PROVIDING A RESOURCE: TELEMEDICINE AT NEEDLE EXCHANGES TO REACH UNDERSERVED POPULATIONS - GREENSBORO

NCT05108935
Version 6/23/2022

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

CONCISE SUMMARY

This is a research study to understand how buprenorphine/naloxone (bup/nx) and pre-exposure prophylaxis (PrEP) for HIV prevention can be provided as part of a comprehensive harm reduction program for people who inject drugs using syringe services programs (SSPs). Bup/nx (or Suboxone) has been shown to reduce cravings, overdoses and death in persons with opioid use disorder. PrEP (or Truvada) is a daily pill that has been shown to reduce the risk of HIV in persons who may be at risk. The drugs being used in this study are FDA approved.

If you agree to be in the study, you will be asked to:

- Take part in the study for six months with a follow up survey at month 7.
- Take both bup/nx (Suboxone) and PrEP (Truvada) for six months. Medication costs will be covered by the study and/or your insurance, if you have insurance. You will not be responsible for medication costs.
- Have your blood drawn for laboratory testing at the beginning of study, and at months 3 and 6.
- Have weekly visits with the study doctor until you no longer have cravings. After that, you will visit with the study doctor once a month until month 6. For the first visit, you will meet the study doctor in person or via telemedicine at the SSP. After that, all visits with the study doctor will take place via telemedicine on a computer with a video camera located in the SSP.
- Complete baseline and follow up questionnaires about yourself including your medical health history, your education, job status, substance use, sexual behaviors, and other behaviors which may put you at risk for HIV, in addition to questions on your knowledge and interest in PrEP and Suboxone.
- Take part in 1-2 telephone interviews to share what you like and do not like about this program. These interviews will be conducted by staff who are not involved in delivering the program so you can be open and honest about your thoughts. If you prefer not to participate in these interviews, you can still participate in this study.

There are risks to taking part in this study. These may include feeling anxiety about your HIV test results or uncomfortable when asked personal questions, and having side effects from Suboxone or Truvada. The study doctor will talk with you about any side effect you have.

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

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

INTRODUCTION

You are being asked to take part in this research study because you use a syringe services program (SSP). Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the study doctor or study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Mehri McKellar of Duke University in Durham, NC is the medical doctor and lead for the study. A grant from The Duke Endowment provides funding for the study. Portions of Dr. McKellar and the research team's salaries will be paid by this grant. The grant from the Duke Endowment will pay the SSP to perform this research, and portions of the SSP research team's salaries will be paid by this grant.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

There will be approximately 20 people in this research study at Duke, and approximately 10 people will be from your SSP.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to see if persons using SSPs are interested in and can successfully take Suboxone for opioid use disorder and Truvada for HIV prevention when follow-up visits are conducted via telemedicine (on the computer with a video camera located in the SSP). The purpose is also to assess the feasibility and acceptability of the program.

WHAT IS INVOLVED IN THE STUDY?

If you agree to take part in this study you will be asked to sign and date this consent form.
You will be asked to take bup/nx (Suboxone) and PrEP for HIV prevention (Truvada) for six months.
You will also be asked to have several laboratory tests and complete questionnaires. More information is described below.

A. Medications

1. Buprenorphine/naloxone (bup/nx) (also called Suboxone)

What is Suboxone?
Suboxone combines an opioid (buprenorphine) with an opioid antagonist (naloxone). It is used to treat opioid dependence and will help with cravings.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

When will I take it?
We will ask you to start Suboxone when you are starting to feel withdrawal symptoms, usually 12 hours from using heroin or pain medications and at least 24 hours from using methadone. It will be administered as a dissolvable wafer to put under your tongue every day. Once you are stabilized on the correct dose, you should not feel 'high' and there should not be any excessive sleepiness or intoxication. Dr. McKellar will work closely with you to get the right dose and you will be given specific instructions on how to increase your dose for the first couple of days as needed. Most patients can be stabilized within a couple of days. Occasionally, it takes a little longer to find the right dose (up to few weeks). You are asked to take Suboxone daily for six months.

2. PrEP (called Truvada)

What is Truvada?
Truvada is a tablet that is very effective at preventing HIV.

