Peer Recovery Coaching to Facilitate Comprehensive Infectious Diseases Prevention and Care among Patients with Opioid Use Disorder: An Open Pilot Study

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1 List of Abbreviations

Abbreviation	Abbreviation definition
HIV	Human immunodeficiency virus
HCV	Hepatitis C
PRC	Peer recovery coach
PrEP	Pre-exposure prophylaxis

2 Protocol Summary

Title:	Recovery coaching for HIV, HCV and substance use
Population:	We will include 40 individuals with a history of substance use disorder who are seen at the Boston Medical Center's (BMC) Faster Paths (urgent care walk-in clinic).
Intervention:	Peer recovery coaching (PRC) to improve linkage to HIV prevention in the form of HIV pre-exposure prophylaxis (PrEP) and hepatitis C (HCV) treatment.
Objectives:	Our goal is to determine if a peer recovery coaching intervention will help patients initiate HIV prevention in the form of HIV pre-exposure prophylaxis (PrEP), HCV treatment and substance use disorder (SUD) treatment.
Design/Methodology:	Participants who consent will work one-on-one with a peer recovery coach who will provide support and linkage to various HIV, HCV and SUD resources.
Total Study Duration:	Time from initial enrollment until completion of data analysis= 12 months
Subject Participation Duration:	Time it will take to conduct the study for each individual participant =6 months

3 Background/Rationale & Purpose

3.1 Background Information

The U.S. opioid epidemic is associated with a surge in human immunodeficiency (HIV) and hepatitis C virus (HCV) infections among persons who inject drugs (PWID).[1, 2] HIV pre-exposure prophylaxis (PrEP) and HCV curative therapy are evidence-based interventions that are recommended for PWID to prevent HIV and HCV transmission, respectively.[3, 4] These evidence-based tools have, however, not been widely adopted in

real-world settings where individuals at-risk access care.[5] We have published studies on models of care to improve outcomes related to infectious complications of substance use such as HIV and HCV. In terms of HIV prevention, we determined in a survey of individuals admitted to a drug detoxification center that participants had limited knowledge of HIV PrEP, but expressed interest in this biomedical prevention method.[6] As for our work related to HCV, we demonstrated that the majority of individuals with substance use disorder tested for HCV at a drug detoxification center do not link to HCV care and that active substance use was a major barrier to accessing curative HCV therapy.[7, 8] Participants also reported the need for walk-in high-touch care to assist with navigation along the HCV continuum of care. In addition to our work related to HIV and HCV care, members of our team have also shown that a peer-delivered brief motivational intervention was effective in assisting individuals to abstain from heroin and/or cocaine use.[9] This intervention delivered by non-professionals who are themselves in recovery has been widely replicated around the country to address substance use; however, little is known about its potential role in improving HIV and HCV outcomes among individuals with opioid use disorder.

Our long-term goal is to improve HIV and HCV prevention and treatment outcomes among at-risk individuals with history of substance use. The goal of the current proposal is to determine the efficacy of a brief motivational peer recovery coaching (PRC) intervention to improve infectious diseases (HIV/HCV) prevention and care alongside substance use disorder (SUD) management for PWID. PRC will bridge the gap between professional assistance in clinical settings and sustainable recovery in the community. Our multisite study will be performed at low-barrier BMC FASTER PATHS bridge clinic (the Boston Medical Center Faster Paths walk-in bridge clinic) which links individuals with SUD to evidence-based addiction treatment such as buprenorphine and methadone.[10] Bridge clinics have been especially valuable for engaging individuals who do not always feel comfortable in traditional clinical settings. The central hypothesis of the current study is that a PRC intervention will be effective in improving HIV, HCV and substance use outcomes.

Potential risks associated with participation in the study include risk associated with discussing issues related to HIV, HCV or substance use disorder and risk of breach in confidentially. Related to emotional risk, if any participant were to experience any distress we will remind him/her of his/her right to decline answering any questions. In terms of risk of breach in confidentiality, the research staff will be trained in the importance of assuring confidentiality in record keeping. In addition, all documents will be kept in locket cabinets and computers will be password protected. In addition, the study will be conducted in compliance with the protocol, applicable regulatory

requirements, and BMC/BU Medical Campus Human Research Protection policies and procedures.

