Study Title: Peer Intervention to Link Overdose Survivors to Treatment (PILOT)

NCT#: NCT05123027

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[Insert Relying Site Name]
CONSENT TO BE A RESEARCH SUBJECT

Peer Intervention to Link Overdose Survivors to Treatment (PILOT)
NIDA CTN-0107

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This research study is being completed to find out if a specialized peer intervention for overdose survivors is better than treatment as usual in reducing risky behavior and getting people engaged in recovery support. The peer intervention to be tested is called PILOT and that stands for Peer Intervention to Link Overdose Survivors to Treatment. If you are not interested in participating, this will not affect the medical care you are receiving.

If you agree to participate, you will be asked questions about your substance use history and current use, past overdoses, your health, and other questions. You will also be asked to provide a urine sample.

If you are enrolled in the study, you will be randomly assigned to either treatment as usual (TAU) or PILOT + TAU. Everyone will receive treatment as it is normally provided in the Emergency Department and will be given resources for recovery support. PILOT participants will also receive additional support and connection to a PILOT peer. The research staff will stay in touch with you and will ask you to complete research visits during the study. If you are randomly assigned to PILOT, you will meet with a PILOT peer, who you will continue to meet with during the 6-month study. No matter what group you're in, the research staff will continue to keep in contact with you and ask you to complete research visits during the study. You will also be asked to complete brief weekly surveys on your mobile device throughout the study.

This study will last for 7 months. We will ask you to complete research visits at Months 1, 3, 6, and 7, which can be done over the phone, by video chat, or in a convenient location in the community.

There may be no direct benefit for participating in this study. There are risks to participating in this study and those are described in this document. The main risks include loss of confidentiality or discomfort/distress from questions being asked.

You do not have to participate in this study to receive medical care and care for your overdose or health condition. You may choose to receive treatment as it is normally provided in the Emergency Department setting. You will have the option to fill out an anonymous survey explaining why you are not interested in this study.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you, please ask the staff member to explain any words or information that you do not clearly understand. Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions of the research. You should also be told what alternatives are available to you if you do not participate in the research study. The informed consent document is a written summary of this information.

The purpose of this study is to improve outcomes for individuals after surviving an overdose involving opioids. This study will be comparing the enhanced peer intervention known as PILOT for overdose survivors with treatment as usual (TAU) provided in the Emergency Department. You are being asked to participate in this study because you have had a recent overdose involving opioids and are over the age of 18.

The study is sponsored by the National Institute on Drug Abuse Clinical Trials Network. The investigator in charge of this study at the [Insert Site Name] is [Insert Local PI Name]. Portions of [Insert Local PI Name] and his/her research team's salaries will be paid by this grant. The study is being done at 3 sites across the United States. Approximately 150 people will take part study-wide, with approximately 50 individuals enrolled per site.

B. PROCEDURES

If you agree to be in this study, the following will happen:

Screening and Randomization (2-2.5 hrs.):

During this screening visit, you will be asked questions about your substance use and overdose history, as well as questions about your mood, pain, general health, and quality of life.

The research team will use several methods of contact to keep in touch with you. We will ask you to provide us with phone numbers, e-mail addresses, your social security number, and a current home address (if possible) as well as contact information of family and friends who may know how to best reach you. At least two contacts must be provided to the study team member.

If you are eligible for the study and you wish to continue, you will be randomly assigned to one of the two groups: Peer Intervention to Link Overdose Survivors to Treatment (PILOT) or treatment as usual (TAU). This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. By providing your consent, you are agreeing to participate in this study regardless of your assigned group. A urine sample will be collected for a drug screen during this visit.

It is important to note that the management of opioid use disorder, if present, will be taken care of as it normally is at this specific Emergency Department. Your participation in this study will not affect the medical care that you are receiving. All participants will get the same medical care from this Emergency Department and hospital.

Meeting with a Certified Peer Support Specialist (15-20 mins.):

If you are randomized to the Treatment as Usual (TAU) group: For this study, TAU will include being provided information about recovery resources available in your area and may include peer support services as offered at this Emergency Department. The research team will keep in contact with you and you will be asked to complete study visits at 1-, 3-, 6- and 7-months which can be done via phone/video chat or in the community. You will also be asked to complete weekly surveys on your mobile device while you are enrolled in the study.

If you are randomized to the Peer Intervention to Link Overdose Survivors to Treatment (PILOT) group: You will meet with a PILOT peer support specialist after screening procedures are completed. The PILOT peer support specialist is someone who has lived experience with substance use disorder, is now in remission, and is trained to provide support to those who have experienced an overdose and/or have substance use disorder. The PILOT peer will be in touch with you regularly throughout the study, and you will meet with the PILOT peer (in person or remotely) regularly over the next 6 months. The PILOT peer will provide you with resources for recovery support, talk to you about your drug use, and help to reduce your risk of another overdose. They will make all efforts to stay in touch with you during the 6 months. The research team will keep in contact with you, and you will complete study visits at 1-, 3-, 6- and 7-months which can be done via phone/video chat or in the community. You will also be asked to complete weekly surveys on your mobile device while you are enrolled in the study.

After you have been discharged from the Emergency Department and throughout the study, the research team member will send you reminders about your upcoming study visit in the mail or via text/email (based on your preference).

Weekly Mobile Surveys (5 min. each):

You will be asked to complete weekly surveys on your mobile device while you are enrolled in the study. These surveys will be brief and will ask about your use of substances, health, and any recovery activities. If you do not have a mobile phone, we will lend you one during the study. We will ask that you return this phone after the study is complete.