When will I take it?
Daily

B. Laboratory tests

There will be blood tests performed at the initial study visit and then every 3 months. The blood tests will be performed by study staff. The blood collected at the visits is less than a teaspoon.

1. HIV test (HIV antigen/antibody combo):

What does this test do?
If you agree to be in this study, you will be asked to have blood drawn for the test for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome [AIDS]). Prior to the test, the staff will provide information on HIV and the meanings of a positive and negative test, during which you will have an opportunity to ask questions. The results will be available in the next 1-2 days following the test. If you are HIV negative, you will have the opportunity to start PrEP and you will be informed of this either by the telephone or in person. If you are HIV positive, you will be informed of this either by telephone or in person and you will be referred for HIV care and treatment. You will receive additional counseling about the significance of your care and possible risks to other people. If you are HIV positive, you will not have the option to enroll in this study. We are also required by law to report the positive results to the North Carolina Department of Health and Human Services, Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

How often will I be tested for HIV?
HIV testing will be performed at the initial visit and at the Month 3 and Month 6 visits. The amount of blood required for this test is 2 ml (about half a teaspoon).

2. Hepatitis B and C tests

What do these tests do?
As part of this protocol, blood will also be drawn to test for hepatitis B and hepatitis C, the viruses which cause liver infections and liver damage. We will check to see if you have been exposed to hepatitis B or if you need the hepatitis B vaccine. You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with hepatitis B or hepatitis C, you will receive additional counseling about the significance of your care and possible risks to other people. We are required to report all positive results to the North Carolina Department of Health and Human Services, Division of Public Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for hepatitis B or hepatitis C, then you should not agree to participate in this study.

If you are hepatitis B positive, you will not be able to participate in this study. If you are hepatitis C positive, you will be able to enroll in this study. Persons with hepatitis will be given information about where to seek care.

How often will I be tested for hepatitis?
Hepatitis testing will be performed at the initial visit only. The amount of blood required for this test is 4 ml (about 1 teaspoon).

What other testing is there?
Blood will be drawn to check your kidney and liver function through a test called the comprehensive metabolic panel (which includes the serum creatinine and liver function tests). The blood tests will be performed at the initial visit, and at the Month 3 and the Month 6 visits. The amount of blood required for this test is 1 ml (about a quarter teaspoon).

If you are female, under the age of 55 years, and do not have a documented sterilization, you will also be asked for a urine sample during the initial visit and at each following visit to test for pregnancy.

If you become pregnant during this study, you will have to withdraw from the study and we will do our best to link you with a local medical provider.

Urine or oral swabs for drug screening to check for Suboxone levels will also be requested at weekly visit but is not mandatory.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

Dr. McKellar will be responsible for facilitating your participation in this study, including discussing your use of the medications provided to you by the study. She will not be able to offer any other medical services to you that are not described in this consent form as being a part of this study. You will need to continue to pursue your health care through whatever means work best for you. If you have any urgent or emergent concerns or changes in your health, you should go to the nearest Emergency Department to be evaluated.

C. Questionnaires (baseline and follow-up) and interviews

At the initial visit, you will be asked to answer some questions about yourself including your medical health history, your education, job status, substance use, sexual behaviors, and other behaviors which may put you at risk for HIV, in addition to questions on your knowledge and interest in PrEP and Suboxone. You will be asked to complete a similar follow up questionnaire at months 3 and 6. You will also be asked to complete a brief survey on linkages to care at month 7. We will take many steps to keep your information confidential.

At follow up visits, you may also be asked more questions including medical questions on how you are feeling, whether you are experiencing withdrawal symptoms, your medication adherence and substance use.

We will also ask your permission for another researcher to contact you about taking part in 1-2 telephone interviews. The interviewer will ask questions about your thoughts on taking part in this program. This interview team is not directly involved in the delivery of program. The first interview will be done at the end of the first month of the study. The second interview will be done at the end of the fourth month of the study. You may be asked to participate in one or both of the interviews. You can decide not to take part in these interviews and still take part in the study. You will be asked to provide your consent for those interviews when you are contacted by the interview team.

We will ask for your permission to share your contact information (name, telephone number and address) with the interview team so that they are able to contact you.