3.2 Rationale and Purpose

The U.S. opioid epidemic is associated with a surge in human immunodeficiency (HIV) and hepatitis C virus (HCV) infections among persons who inject drugs (PWID). HIV pre-exposure prophylaxis (PrEP) and HCV curative therapy are evidence-based tools that are recommended for PWID. These evidence-based measures have, however, not been widely adopted in real-world settings. A peer-delivered brief motivational intervention was shown to be effective in assisting individuals to abstain from heroin and/or cocaine use, but little is known about its potential role in improving HIV and/or HCV-related outcomes among individuals with opioid use disorder.

4 Objectives

4.1 Study Objectives

The goal of the current proposal is to determine the feasibility and acceptability of a peer recovery coaching (PRC) intervention to improve infectious diseases (HIV/HCV) prevention and care alongside treatment for opioid use disorder.

Aim 1: To implement a pilot peer recovery coaching intervention at a walk-in low-barrier bridge clinic to increase uptake of a comprehensive intervention for HIV PrEP, HCV and substance use treatment among PWID accessing care at Boston Medical Center (BMC).

Aim 2: To determine the feasibility and acceptability of a combined PrEP, HCV and substance use treatment intervention at the BMC FASTER PATHS bridge clinic

We hypothesize that the peer recovery coaching intervention will facilitate both access to PrEP, HCV treatment and sustained engagement with treatment for opioid use disorder among participants. The primary outcome is patient satisfaction as a measure of the intervention's acceptability. Secondary outcomes will include (1) the proportion of patients with linkage to PrEP and treatment initiation within 3 months; (2) the proportion of patients with HCV treatment initiation within 3 months; (3) the proportion of patients with sustained linkage to opioid use treatment within 3 months (follow-up with at least one subsequent visit after the initial prescription for medication for opioid use disorder).

4.1.1 Primary Outcome Measures

This is an open pilot study. The Primary outcome will include patient satisfaction as a measure of the peer recovery coach intervention's acceptability.

4.1.2 Secondary Outcome Measures

Secondary outcomes will include the following:

(1) The proportion of participants with linkage to care.
(2) The proportion of participants retained in care
(3) The following additional outcomes:

HIV PrEP-related outcomes: Testing for sexually transmitted diseases including HIV, gonorrhea, chlamydia, syphilis, and hepatitis B and C.

HCV continuum of care outcomes: HCV RNA testing, liver fibrosis staging, treatment initiation and cure.

Opioid use disorder treatment-related outcomes: The proportion of individuals with repeat MOUD clinic visits and/or repeat prescriptions for opioid use disorder including buprenorphine and naltrexone, or linked to methadone treatment.

5 Study Design

The study is prospective open pilot study (N=40).

We will include 40 persons with a history of substance use recruited from the BMC FASTER PATHS bridge clinic, a facility caring for approximately 500 unique patients annually. The BMC FASTER PATHS bridge clinic provides universal HIV and HCV testing at the initial clinic intake. After reactive HCV testing, patients are linked to care at the BMC General Internal Medicine (GIM) primary care clinic.

The goal of the current study is to determine feasibility and acceptability of a peer recovery coaching intervention to improve the uptake of HIV prevention, HCV treatment

and substance use treatment at a low-barrier bridge clinic. Along with the research assistant, the peer recovery coach is part of the research staff. The peer recovery coach will carry out the intervention (ie. use motivational interviewing to help participants address their history of opioid use while also accessing treatment for hepatitis C and HIV prevention methods). The peer recovery coach will carry out a baseline motivational interviewing intervention with participants and they will continue to follow the participants over a 6-month time frame. Frequency of follow-up calls will vary depending on the participant's need. The recovery coach will initially start with weekly calls.

