Title: Optimizing a bio-behavioral intervention to promote viral suppression among HIV + people who inject drugs on the U.S.-Mexico border

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Protocol Title: Optimizing a bio-behavioral intervention to promote viral suppression among HIV+ people who inject drugs on the U.S.-Mexico border.

Principal Investigator: Julia Lechuga and John Sauceda

UTEP: Public Health Sciences

In this consent form, "you" always means the study subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

Introduction

You are being asked to take part voluntarily in the research project described below. You are encouraged to take your time in making your decision. It is important that you read the information that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

Why is this study being done?

We are doing this study to help us develop a better way to support people who are living with HIV and who may also suffer from a substance use disorder and depression, better adhere to Antiretroviral Medication.

Approximately, *384 individuals,* will be enrolling in this study in Ciudad Juarez.

You are being asked to be in the study because *you are living with HIV, may have a substance use disorder, have never been prescribed Antiretroviral medication (ART) or have sub-optimal ART adherence, screen positive for depression, qualify to receive free HIV medical care in Mexico, are willing to discuss getting on Methadone with a peer, have no plans of moving out of the city in 12 months, are willing to return regularly to Companeros for several visits in the lapse of 12 months, and are willing to provide information to be able to locate them to remind them of future appointments and to provide services.*

Individuals who are not living with HIV, do not have a substance use disorder, are HIV negative, currently receiving methadone, or are unwilling to discuss getting on methadone with a peer, don't qualify to receive free HIV care services in Mexico, do not screen positive for depression, are planning on moving out of the city in less than 12 months, are not willing to return to companeros regularly for several visits in the lapse of 12 months, are not willing to provide information to be able to locate them to remind them of future appointments and provide services are not eligible to participate in the study.

If you decide to enroll in this study, your involvement will last 12 months*. First, we will ask you to take part in one or any combination of the following interventions. It is also possible that you may be assigned to participate in none of the interventions. If you are assigned to participate in some of the interventions, the sessions will take place at Compañeros or supporting facility:*

1. Psychoeducational sessions to provide you with information about HIV medication and strategies to not forget to take your medication every day. You will be asked to talk with a staff member to learn about how HIV medications work, how to store them and remember to take them as directed. We will ask you to come to one visit and after this first visit, we will have a phone call with you, or you can come back to *Compañeros*, to talk more about your HIV medications and what problems you may be having and to review what we have talked about. Each visit will take up to two hours.

2. Psychological therapy sessions to help you with your depression. You will be asked to talk about your depression with a counselor and record how you are feeling throughout the week. You will be asked to come back to *Compañeros* weekly to attend the sessions with the counselor. These sessions will last between 5-8 weeks. Each session will last between 1 to 3 hours.

3. Patient navigation sessions to assist you to obtain and remain in HIV care. You will be asked to meet with a staff member who will assist you to obtain needed documentation to obtain free HIV care, arrange appointments at the HIV clinic CAPASITs, and provide support to attend clinic appointments and ask any questions or concerns that you may have to your HIV care provider. The support will be provided to you in 2 separate sessions. Each session will last between 2 to 3 hours. After these 2 visits, we will ask you to come back to *Compañeros* to provide additional support so you can attend your clinic appointments such as transportation and a place to wash your and shower if you need it.

4. Psychoeducational sessions to provide you with information about Medication Assisted Treatment (Methadone) for substance abuse. You will meet twice with a staff member to learn about Methadone, risks, and benefits, and to work on a substance use reduction plan. Each of these two sessions will last between 1 and 3 hours. We will ask you to come back for a third time to help you enroll in methadone treatment at Centros de Integracion Juvenil (CIJ), and to provide additional support with scheduling appointments, transportation, to fill forms required by CIJ. The study will cover the costs associated with receiving Methadone for 5 months. After you enroll in Methadone treatment, we will have phone calls with you, or you can come back to *Compañeros*, to talk more about any problems you may be having with the substance use reduction plan you and the staff member came up with, and to continue to provide additional support to attend your clinic appointments. After you enroll in You will be asked to meet with a staff member.

You will be assigned to take part in none, one or more of the four interventions listed above at random.

In addition to being assigned to take part in none or some of the interventions, you will be asked to return to Compañeros after 3, 6, 9, and 12 months have passed since you first enrolled in the study to complete a survey and to travel to a private laboratory to donate a blood sample to assess your viral load. The study will pay for the laboratory fees and the transportation cost of going to Compañeros and to the laboratory. We will tell you the results of any tests we do, which may impact your health.

What is involved in the study?

If you agree to take part in this study, the research team will ask you to come back regularly to Compañeros for the following visits:

Enrollment visit:

During this first visit, the study will be explained to you. You will have time to ask questions and discuss any concerns you may have with the study staff. This visit may last up to 2 hours. This visit may be broken down into two visits. *During this visit a member of the research team will also:*

- Ask you to fill a contact information sheet asking for your contact information including phone number, address, places you frequent most regularly socially and for entertainment, and the contact information of a close friend or relative

who we may contact if we have trouble reaching you to remind you of your upcoming appointments.

- Ask you to answer a survey on a computer that uses an interface called RedCap. The survey will ask you demographic questions such as your age, gender, education level; questions about history of incarceration, housing, and migration; questions about substance use, depression, adherence to HIV medication, barriers and perceptions of HIV care engagement.
- Ask you to consent to having a staff member access your medical record information from CAPASITs.
- Ask you to consent to having a staff member access your medical record information from CIJ in the case you are assigned to enroll in Methadone assisted treatment.
- Take you to a private laboratory near Compañeros for you to obtain a viral load test.
- Assign you to participate in none, one, or a combination of the intervention(s) described in 1-4 above.
- Give you a card with the appointment days and times for your next visits.
- Give you 3 to 5 coupons to refer members of your social network for potential study participation. You will receive coupons only if you were referred to the study by a peer who provided you with a coupon.

