Official title: A Community-Clinic Collaboration to Improve Outcomes in HIV+ Substance Users Released from Jail

NCT number: NCT03834779

IRB Approved date: 04/23/2020

The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: A Community-Clinic Collaboration to Improve Outcomes in HIV+ Substance Users Released from Jail

Funding Agency/Sponsor: National Institute on Drug Abuse

Study Doctors: Dr. Ank Nijhawan, Dr. Robrina Walker

Research Personnel: Laura Hansen, Gerald Strickland

You may call these study doctors or research personnel during regular office hours at 214-648-2777. At other times, you may call them at 214-648-2777.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to find out whether working together with a community health worker and a re-entry organization helps patients who have HIV and drug use issues have better results after they get out of jail. Specifically we want to know whether or not those who receive the intervention (by meeting with the community health worker and working with the re-entry organization) have better HIV lab results and less drug use.

Why is this considered research?
This is a research study because the combination of a community health worker and re-entry organization is being compared to the standard of care. The researchers are learning which is more effective and why.

The following definitions may help you understand this study:
- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups.

- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have HIV and a history of substance use.

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?
About 85 people will take part in this study at the Dallas County Jail.

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. Some of the procedures may be part of your standard medical care, but others are being done solely for the purpose of this study.

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including medications you take and any surgical procedures you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Demographic information (age, sex, ethnic origin).
- Employment, housing
- Barriers to HIV care
- HIV treatment history, adherence
- Substance use history
- Mental health
- Blood tests

Group Assignment
If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive either the intervention with a community

health worker and re-entry organization or standard of care. You have a 1 in 2 chance of receiving the intervention.

The group you will be in is decided by a computer program that randomly assigns people to one group or the other. Neither you nor the researchers will be allowed to choose which group you are assigned to.

Study Intervention

If you decide to participate in this study you will either:

- Meet with a community health worker and work with the re-entry organization Unlocking DOORS, OR
- Receive standard of care (referral to the HIV clinic after release from jail)

Procedures and Evaluations during the Research
Everyone involved in the study will undergo a study visit at baseline, 3, 6 and 12 months. Most visits will involve answering questions about you, your HIV medical history, alcohol and drug use, mental health, living situation, level of social support, and barriers to getting healthcare.

At the 6 month visit, blood will be drawn (about 15 mL, which is one tablespoon).

The first study visit will take the longest, about 1 hour, the other visits will take about 30 minutes.

The HIV viral load and substance use tests in this study are designed for research, not for medical purposes. Even though the researchers are not looking at your HIV viral load and substance use to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment.

The researchers will record and use your Social Security Number (SSN) in order to pay you for your participation. You do not have to give this information to the researchers; however, it may result in a smaller amount of money that we can give you for participation. This information will remain confidential unless you give your permission to share it with others or if we are required by law to release it.

How long can I expect to be in this study?
The study will last 12 months.

You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks of Blood Drawing

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

You will have the same amount of blood collected whether you receive standard medical care for your health problem or take part in this research.

At the 6 month study visit, you will have 1 tablespoon of blood collected because you are in this research study.

Other Risks

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?

The major risk in this study is that of confidentiality, and several measures will be taken to protect your personal health information:

a) All investigators and co-investigators will have completed HIPAA training, both for clinical care and research, and Human Subjects protection training.
b) Study data will be stored in a secure, password-protected HIPAA compliant database
c) A master file with your personal information (name, contact information, birth date, and medical record number) will be stored separately from the research database and linked with a unique study identification number.
d) Any study forms or recordings which contain personal identifying information will be secured in a locked cabinet in Dr. Nijhawan's research office.
e) Study visits will be conducted in a private space.

Reduce blood draw risks

With regards to blood draw, all blood draws will be performed by a skilled phlebotomist. The smallest gauge needle will be used to draw blood (e.g. butterfly needle) and you will be provided with water and other fluids to drink prior to blood draw to ensure

adequate hydration. The blood draw itself will be done in a private and clean setting where you can be seated and rest your arm; blood will be drawn using appropriate technique and universal precautions.

Vulnerable populations

Pregnant women with HIV may be incarcerated at the Dallas County Jail and therefore may be eligible to participate in the study. As this study poses minimal risk but may have potential benefit for both the pregnant woman and her fetus, we will include you in the study even If you are pregnant or become pregnant during the study.

For incarcerated individuals, we will ensure the following:

a) If you participate in the study while you are incarcerated, you will not receive any special treatment with regards to general living conditions, medical care, quality of food, amenities or opportunity for earnings in the prison. You are not eligible to receive payment for study visits while you are in jail.
b) The risks of this study are minimal and the same as if we were doing the study with non-prisoners.
c) We will follow the same recruitment and enrollment procedures for everyone who is eligible for the study, whether they are in jail or recently released. Assignment to the intervention is random.
d) Participation in the research study will not influence the parameters of probation or parole.
e) This is a 12 month study, with visits at baseline, 3, 6, and 12 months. The follow-up visits will generally be done in the community. If you end up back in jail, we will try to complete study visits during the time you are back in jail, though we will not be able to do study visits in other correctional facilities.

What will my responsibilities be during the study?

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Tell your regular doctor about your participation in this study.
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?
It is possible to benefit directly or indirectly from this study. Having better access to social services, substance use disorder treatment, and HIV care after release from jail may result in better overall health for participants randomized to the intervention arm. For those who do not receive the intervention, there is an indirect benefit from learning more about the specific needs of released inmates and possible future programs based on what is learned from this project.

If you agree to take part in this study, there may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research.

We hope the information learned from this study will benefit others with HIV and substance use issues in the future. Information gained from this research could lead to better care for people with HIV when they are released from jail.

What options are available if I decide not to take part in this research study?
This is not a treatment study. You do not have to be part of it to get treatment for your condition.

Will I be paid if I take part in this research study?
Yes.

You will be given a $25.00 gift card at each study visit, with an additional $25.00 gift card given at the 6 month visit. If you are incarcerated at the time of the study visit, we cannot give you payment for that visit.

There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or

Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately.

Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas or Parkland Health & Hospital System.

You retain your legal rights during your participation in this research

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

Dr. Ank Nijhawan is a research investigator in this study. Dr. Nijhawan is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The

information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- National Institute on Drug Abuse
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by the 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 results. You can search this Web site at any time.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

To help us further protect the information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The researchers will not, in any case, disclose information about you or your participation in this study unless it is included in the Authorization for Use and

Disclosure of Protected Health Information for Research Purposes as stated above.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Whom do I call if I have questions or problems?
For questions about the study, contact Dr. Ank Nijhawan at 214-648-2777 during regular business hours and at 214-648-2777 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time