Criminal Justice Coordinated Transitional Care (CJC-TraC)

NCT05376371

3/14/2023

Study #: 2022-0398
Lead Researcher: Ryan Westergaard; 608-265-7927
Version: January 23, 2023, V6

University of Wisconsin-Madison
Consent to Participate in Research and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: CJC-TraC

Formal Study Title: Health Systems Innovations for Supporting Transitions of Care for Incarcerated People Living with HIV, Hepatitis C and Opioid Use Disorder.

Lead Researcher:

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Institution: UW Madison

Funding: National Institute of Health, National Institute of Drug Abuse

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Key Information: The information in this section is to help you decide whether to be a part of this study. You can find more detailed information later in this form.

Why are researchers doing this study? People with drug or alcohol use, and people living with HIV or hepatitis C sometimes encounter challenges when trying to access needed health services after being released from prison. Our research team at the University of Wisconsin-Madison is studying whether a brief tailored program called "CJC-TraC" can help connect people to the medical care they need to keep them healthy.

We invite you to take part in this research study because you are scheduled to be released from prison within the next 6 months and have one or more medical conditions that may need outpatient medical care.

What will I need to do in this study? Participation in the study includes 3 in person and phone meetings with a Nurse Case Manager before and weekly phone calls after release until you complete prescheduled medical appointment. You will be asked to complete 2 research questionnaires over the course of 6 months, one before you leave prison, and the second 3 months after. The research questionnaires will ask you questions about your medical history, previous experiences accessing health care, and what your priorities are when getting medical care or other helpful services after getting released from prison. The Nurse Case Manager is a UW-Madison employee working within DOC facilities who will assist participants with enrolling in Medicaid, identifying a medical or mental health provider, scheduling post-release medical appointments, and identifying and addressing worsening medical conditions and potential barriers to attending a medical appointment after release.

You will be in this research study for up to 6-9 months, starting today, and continuing until 3 months after you are released from prison.

What are some reasons I might – or might not – want to be in this study? Participating in this study may be beneficial for you to get direct support with managing your health and getting connected to health care. The study may also benefit other people in the future by helping us learn more about how this program can improve health care outcomes for people releasing from prison.

You may want to be in this study if you are:	You may NOT want to be in this study if you:

Interested in getting support to manage chronic health conditions. Interested in scheduling health and wellness appointments with assistance prior to release. Trying to prioritize your health. Willing to participate in the study for up to a year. Interested in contributing to scientific knowledge.	Do not have an interest in connecting to medical or mental health care after release Are not comfortable having researchers ask questions about your physical and mental health. May not have time to complete study questionnaires or want to share personal information.

Taking part in this research study will not help you get the housing or correctional program assignments you want. Taking part in this research study will not affect your date of parole or release.

Do I have to be in the study? No, taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

How is research different from health care? When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study? If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at 1 (608) 501-5987. If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

Study Phase:	**Screening**	**Study Visits – *While Incarcerated***			**Study Visits –*After Release***		
Visit Number:		1	2	3	Weekly phone calls until appointment is made		
Length of Visit:	30 Minutes	Up to 60 minutes	Up to 60 minutes	Up to 60 minutes	Up to 15 minutes	Up to 15 minutes	Up to 15 minutes
Questionnaire:		Baseline Study Assessment			End-of-Study Assessment		
Where:	Within DOC				Phone Call		

You will be asked to meet with a Nurse Case Manager at least 3 times before your release. These meetings can be in person, virtually, or by phone. The Nurse Case Manager will complete a baseline study assessment with you at one of these meetings prior to your release. This assessment will ask you a variety of questions related to your personal history and medical care.

After you are released from prison, you will be asked to have weekly phone calls with the Nurse Case Manager or study staff. The phone calls will last 10-15 minutes, and you will be asked questions about barriers to accessing health care and questions about medications. Others will be more sensitive in nature, including topics such as drug use and mental health. After you complete the study activity of attending your prescheduled medical appointment, you will be asked to complete an end of study assessment that includes questions related to your personal history, medical care, and attitudes towards the CJC-TraC programming.

If you plan to participate, you will likely spend between 4-6 hours interacting with study staff over the

course of the study.

If you become re-incarcerated during the study, we request your permission to contact you at the facility where you are staying. If we talk to staff at the facility to set up a phone call, we will not tell them any details about the study or why you were eligible. We will just say you are enrolled in a health study.