Three, six, nine, and twelve month visits:

3, 6, 9, and 12 months after the enrollment visit, we will ask you to come in for a visit which will last up to 2 hours. During this visit we will:

- Ask you to confirm or update your contact information.
- Ask you to answer a survey administered through a computer using an interface called Redcap. The survey will consist of questions about your substance use, depression, adherence to HIV medication, barriers to adherence and perceptions of participation in your HIV care and the nature of your interactions with the HIV clinic as a whole and providers.
- Transport you to a private laboratory for a viral load test, in case CAPASITs does not have your updated viral load. The study will pay the cost of transportation and the exam.

What are the risks and discomforts of the study?

The following risks or discomforts may occur as a result of your participation:

- You may experience negative consequences if the information you provide to us were to be seen by others who are not part of the study. Every effort will be made to keep your study records confidential, but we cannot guarantee it.
- You may feel embarrassment, discomfort, or distress when answering survey questions related to your substance use or depression. You have the right to refuse to answer specific questions or end the survey at any time without penalty.
- You may experience anxiety related to HIV, substance use problems and need for treatment.
- Your social relationships may be disrupted as a result of the behavior change efforts you may make.
- If you are assigned to the depression intervention, you may be surprised to learn that you screened positive for depression and become anxious or worried.
- If you are eligible to receive coupons to recruit members of your social network as potential participants to the study, you may experience loss of privacy regarding your HIV-status and substance use and could experience discrimination or violence from community members.

What will happen if I am injured in this study?

The University of Texas at El Paso and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness. You will not give up any of your legal rights by signing this consent form. You should report any such injury to *(Dr. Julia Lechuga, 915-747-7221, julialec@utep.edu)* and to the UTEP Institutional Review Board (IRB) at (915-747-6590) or irb.orsp@utep.edu.

Are there benefits to taking part in this study?

You are not likely to benefit by taking part in this study. This research may help us design better programs for HIV care and treatment for depression. You may also

1. Receive some relief from your depression if you are assigned to take part in an intervention for depression, given you will be taught skills to learn how to self-manage it. This benefit is not guaranteed but can occur if you complete the program.

2. Reduce your substance use if you are assigned to enroll in methadone treatment.
3. Persist taking your HIV medications as prescribed if you are assigned to interventions where you will learn strategies for better adherence and where you will be provided support to be able to go to your medical appointments.

These benefits cannot be guaranteed but can occur if you complete the intervention programs you are assigned to.

Who is paying for this study?

UTEP and *Dr. Julia Lechuga and UCSF and John Sauceda* are receiving funding from *The National Institutes of Health* to conduct this study.

What are my costs?

There are no direct costs.

Will I be paid to participate in this study?

You will be compensated in cash by a research staff member in person for your participation in the surveys you will be asked to answer at enrollment, 3, 6, 9, and 12 months:

- $20 for the survey completed at enrollment
- $25 for the survey completed at 3 months
- $35 for the survey completed at 6 months
- $45 for the survey completed at 9 months
- $55 for the survey completed at 12 months
- $25 bonus if you answer all surveys

What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study. Choosing to withdraw or not participate will not affect the services you can receive or are receiving at *Compañeros*.

What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty or loss of benefit.

If you choose to take part, you have the right to skip any questions or stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The researcher may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, AND

- The study is stopped or cancelled.
- You are not able to attend study visits or complete study procedures.
- You are have just consumed drugs, become aggressive, or if you cannot stay alert during study visits.

Who do I call if I have questions or problems?

You may ask any questions you have now. If you have questions later, you may call insert *study contact(s) Julia Lechuga, 915-747-7221, julialec@utep.edu*

If you have questions or concerns about your participation as a research subject, please contact the UTEP Institutional Review Board (IRB) at (915-747-6590 or irb.orsp@utep.edu.

What about confidentiality?

Your part in this study is confidential. The following procedures will be followed to keep their personal information confidential:

- All paper records will be maintained in secured locked files in Compañeros and the office of the researcher.

- All digital files will be password-protected, encrypted and stored on a secure network.

- Numeric ID numbers will be used for identification on all data records. Only these ID numbers will be used to identify you after you have signed the consent form.
- The identifying information that links your ID to your name will be kept separate and locked in a digital file.
- No identifiable data will ever be used and only aggregated data will be presented for publications and presentations.
- You will answer the survey on a computer which will use the system RedCap which utilizes encryption to protect your information from confidentiality breaches.
- The results of this research study may be presented at meetings or in publications; however, your name will not be disclosed in those presentations.
- Information you provide will be retained for 3 years after the study ends and then it will be permanently destroyed.

Every effort will be made to keep your information confidential. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:

- The sponsor or agent for the sponsor
- Office of Human Research Protections
- UTEP Institutional Review Board

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed.

Mandatory reporting

If information is revealed about child abuse or neglect, or potentially dangerous future behavior to others, the law requires that this information be reported to the proper authorities.

Authorization Statement

I have read each page of this paper about the study (or it was read to me). I will be given a copy of the form to keep. I know I can stop being in this study without penalty. I know that being in this study is voluntary and I choose to be in this study.

_____

Participant's Name (printed)

_____ _____

Participant's Signature Date

_____ _____

Signature of Person Obtaining Consent Date