ICF for: **Stigma, Risk Behaviors, and Health Care among HIV-infected Russian People Who Inject Drugs (SCRIPT)**

NCT 03695393

Date: 1-14-2020

Basic Information

Title of Project: Stigma, Risk Behaviors, and Health Care among HIV-infected Russian People Who Inject Drugs (SCRIPT)

IRB Number: H-38069

Sponsor: National Institute on Drug Abuse (NIDA)

Principal Investigator: Karsten Lunze, MD, MPH, DrPH
lunze@bu.edu
801 Massachusetts Avenue, Crosstown Bldg, 2nd Floor, Boston, MA 02118

Study Phone Number: Regular business hours: 7-812-338-6051
24 hours: 7-952-097-8173

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to see if attending three group training sessions can help you better deal with feeling badly because you have HIV and you use substances. This kind of training is called Acceptance and Commitment Training (ACT). If you agree, you will be asked to meet privately with a member of the research team who will ask you questions about your HIV status and substance use and how that makes you feel, about your mental health, risk behaviors, and your demographics. You may also be asked to meet in a group setting to complete a series of three group sessions. You will be in the study for 6 months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are that you may feel uncomfortable with some questions about your personal background as well as a small risk of loss of confidentiality. You will find more information about risks later in this form.

You might benefit from being in the study because you might receive help to cope when you feel excluded because of your HIV and substance use. You will find more information about benefits later in this form.

You could get these benefits without being in the study by continuing to access the civil society organization services, such as counseling and referral for substance use treatment and HIV treatment. You will find more information about alternatives later in this form.

Purpose

The goal of this study is to compare Acceptance and Commitment Training (ACT), which involves three group sessions with trained interventionists, to help you deal with negative attitudes related to both your HIV and substance use, with the support currently being provided at civil society organizations in St. Petersburg.

What Will Happen in This Research Study

You will be one of 100 people asked to participate in this study. This research will take place at the Center of the Medical Rehabilitation #1 in St. Petersburg, Russia and First St. Petersburg Pavlov State Medical University. To participate, you will need to give contact information for at least 2 people. We will call them to confirm there is an active line. Once the study begins, we will only contact them in the event that we cannot reach you.

Although your participation will be at the above mentioned locations in Russia, your data will be securely transferred to Boston, Massachusetts (USA): Boston Medical Center and Boston University Campus for evaluation with the collaborative Russian-US team.

Baseline Visit:

After you are enrolled in the study, you will complete your baseline assessment at the Center of the Medical Rehabilitation #1. You will be asked about your demographics (e.g. age, gender), general health, substance use, HIV medical care, HIV/substance use risk behaviors, sexual activity, and sexual violence. The interview will take place in person. It will take approximately 60 minutes to complete.

At the completion of the baseline visit, you will be randomly placed in one of two study groups. Random means that the group you are assigned to is pure chance, like flipping a coin. You have a 2 out of 3 chance of being in the intervention group, and our study staff have no control over which group you will be placed in.

Group 1: Comparison Group

If you are in the comparison group, you will received standard of care. This is care that would normally be provided to people at civil society organizations. This includes counseling and referral to addiction treatment clinics (for detox and rehabilitation) and to HIV treatment clinics (for ART and HIV care) in St. Petersburg.

Group 2: Intervention Group

If you are in the intervention group, you will also receive standard of care as normally provided to patients at civil society organizations, as well as Acceptance and Commitment Training, as outlined below:

- You will participate in three group sessions of approximately five people with interventionists within the first 1-month of study participation. These sessions will be held here on site or at First St. Petersburg Pavlov State Medical University.
- The group sessions are intended to help you overcome shame, negative feelings, and judgments of self and others. The interventionists will help you and your peers utilize techniques to manage the negative attitudes or social exclusion you feel; and will teach you to respond to and refocus these thoughts. Sessions will also focus on identifying life goals and values.

Follow-Up Visits:

All participants will be asked to come in for individual in-person assessments at 1 and 6 months after their first intervention session (intervention group) or 1 and 6 months after enrollment (control group). The follow-up assessments will occur in person at the Center of the Medical Rehabilitation #1 with a research assessor. These interviews will take approximately 60 minutes to complete and will ask questions about your demographics, general health, substance use, substance use treatment, HIV care, risk behaviors, and satisfaction with the group sessions (intervention group only).

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

We are audio recording the group sessions to make sure they are performed well.

We would like permission to store your research data for future studies. All data that we collect from you as part of this study (screener and study data) will be placed in a repository for future research. When investigators want to perform a study on repository data they will submit a study plan for review and approval and will need to obtain any necessary approvals, such as approval from their IRB, to carry out the work with repository data. Prior to receiving the data, the researchers will agree not to share the data and not to attempt to identify any individual participants. In all cases the data will be released from the repository in coded form (i.e., names and contact details will not be included and data will be identified by a subject ID number). Please indicate below if you will allow that. Agreeing to the retention of data is optional and you can agree to participate in the main study but not agree to have your data retained.

My research data may be kept for future clinical, virological, and immunological research studies related to HIV disease, substance use disorder, and other associated illnesses.

