send you a signed copy of the consent form. Where should we send the form?
[ ] Email
[ ] Mail

Email address:

Mailing address:

Can we contact you by text message?

With your permission, we will send you text messages when it is time to do the second questionnaire, about 3 months from now. You will be able to complete the questionnaire using a link in the text message.

Standard text messaging rates will apply. Before you agree, you may want to think about who else besides you might see your text messages. The text message will not say what the study is about.

You can stop receiving text messages from us at any time if you change your mind.

If you agree to receive text messages for the study, please enter your mobile phone number in the box.

Cell phone number:

Electronic Signature Page: Sharing Medical Record Information

I do not want to join the study, but I agree to allow my medical record information to be used as stated in this form. My questions have been answered.

_____
Research Participant's Printed Name

_____ _____
Research Participant's Signature Date

Thank you for agreeing to let us use your medical record information. We will send you a $15 electronic gift card.

What type of gift card would you like?
[ ] Amazon (if you do not already have one, you will need set up a free Amazon account to use this gift card)
[ ] Walmart

Where should we send your electronic gift card?
[ ] Email
[ ] Mail

We will send you a signed copy of the consent form. Where should we send the form?
[ ] Email
[ ] Mail

Email address:

Mailing address:

Please share with us why you are not interested in joining the study.
[text box]