We may ask you to do an interview after the final study assessment. During this interview, you will be asked several questions about your experience in the study. The interview will be recorded, and the transcript will be used by the research team. We would remove all personal information about you before using the transcript, so you cannot be identified. The transcript may be used in publications and/or to help inform future research, but not in a way that anyone could identify you.

In addition, the research team will also ask for your permission to get records from the clinic where you will receive care in the community after you are released. If you give permission, the study will also get copies of your lab results. The information you can agree to share includes the dates that you went to clinic, the medications you were prescribed, and the results of lab tests. Your clinic will not share this information with the research team without your written permission, and the research team will not share this information with anyone else.

Protected health information (PHI) used in this study. Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI: Things you tell the researchers about your health, information currently in your medical records, as well as information added to your medical records during this study. This information could include your medical history, your diagnosis, lab test results.

What happens if I say yes, but I change my mind later? You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights. No additional patient data will be collected. Data previously collected to that point will be used in analyses as appropriate.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to continue participating in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Ryan Westergaard at 1685 Highland Ave 5th Floor, Madison, WI 53705.

What are the study risks?

1. Reporting on sensitive issues (such as drug and alcohol use, mental health, HIV and Hepatitis C status) may cause anxiety, distress, embarrassment, or feelings of sadness. However, you do not have to answer any questions that you do not want to answer.
2. There is a risk that your information could become known to someone not involved in this study and this could violate your privacy. Study staff will take all the steps they can to protect your privacy.

What happens to the information collected for the research? We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a

legal request without your consent. Parole boards will not consider your participation in the research in making decisions regarding parole, and participation will have no effect on your parole.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes the University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program. Data recipients may include NIDA and federal research oversight and monitoring groups.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your Personal Health Information means that we can release it to the people or groups listed above for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

Data for the project will be securely stored in compliance with university and federal regulations and that no unauthorized persons have access (electronic or physical) to any participant-identifiable data. Electronic information will be stored on university secured servers and physical documents will always be stored in a locked cabinet when not in use.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research or share it with other researchers without additional consent from you. All information will be coded, and they will not have access to the key that connects data to names, so it will not be able to be traced back to you.

We will keep your data for an indefinite period, meaning we have no plans of ever destroying them. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers. The banked data will be labeled with a code number that allows only the members of this research team to identify you. We will use the data in future research projects about research on HIV, HCV, or substance use disorders. Banked data and biospecimens will not be shared with your health care providers or used in your treatment outside this study. If you decide you no longer want your data banked, you must request in writing to the research team that it be withdrawn.

A description of this clinical trial will be available on http://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 study results. You can search this Web site at any time.

Can I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. This would occur if you do not follow the study rules or no longer meet the requirements to be in the study

Will I receive anything for participating?

Study Activity	Compensation
Baseline Study Assessment	$5

End-of-Study Assessment	$30
Exit Interview	$30
Max amount of payment: $65	

If you do not have a phone upon release, we will provide a smart phone with an active unlimited plan for up to 4 months for communicating with the Nurse Case Manager. While you're enrolled in the study, you may also use the phone for personal calls and text. You may also be invited to participate in a exit interview where you would be compensated $30.

Permission to communicate about the study by email

We are requesting your email address so we can have another way to contact you after being released from prison. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact the research team at 1 (608) 501-5987. You do not have to provide your email address to participate in this study.

How many people will be in this study?

We expect about 220 people will be in this research study.

Who is funding this study?

This research is being funded by the National Institutes of Health.

What will happen to my data after my participation ends?

We will keep your data for an indefinite period, meaning we have no plans of ever destroying them. Keeping data for future research is called "banking." The banked data will be kept in a secure password protected folder on an encrypted server managed by the University of Wisconsin-Madison Department of Medicine IT team, and accessible to only IRB approved members of the research team who conduct project management or data analysis. The data will be fully anonymized prior to banking, removing any identifying information about participants. We may use the data in future research projects about improving HIV, HCV, and substance use care.
The anonymized data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study. Due to the anonymity of the banked data, participants will not be able to withdraw their information once it has been banked.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.

- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Signature of participant	Date

Printed name of participant

Signature of person obtaining consent	Date

Printed name of person obtaining consent

The following witness line is to be signed only if this consent form is provided as a written summary and accompanied by a short form foreign language consent, or if this consent form is read aloud to a participant unable to read.

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, that the participant's questions were answered, and that consent was freely given by the participant.

Signature of witness to consent process	Date

Printed name of person witnessing consent process