NCT03464422

Title of Research Project: Adapting an Evidence-based Intervention for Stigma-related Stress, Mental Health, and HIV Risk for MSM of Color in Small Urban Areas (ESTEEM-conneCT)

Consent Form Last Approved by IRB Date 4.24.2019

YALE SCHOOL OF PUBLIC HEALTH

Consent for Participation in a Research Study

ESTEEM-conneCT: A Unified Intervention for Young Gay and Bisexual Men of Color's Minority Stress, Mental Health, and HIV Risk

Under the supervision of John E. Pachankis, PhD and Krystn Wagner, MD
Sponsor: National Institute of Mental Health (NIMH)

PURPOSE AND BACKGROUND

Dr. John Pachankis at the Yale School of Public Health and Dr. Krystn Wagner and Fair Haven Community Health Center are conducting research about mental health, sexual behavior, and ways of coping with stress among young gay and bisexual men of color. The purpose of this study is to test whether a group therapy can help gay and bisexual men of color improve their mental health, including depression and anxiety, reduce their risk of HIV transmission, and improve their ability to cope with negative emotions and stress. We anticipate that 30 men between the ages of 18 and 35 will participate in this study. Should you choose to participate in this study, you may complete the following study tasks, outlined in detail below. You can receive up to $240 plus transportation costs for participating in this study.

PROCEDURES

1. **Pre-Counseling Phone Interview:** The phone interview will take place at a time agreed upon by you and the study staff. During this call, a trained member of the research team will review details of participation of the research study and answering any questions you may have. Once you feel knowledgeable about the requirements of study involvement, a study team member will gain your consent to participate in study. The second portion of the call will be dedicated to completing an interview over the phone where you will answer questions about your experiences being gay or bisexual and sexual practices over the last 90 days.

2. **Pre-counseling Survey:** After completing the interview call, you will receive a survey via email that will ask you questions about your experiences being gay or bisexual, your mental health, sexual health, and stress you may have experienced because of your sexual and racial identity. You will receive $40 for completing this survey.

3. **Group Counseling:** After completing the survey, you will begin group counseling. You will meet for 10 weekly sessions for about 90 minutes each with a counselor and other participants in a private room at Fair Haven Community Health Center to discuss your mental health, sexual behavior, and ways of coping with stress and negative emotions. These 10 sessions must be completed within 4 months. All group counseling sessions will be conducted in English. The first group counseling session will be held on [*insert day of the week*], [*calendar date*]. All group sessions will run from 6-8 PM. During your first group counseling session, you will be asked to meet with a study staff member to review and sign a physical copy of this consent form. After 4 months, you will not receive any more compensated counseling sessions on behalf of the research study. You and your counselor and the other group members might discuss skills and exercises to help with coping with negative emotions that might be related to negative experiences you have faced (like discrimination and stigma) because of your sexual orientation and racial identity. Your counselor might ask you to practice skills or complete exercises (like worksheets or activities tracking the way you feel each day) between your counseling sessions so that you can learn how to use them in your daily life. Some of the skills

and exercises might make you feel temporarily uncomfortable, like feeling sad or anxious. These sessions will be audio recorded for research and supervision purposes; therefore, audio recording is not optional. You will have the choice of using pseudonyms in the audio-recordings to protect your confidentiality on the audio-recordings. Your counselor will take notes on each session and securely store those notes in a locked file cabinet; your name will not be attached to the notes, only your ID number. You will be compensated $10 for each session completed plus transportation costs (up to an additional $10). The $40 compensation for the pre-counseling survey will be paid during the first counseling session along with the first counseling session payment ($10) for a total initial payment of $50 plus transportations costs (up to an additional $10).

4. **Post-Counseling Phone Interview:** The phone interview will take place 3 months after the final group session at a time agreed upon by you and the study staff. The call will be dedicated to completing an interview over the phone where you will answer questions about your experiences being gay or bisexual and sexual practices over the last 90 days.

5. **After-counseling survey:** 3 months after the final group session, you will be asked to complete the same online survey you completed before the first group session. This survey will ask you questions about your mental health, sexual behavior, and ways of coping with the stress you might have experienced because of your racial identity and sexual orientation. You will receive $40 for completing the follow-up assessments & phone interview.

6. **Final Interview**: 3 months after the final group session, both therapists and all study participants will be individually contacted by the project coordinator to complete a final interview about your experience participating in the ESTEEM-conneCT group counseling and suggestions for future improvements. You will receive $60 for completing the final interview.

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.

CONFIDENTIALITY AND THE PROTECTION OF YOUR PRIVACY

We will guard your confidentiality and protect all information about you and your participation in this study to the extent permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. The following procedures will be followed in an effort to keep your personal information confidential and private in this study.

Your identity will be held strictly confidential by project staff, who are trained not to discuss any details of this study with individuals outside of this project. All information you provide (emails, worksheets, the audio files from your interview, and video files from the group therapy sessions) will be encrypted and stored on our research center's secure server and your name will not be attached to this information. You will be given a unique identification number and asked not to discuss any personally identifiable information (for example, your name, address, the names of sex partners) during the duration of your participation to minimize the risk of your personal information being disclosed. However, if you decide to share your study information with people other than our staff, then your privacy might be compromised.