Estimated Study Timeline

Week	Description of visit
Week 1 *Enrollment Visit*	*Consent and demographics:* participant consent; baseline questionnaire *Initial visit with Dr. McKellar:* screening; baseline laboratory investigations; patient assistance application for PrEP; prescriptions sent to pharmacy; begin medications
Week 2	Telemedicine visit with Dr. McKellar; urine toxscreen; urine pregnancy test
Week 3	Telemedicine visit with Dr. McKellar; urine toxscreen; urine pregnancy test
Week 4	Telemedicine visit; urine toxscreen; urine pregnancy test
Month 2	Telemedicine visit; urine toxscreen; urine pregnancy test

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

Month 3	Telemedicine visit; follow up questionnaire; laboratory investigations (including urine tox and pregnancy tests)
Month 4	Telemedicine visit; urine toxscreen; urine pregnancy test
Month 5	Telemedicine visit; urine toxscreen; urine pregnancy test
Month 6	Telemedicine visit; follow up questionnaire; laboratory investigations (including urine tox and pregnancy test)
Month 7	Follow up survey on linkages to care

HOW LONG WILL I BE IN THIS STUDY?

The study will continue for 6 months with a follow up survey at month 7. You will be asked to come back on a weekly basis until the Suboxone dose is at a therapeutic level and you are no longer experiencing withdrawals or cravings. You will then be asked to return on a monthly basis until the end of 6 months. At the end of the study, we will help link you to a Suboxone and/or PrEP provider in your community for continuation of care. At month 7, we will reach out by phone to complete a survey about whether you've been linked to care.

WHAT IF I WANT TO STOP TAKING PART?

You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. You can also remain in the study if you stop one of the two medications (Suboxone or Truvada). If you decide to stop both medications, you will be withdrawn from the study.

If you decide to stop both medications, you will be withdrawn from the study, however, you may still be contacted at month 1 and month 4 to take part in the two interviews to share what you like and do not like about the program. Again, these will be conducted by staff who are not involved in delivering the program so you can be open and honest about your thoughts. Your participation in these interviews is voluntary.

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS STUDY?

As part of your participation, you will receive Suboxone at no charge, which if taken, can help you with withdrawal symptoms. You will also receive Truvada for HIV prevention without cost to you. If taken as prescribed, Truvada will reduce your chances of getting HIV. You will also get HIV, hepatitis, and other medical testing at no charge. The results of this study may also help other people with opioid use disorder in the future.

WHAT ARE THE RISKS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

Buprenorphine/naloxone (bup/nx) (also called Suboxone) may cause some, all or none of the side-effects listed below.

More likely
• Nausea and/or vomiting
• Drug withdrawal syndrome
• Headache
• Constipation
• Numb mouth
• Sedation or stimulation
• Sweating
• Decreased sleep
• Blurred vision
• Back pain
• Fainting
• Dizziness
• Sleepiness
• Swollen and/or painful tongue
• Irregular heartbeat

Less Likely
• Respiratory problems
• Higher risk of death and come if you take Suboxone with other medication such as benzodiazepines
• Sleepiness, dizziness, and problems with coordination
• Dependency or abuse
• Liver problems
• Allergic reactions
• Opioid withdrawal
• Decreased in blood pressure

You will be asked to check in with Dr. McKellar on a weekly basis until you are no longer having cravings. Your Suboxone will be refilled weekly or biweekly (every 2 weeks). If you miss an appointment, you may not be able to refill the medication on time and you may even go into withdrawal. We ask you to keep the medication in a safe place as replacement medication cannot be given if you lose it.

Female Contraception:
The data on use of buprenorphine, one of the active ingredients in Suboxone sublingual tablets, in pregnancy, are limited; however, these data do not indicate an increased risk of major malformations

specifically due to buprenorphine exposure. If you do become pregnant, there may be risks to the embryo or fetus which are currently unforeseeable.

PrEP (called Truvada) may cause some, all or none of the side-effects listed below.