As part of this study, we are partnering with Dr. Cruz, the PI for project RECOVER (Referral, Engagement, Case Management, and Overdose Prevention Education in Recovery), an HHS-funded study using peer recovery coaching to support individuals in recovery. Dr. Cruz is part of the General Internal Medicine section at BMC and he has experiences training recovery coaches for HHS-funded grant. He is a co-investigator on the current proposal. The project RECOVER team will provide assistance with hiring and training recovery coaches. Recovery coach training will involve the following topics related to substance use: (1) Addiction 101 for recovery coaches; (2) Ethical considerations for recovery coaches; (3) Mental wellness and recovery coaching; (4) Cultural competency for recovery coaches; (5) Motivational interviewing for recovery coaches. In addition to the substance use related topics, we will also add information about HIV natural history, HIV prevention methods, PrEP efficacy studies, PrEP eligibility and medical management.

The research assistant will be in charge of all the regulatory aspects of the research, recruitment (eg. approaching and consenting participants) and carrying out the baseline interviews to obtain demographic information. The research assistant will also review the participant's electronic medical records to abstract information on key outcomes measures such as linkage to substance use care, HCV treatment or HIV prevention.

- Recruitment: Participants will be recruited through flyers posted at the LBA walk-in clinic and brief information provided at intake.
    - Flyers advertising the study will be placed in the waiting and common areas of the BMC FASTER PATHS bridge clinic.
- Flyers advertising the study will be placed in the waiting and common areas of the BMC Faster Paths walk-in clinic. Patients will be approached for participation

after the medical provider has explained the study at length. Some participants will reach out to our study staff through flyer contact information, while other participants will be pre-screened by medical providers and referred to the RA. Using an electronic medical record (EMR), the RA will notify the medical provider prior to the visit so proper handoff can be made. Once the RA has initiated contact with interested participant, the RA will provide a description of the study including its objectives and will provide adequate time for participants to ask questions and address concerns. Risks and benefits of the study will be discussed and interested individuals will be reminded that participation is voluntary. The RA will emphasize that participation in the study will not impact the care received at the Faster Paths clinic and that individuals may withdraw from the study at any time. Those who wish to be involved with the study will provide informed consent. The RA will obtain reason for refusal if approached individuals are not interested in participating in the study. After reactive HCV testing at the BMC Faster Paths walk-in clinic, all participants will be linked to care at the BMC General Internal Medicine (GIM) clinic.

6 Potential Risks and Benefits

6.1 Risks

Participation in the study includes risks associated with emotional distress related to discussing HIV or HCV status and history of substance use disorder. There is also a risk of possible breach of confidentiality. In terms of emotional distress, participants will be informed that they can choose to not answer some question that might be uncomfortable and end the interview early if he/she were to experience any emotional distress.

There is also a potential risk of breach in confidentiality. We will take steps to prevent this by keeping information in locked cabinets and using computers with password protection.

6.2 Potential Benefits

There will be no direct benefits to participants from taking part in the study; however, the information collected will help improve the care of patients with a history of substance use disorder with or at risk for HIV and HCV.

Participants will receive $20 for your participation in each interview session with the RA at baseline, 3-and 6 months post-enrollment.

6.3 Analysis of Risks in Relation to Benefits

As noted above, the information collected will help improve the care of patients with a history of substance use disorder with or at risk for HIV and HCV.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

- Inclusion criteria
    - Must be at least 18 years of age at time of enrollment.
    - Individuals with opioid use disorder, non-reactive HIV antibody test and reactive HCV antibody testing at the BMC low-barrier bridge walk-in clinic.
    - Participants providing contact information of two family members or friends.
    - Individuals signing a medical records release form.

7.2 Subject Exclusion Criteria

An individual who meets any of the following criteria will be excluded from participation in this study:

- Individuals unable to provide informed consent
- Unable to speak English
- Individuals already linked to substance use care
- Individuals co-infected with HIV and HCV and engaged in care.

8 Study Intervention

- The intervention: The peer recovery coach with lived experience with recovery from substance use will deliver a semi-scripted brief motivational interview at the time of enrollment. The intervention will last approximately

20 minutes and will take place at the time of the clinical visit while participants are waiting to be seen by a clinician or are awaiting laboratory testing. The intervention will involve the following elements: establishing rapport, asking permission to discuss drugs, discussing the pros and cons associated with drug use, uncovering the gaps between current and desired quality of life and determining readiness to change. Participants will also receive a telephone booster call 5 days following enrollment. The RA will assemble detailed contact information for the patient and will record addresses of two family members or friends. The RA will also collect demographic information and reasons for refusal from individuals who do not participate in the study. Patients seen at the BMC FASTER PATHS bridge clinics usually follow-up at the general medicine clinics at BMC. Following the initial brief motivational interview, the peer recovery coach will remain in contact with participants by phone or in person at least once a week over the following 6-month period and help with facilitating linkage to HIV pre-exposure prophylaxis, HCV and substance use care and treatment.