1-, 3-, and 6-month Assessments (30-45 min. each):

Study visits will be conducted at 1-, 3- and 6-months after you are enrolled into the study (today). These will be done by telephone, video chat, or in-person.

During these visits, we will ask you to complete study assessments that include the collection of self-report data and questionnaires that ask about substance use, any involvement in recovery or treatment, including medication, your health, mood, visits to the emergency room or any overdoses

since the last visit, etc. We will also ask you to complete a urine drug test. We will provide all the supplies needed to complete these tests.

If you are unable to use a phone or video chat for any reason to complete these study visits, the research team member will use your locator information to arrange to meet you in the community to complete study procedures.

7-month Assessments (1 hr.):

A follow-up visit will be scheduled 1 month after you complete the study intervention period (7 months after enrollment). This visit will include study assessments and a urine sample.

C. DURATION

Participation in this study will last for 7 months and will involve 4 visits with a research team member. If you are assigned to the PILOT group, you will also meet with your peer in-person or remotely regularly over the 6-month intervention period.

D. RISKS AND DISCOMFORTS

There are some potential risks involved with participating in this study.

1. Risk of Loss of Confidentiality: There is a risk of a loss of confidentiality of your personal information because of participating in this study. Information about you will be kept in password-protected databases and computers and will only be accessible by the Principal Investigator and research staff. To ensure confidentiality, all participant information (questionnaires and identifying information) will be identified with a number (when possible) and kept under lock and key and in password-protected databases.

2. Interview Questions and Study Assessments: The questions that will be asked may be sensitive in nature and make you feel uncomfortable. You may be asked personal questions that you find distressing. You may refuse to answer any question(s) that you do not wish to answer.

3. PILOT Peer Communication: If you are assigned to the PILOT group (enhanced peer support), you may experience some discomfort or irritation when the PILOT peer attempts to communicate with you over the 6-month period.

4. Unknown Risks: Unknown risks may occur during the study. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

5. Randomization: One group may be better than the other in terms of reducing risky behavior or linkage to recovery support.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that, except as explained below and in Section L, the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information and details about your study participation, except as explained below and in Section L, will not be in your [Insert Site Name] medical record. This means that neither your research participation nor any of your research results will be included in any [Insert Site Name] medical record. [Insert Site Specific EMR details, if needed] A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, elder abuse or neglect, but there could be others. In instances where there is concern that urgent clinical assessment may be needed to protect your personal safety or welfare and the study medical provider is not readily available, researchers may need to disclose medical and health-related research data to non-study care providers to support your urgent care. Any information disclosed in support of your urgent care may be added to your medical record. However, this information would still be covered by the protections applied to Protected Health Information in a patient care setting. Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

There may be no direct benefit for participating in this study, though participants may benefit from recovery support services and may reduce their risk of future overdoses.

G. COSTS

There may be additional costs to you for the use of mobile data and text messaging fees, if you are using a personal smartphone for this study. There will be no other additional costs to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, participants in both the PILOT group and treatment as usual group will be paid for participation in this study after all visit study procedures have been completed. You will be paid following each study visit based on the schedule below:

1. Screening and randomization visit: up to $75 for completing all study procedures (this payment may be pro-rated, if not all procedures are completed)
2. 1-month assessment: $75
3. 3-month assessment: $75
4. 6-month assessment: $125
5. Follow-up assessment (Month 7): $50
6. Mobile surveys: $5 per weekly survey completed (24 surveys possible over 7 months; $120 possible)

You may earn a total of $520 for study participation and completion of all study procedures within the visit window. Compensation may be given if study procedures occur outside of the visit window but will not be the full amount.

If you do not complete the study, you will receive the listed amount for each visit that you complete. If you are not eligible to participate or decline to be in the study, we will ask you to complete a brief survey to understand the reasons for why you declined or were not eligible. You will be paid $15 for completing this survey.

Payment for study visits will be made using a reloadable debit card. It works like a bank debit card and you may use the card to purchase goods or services everywhere major credit or debit cards are accepted. You will be given or mailed a debit card at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above.

Payments that you receive from [Insert Site Name] for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from [Insert Site Name] reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

At the end of this study, some identifiable information about you (full name, date of birth, social security number, race, sex, state of residence) will be provided to the lead research team at the Medical University of South Carolina and will be transferred and stored securely. This is being done so the lead research team can check national databases (National Death Index), which will be updated 18-24 months after the study has ended. Your information will not be shared with anyone outside the lead research team or used for any other purpose.

Agreeing to share your personal information after the study has ended is voluntary and refusing to share your information will not affect your participation in this study. Please initial by your choice below for paper consents, or scroll down to select your choice electronically:

____Yes, I agree to share identifiable information with researchers after the end of the study

____No, I do not agree to share identifiable information with researchers after the end of the study

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

Data from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data analyzed. The data will also be deposited in PubMed Central https://www.pubmedcentral.nih.gov/. These websites will not include information that can identify you. You can view this website at any time.

K. DISCLOSURE OF RESULTS

If there are significant new findings which may relate to your willingness to continue participation during the course of this study, you will be notified.

Results from this study will be shared with study participants upon request and once they are available.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information [Insert Site Name] may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact [Insert Site Name] Privacy Officer at _____.

O. CLINICAL TRIALS.GOV

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.

P. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Participation in any future study is entirely voluntary and refusing to volunteer for a future study will not affect your participation in this study. Please initial by your choice below for paper consents, or scroll down to select your choice electronically:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the [Insert Site Name], or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the [Insert Site Name] and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***[site PI]***. I may contact the _____ concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records. Please sign below for paper consents or scroll down to provide an electronic signature.

_____ _____

Signature of Participant Date *Name of Participant

_____

Signature of Person Obtaining Consent Date