Yes [ ]_____(initial or sign) No [ ]_____(initial or sign)

If you would like to use my research data for future studies not listed above, I am willing to be contacted about those studies for my permission.

Yes [ ]_____(initial or sign) No [ ]_____(initial or sign)

Risks and Discomforts

You may experience stress from the research assessments, as you will be asked sensitive questions regarding substance use and HIV status. The risk of stress from interviews will be minimized by using trained interviewers and a standard interview process. You may be stressed by the length of the interviews (estimated 60 minutes). You will be allowed to stop at any time during the interviews to take a break and come back to complete them. You may also choose to skip any questions or stop the interview entirely.

There is a small risk that you may experience psychological distress from the group sessions. The study team will provide resources to minimize this risk.

Potential Benefits

You may not receive any benefits from participating in the study. It is possible that you could benefit if you are in the intervention group, otherwise you will get standard care. Your being in the study may help the investigators learn the benefit of ACT as a therapy method to reduce feelings of stigma.

Alternatives

Your alternative is to not participate in the study. If you choose not to participate you will be able to access civil society organization services that are currently available to you. You will be able to continue receiving standard of care at your civil society organization, such as counseling and referral for substance use treatment and HIV treatment.

Costs

There are no costs to you for being in this research study. Although you may incur costs traveling to and from study visits.

Payment

You will receive 2000 rubles in cash at baseline and for your participation at 1- and 6-month study visits. If you are randomized to the intervention group, you will receive 2000 rubles for each of the group sessions, which includes the 1-week, 2-week, and 3-week group sessions. If you arrive more than 1 hour late to a session, you will receive 1000 rubles. If you arrive to the third session, and there are only 30 minutes remaining in the session, you will not be compensated. If you complete the follow-up assessments over the phone, instead of in-person, you will receive 500 rubles in cash or through phone card.

Confidentiality

There is a risk of loss of confidentiality if you take part in this study. However, the chance of someone seeing the responses to your interview assessments is unlikely because specific procedures will be put in place to prevent this from occurring. There is a small risk that you may experience a loss of confidentiality when research assessors contact you for follow-up. All study staff received training on the protection of human subjects in research. Study records are confidential, but there is a very small chance that someone outside the study could see them. Paper records are kept locked up and electronic records are in password protected computers. Access to these records is limited to specific individuals on the study staff. There is also a risk of loss of confidentiality from the intervention group sessions. However, participants will be instructed to not repeat anything they have heard in these sessions.

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. The data repository, the location where we store your information, has standard operating procedures to protect your confidentiality. Data is shared only in coded form and only after approval to use the data has been received. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

Research assessment questionnaires will be completed with the majority of data entered directly into computers, which will require a username and password to logon. Data will not have your name, only your unique study ID number. Locator contact information and the master enrollment list will have participant names. Paper forms will be kept in locked filing cabinets and electronic data will be stored on password protected computers. Study information will be accessible to study staff for purposes of conducting or monitoring the study. Intervention sessions with the interventionists will be audiorecorded, and your name could be mentioned or your identity could otherwise be revealed during the interview; however, audio files will be stored on password protected, secure computers accessible only to Russian study staff. The files will be labeled with your study ID number and not with your name or any other identifying information. All audiorecordings will be kept on the secure server until seven years after completion of study analyses and publication of study manuscripts and then deleted.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information. The Certificate of Confidentiality applies to information collected for this study which are sent to or kept in the United States of America.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health. Any people who you give us separate permission to share your information.
- Any people who you give us separate permission to share your information.
- People who will get your data as we described in the section What Will Happen in This Research Study. These people are expected to protect your information in the same way we protect it.

You should know that we are required to report if you intend to harm yourself or other people.

If you are in immediate danger of hurting yourself at any time in the study, the study team will try to work with you on a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

We will ask everyone in the group not to talk about the discussions outside the group. However, we can't promise that everyone will keep what you say confidential.

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

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study_____(initial or sign)

____Yes_____No You may contact me again to let me know about a different research study_____(initial or sign)

Protection of Subject Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below.

You authorize Karsten Lunze and study staff at Boston Medical Center who are working on this research project and their employees to use and disclose information concerning you and your identity, medical history, and information collected during this study for the following purpose: to study the effectiveness of Acceptance and Commitment Training (ACT).

Such information may also be disclosed to or used by others involved in or overseeing the study including Boston University and Boston Medical Center Institutional Review Board and the study's sponsor, the United States National Institutes of Health (NIH). We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. If you do not want to let us use your health information, you cannot be involved with this research study. This is because your health information is necessary to the conduct of this research. You may withdraw authorization to collect additional information about you at any time by writing to the local Principal Investigator, but information already collected may continue to be used and disclosed. This authorization has no expiration date.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact EDWIN ZVARTAU at 7-812-338-7023 during the day and EVGENY KRUPITSKY at 7-952-097-8173 after hours. Also call if you need to report an injury while being in this research.

You may also call +7(812)3386617. You will be talking to someone at the St. Petersburg State Pavlov Medical University IRB. The IRB is a group that helps monitor research. You should call or email (spbgmutrials@yandex.ru) the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and release of information that may identify you as described, including your health information

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date