9 Study Procedures

- The study will be conducted at the low-barrier walk-in clinic at BMC. The clinic sees approximately 500 unique patients annually. After reactive HCV testing at the BMC LBA walk-in clinic, all participants will be linked to care at the BMC General Internal Medicine (GIM) clinic. Participants will be followed for 6 months.

- Recruitment: Participants will be recruited through flyers posted at the LBA walk-in clinic and brief information provided at intake.

    - Flyers advertising the study will be placed in the waiting and common areas of the BMC LBA clinic.

A trained RA will perform baseline interviews, as well as 3- and 6-month post enrollment face-to-face interviews using assessments listed in Table 1. The RA will also review the electronic medical records (EMR) to obtain clinical data (HIV and HCV-related test results) as well as information on appointments. If we are not able to perform in-person interviews, then assessments will be performed over the phone, if possible. For each participant we will determine:

(1) The proportion of participants with linkage to care.
(2) The proportion of participants retained in care

(3) The following additional outcomes:

HIV PrEP-related outcomes: Testing for sexually transmitted diseases including HIV, gonorrhea, chlamydia, syphilis, and hepatitis B and C.

HCV continuum of care outcomes: HCV RNA testing, liver fibrosis staging, treatment initiation and cure.

Opioid use disorder treatment-related outcomes: The proportion of individuals with repeat medication for opioid use disorder (MOUD) clinic visits and/or repeat prescriptions for opioid use disorder including buprenorphine and naltrexone, or linked to methadone treatment.

Table 1: List of data to be abstracted

Characteristic	Description
Demographics	Age, gender, employment, housing, social support
HIV PrEP clinical information	HIV antibody, STI testing, prescription for PrEP
HCV clinical information	HCV viral load, genotype, fibrosis staging, HCV treatment
HIV PrEP, HCV care, Addiction services	Appointments attended
Drug Use	Types, ASI[22], dependence by CIDI-SF[23] Urine testing, MOUD prescription
Readiness to change ruler	Self-assessment on readiness to change behavior and enter treatment
Mental Health and Social	Depression symptoms, stigma and disclosure
*ASI=Addiction severity index; CIDI-SF=Composite International Diagnostic Interview Short Form; MOUD=Medication for opioid use disorder; PrEP=preexposure prophylaxis; STI=Sexually Transmitted Infection	

10 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

10.1 Definitions

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's

participation in the research, whether or not considered related to the subject's participation in the research.

10.2 Safety Review

Both the risks listed in Section 4.1 and unknown risks will be monitored as follows

Data safety monitoring plan:

The PI will continually monitor the safety of participants and study data. Adverse events and unanticipated problems will be reviewed to detect any trends and threats to participant safety and concerns for breach of participant confidentiality. Additional issues that arise will be routinely monitored by the PI. Any adverse events will be reported to the IRB and the sponsor, as appropriate, and any necessary revisions to the protocol and/or standard operating procedures will be submitted for IRB review.

10.3 Reporting Plans

The Principal Investigator will report Unanticipated Problems and Adverse Events to IRB. Unanticipated Problems occurring at BMC/BU Medical Campus not involving a fatal or life-threatening event will be reported to the IRB within 7 days of the investigator learning of the event. Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known. Reports from safety monitors with no recommended changes will be reported to the IRB at the time of continuing review.

10.4 Stopping Rules

The study has no stopping rules.

Right to Refuse or Withdraw

Participation in the study is voluntary. Participants will have the right to refuse to take part in the study. If a participant decides to take part in the study and then were to change his/her mind, he/she will be able to withdraw from the research. Withdrawing from the study would not impact the care received at BMC.