More likely
• Headache
• Stomach-area abdominal pain
• Gastrointestinal upset (including burping and flatulence)

Less Likely
• Worsening of Hepatitis B virus infection
• New or worse kidney problems
• Bone problems including bone pain, or softening or thinning of bones
• Too much lactic acid in your blood
• Severe liver problems

Female Contraception:
Although Truvada is generally considered safe to use during pregnancy, the changes your body goes through during pregnancy may affect some of the things we are measuring in this study. Therefore, women who are pregnant or planning a pregnancy are not allowed to participate in this study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

We will provide you with a handout with information and potential side effects associated with both medications and provide time to discuss any questions or concerns

Risks of Drawing Blood: Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

In addition, you may become worried or anxious when waiting for your test results. For the questionnaire, you may become uncomfortable when asked to provide personal information about yourself. You may refuse to answer any of the questions asked during the questionnaires and/or interview, and you may stop your participation in any of these activities at any time.

There is also the potential risk of loss of confidentiality—this means that there is a chance that other people could see the information you tell us. We do not expect this to happen because we take many steps to protect your privacy (including information about substance use or other illegal activities), which are described in the next section. However, this is a potential risk in all research studies.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

Additionally, as discussed below, if we learn of a situation in which you are at immediate risk for self-harm, we will take steps to assure your safety. There may be uncommon or previously unknown risks as well. You should report any problems to Dr. McKellar and research team.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

In some cases, the PrEP (Truvada) study drug is provided through the Gilead Advancing Access Program or through programs offered by the U.S. Department of Health and Human Services ("Ready, Set, PrEP"). Your personal information may be disclosed to the sponsors of these programs in order to verify your eligibility or obtain study drug through the program.

If the co-pay costs of your study drug are paid for using a Gilead co-pay card, certain information pertaining to use of the copay card will be shared with Gilead, the sponsor of the card, and its affiliates. The information disclosed will include the date the prescription is filled, the number of pills or product dispensed by the pharmacists, and the amount of your co-pay that will be paid for by using the card.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

The server and computers on which your data are stored and accessed are secure with password protection and checked regularly for viruses.

To help us further protect your privacy, the U.S. Department of Health and Human Services (DHHS) has issued a Certificate of Confidentiality. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:
1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US 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

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Study documents will be retained for at least six years after the study is completed. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
We will provide the Suboxone and PrEP and the laboratory tests at no cost to you. The cost of Suboxone will be covered by funding from the Duke Endowment. If you have insurance, your insurance plan may cover some of the costs of PrEP. We will provide co-pay cards to cover the costs of PrEP that are not covered by your insurance plan. If you do not have insurance, the costs of the PrEP (Truvada) study drug will be covered through the Gilead Advancing Access Program or through programs offered by the U.S. Department of Health and Human Services ("Ready, Set, PrEP"). Your study doctor may request that you return for a checkup before you stop the Suboxone and/or PrEP if they think that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a

person completes the study. The study will not be responsible for any services you receive that are not part of the study activities described in this consent form.

Please talk with the PI/study team about the specific services and procedures that will be paid for, and any for which you or your insurance will be responsible

We will monitor your patient care charges in your Duke medical record to make sure that costs are directed appropriately. If you have any questions or concerns about appropriate billing, contact your study team coordinator so that he/she can help find a resolution.

WHAT ABOUT COMPENSATON?
Bus passes will be offered to help offset costs with transportation. If you decide to participate in the telephone interviews, you will be offered compensation for your time.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If an adverse event occurs, we may need to review your entire medical record.

Choosing not to take part in this study or to ending early will not result in any loss of services from the syringe services program. If you do decide to withdraw, we ask that you contact Dr. McKellar in writing or through email to let her know that you are withdrawing from the study. Her mailing address is Duke University Medical Center, 315 Trent Drive, Room 175, Box 102359, Durham, NC 27710, (919) 613-6129 or email address mehri.mckellar@duke.edu.

Additionally, the investigators also have the right to stop your participation at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Mehri McKellar, MD by telephone at (919) 613-6129 during regular business hours and at (919) 970-8307 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Duke University Health System

Consent To Participate In A Research Study
Providing comprehensive harm reduction via telemedicine for PWID using syringe services programs: a feasibility study

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject	Date	Time
Signature of Person Obtaining Consent	Date	Time