11 Data Handling and Record Keeping

11.1 Confidentiality

Confidentiality

We will train research staff on the importance of maintaining confidentiality and assuring confidentiality of records. In addition, participants will be assigned a unique study identifier, and their names will not be used. All documents will be kept in locked cabinets in the study office. A master list of subjects' names and code numbers will be stored in a locked file cabinet separate from the rest of the data. Only Dr. Assoumou and the study RA will have access to this information. The list will be destroyed upon completion of the study. All interviews and interventions will be conducted in private locations of the facility. All data will be kept confidential and stored in locked cabinets. Key drives and computers will be password protected.

Certificate of Confidentiality

To help us protect the privacy of participants, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the investigator cannot be forced to disclose information that may identify participants, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

11.2 Source Documents

We will review patients' electronic medical record at BMC to determine outcomes (linkage to care, initiation of HCV and HIV PrEP and substance use treatment). Data will be directly entered into a RedCap database including all the fields that will be necessary for the study.

11.3 Case Report Forms

The study case report form (CRF) will be the primary data collection instrument for the study. All data requested on the CRF will be recorded. All missing data will be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, "N/D" will be written. If the item is not applicable to the individual case, "N/A" will be written. All entries will be printed legibly in black ink. If any entry error has been made, to correct such an error, a single straight line will be drawn

through the incorrect entry and the correct data will be entered above it. All such changes will be initialed and dated. There will be no erasures or white-out on CRFs. For clarification of illegible or uncertain entries, the clarification will be printed above the item, then initialed and dated. The following source data will be recorded directly on the CRFs: data where the CRF will be the source document.

See the Appendix for the following CRFs: list one or more CRF by name

11.4 Study Records Retention

Records will be maintained for seven years after the research is completed.

12 Statistical Plan

12.1 Study Hypotheses

The goal of the current proposal is to determine the feasibility and acceptability of a peer recovery coaching (PRC) intervention to improve infectious diseases (HIV/HCV) prevention and care alongside treatment for opioid use disorder.

Aim 1: To implement a pilot peer recovery coaching intervention at a walk-in low-barrier bridge clinic to increase uptake of a comprehensive intervention for HIV PrEP, HCV and substance use treatment among PWID accessing care at BMC FASTER PATHS bridge clinic

Aim 2: To determine the feasibility and acceptability of a combined PrEP, HCV and substance use treatment intervention at the BMC FASTER PATHS bridge clinic.

We hypothesize that the peer recovery coaching intervention will facilitate both access to PrEP, HCV treatment and sustained engagement with treatment for opioid use disorder among participants. The primary outcome is patient satisfaction as a measure of the intervention's acceptability. Secondary outcomes will include (1) the proportion of patients with linkage to PrEP and treatment initiation within 3 months; (2) the proportion of patients with HCV treatment initiation within 3 months; (3) the proportion of patients with sustained linkage to opioid use treatment within 3 months (follow-up with at least one subsequent visit after the initial prescription for medication for opioid use disorder).

12.2 Sample Size Determination

Given the small sample size, we are not powered to show efficacy, but we will use findings to estimate the effect size for a future efficacy trial.

12.3 Statistical Methods

Primary outcome will include patient satisfaction as a measure of the PRC intervention's acceptability.

Qualitative semi-structured interviews will be audio recorded, professionally transcribed and analyzed using NVivo computer software. We will develop a codebook to determine acceptability and feasibility of the intervention, apply codes to all transcripts and analyze the data to identify emerging themes. We will also use descriptive statistics to summarize findings, and the Wilcoxon test to compare 5-point Likert scales between the two groups. For the secondary outcome, we will use descriptive statistics without hypothesis testing to compare outcomes in the intervention group to the current practice group. We will compare the two groups on demographic characteristics (age and gender), linkage to care, loss to follow-up and other secondary outcomes.

13 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator.

All participants for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

14 Literature References

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15 Appendix

Schedule of Events (required)

As applicable:

Schematic of Study Design
Toxicity Grading Scales
DSMB Charter
Repository Instructions
Biosafety Precautions
Manual of Operations
Laboratory Handling
Pharmacy Manual
IXRS Manual
Case Report Forms (CRFs)
Quality Management Plan
Data Management Plan
Clinical Monitoring Plan
Endpoint Scales
Other Documents