Please note that we cannot prevent participants in this therapy group from disclosing your personal information to other individuals. They might share information about your sexuality, mental health, HIV status, or other

personal information. We will ask all participants to keep each other's information private, but we cannot guarantee that they will do so.

To track and schedule your participation in this study, we will use your unique identification number. Information that links your name to your identification number will be kept in a password-protected database stored on a secure server, to which only Dr. John Pachankis, Dr. Krystn Wagner, and the study staff will have access. We will keep four separate electronic and password-protected files. The first will be a database containing the contact information that you are willing to provide to us for scheduling the study appointments (including your telephone number, email address, mailing address, and date of birth). The second will be the information that you provided in your assessments and interview appointment, which the study team will review to determine how well this program works and to ensure that our counselors are properly addressing discussion topics. The third will be the digital video recordings from the group counseling sessions. The fourth will track study payments made to you. Only the first database will contain your name, while the others will only contain your identification number. The database with your contact information will be deleted three years after the completion of the study, unless you have expressed interest in being informed of possible future studies. Your name will not be used in any reports or publications from this study. All data you provide for this study will be maintained securely by our study staff for minimum of three years after the study ends.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects.

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. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if you tell us of your intent to harm yourself or others (including reporting behaviors consistent with child or elderly abuse). In these cases, confidentiality will be waived and actions may be taken to protect you and/or others. It is your right to decline or stop participation at any time without penalty, should you feel uncomfortable for any reason. If you have any concerns, you may contact the project staff at any point.

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at Yale University and the Fair Haven Clinic are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and *contact information.* This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for *three years after study completion*, after which time the link will be destroyed and the data will become anonymous. The data will *also be destroyed three years after study completion.* Additionally, participants will have the choice of using pseudonyms in the audio-recordings to protect their confidentiality on the audio-recordings and this information will also be destroyed three years after study completion.

The information about your health that will be collected in this study includes: records about phone calls and emails made as part of this research; records about your study visits; information obtained during this research regarding HIV / AIDS, other sexually transmitted diseases, use of illegal drugs, and mental health diagnoses and treatment; questionnaire data;

Information about you and your health which might identify you may be used by or given to:

The U.S. Department of Health and Human Services (DHHS) agencies
Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Subjects Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
The Principal investigators, Dr. John Pachankis and Dr. Krystn Wagner
Study coordinator and members of the research team
Data and safety monitoring boards and others authorized to monitor the conduct of the Study

RISKS

The greatest risk to participation in this study is that your information could be disclosed to other individuals who are not involved in this study. However, we will minimize that risk by storing your personal information in a secure place and not linking it to your other study data. You will be assigned unique study identification number. No identifiers (for example, your name, address, email, date of birth, social security number) will be collected in the baseline or follow-up survey, interview, or counseling sessions. A record that will link unique identification codes with names and contact information for participants will be accessible only to study staff and maintained in a password-protected file on our secure server.

Another risk is that a group member might share your personal information outside of the group, including information about your sexuality, mental health, or HIV status. Although we will ask all group members to keep each other's information private, we cannot guarantee that all group members will do so.

There is also a chance that you may feel uncomfortable or embarrassed sharing personal information in the group sessions or in practicing some of the suggestions given to you by the group therapist. You have the option of refusing to share information or answer a particular question, by stating "I do not wish to share information" or "I do not wish to answer this question." If any of the questions concern you or cause you to feel distress, you may at any time speak privately with Dr. Pachankis, Principal Investigator of the ESTEEM-conneCT study, who is available by phone at 203-785-3710, or Dr. Wagner, Principal Investigator of the ESTEEM-conneCT study, who is available by phone at 203-777-7411 extension 5985, or in-person at our New Haven office.

BENEFITS

It is possible that you may receive benefits from participating in this study. You may learn more about yourself and your mental health, sexual life, and ways of managing stress and negative emotions. You are also helping Drs. Pachankis and Wagner and their research team develop a counseling program to reduce mental health and HIV-transmission risk for gay and bisexual men of color who experience depression and anxiety, which will likely benefit other members of the community.

COMPENSATION & COSTS

You will receive the following compensation for completing each portion of the study:

- Ten counseling sessions: $10 per session plus transportation costs (up to an additional $10 per session), equaling a total of $100 plus transportation costs (up to an additional $100).
- The online survey & phone interview (before the first counseling session): $40
- The follow-up online survey & phone interview (3 months after the final counseling session): 40
- The final interview (3 months after the final counseling session): $60

You will be paid the amounts described above in cash after completing each part of the study. Payment for the pre-counseling surveys & phone interview will be provided during the first counseling session along with the payment for the first counseling session. All other counseling session payments will be provided during those respective counseling sessions. Payment for the post-counseling surveys & phone interview and for the final interview will be provided at a date/time agreed upon by each study participant and the ESTEEM-conneCT research staff. If you withdraw from the study, you can keep the compensation that you have earned up to that point, but you will not receive compensation for those parts of the study that you have not completed.

OTHER INFORMATION

If you have any questions about the research study or experience a negative reaction that might have been caused by being in this study, please call Dr. John Pachankis immediately at 203-785-3710, or Dr. Wagner at 203-777-7411 extension 5985, write to our study staff, or visit our research office in New Haven: ESTEEM-conneCT, 60 College Street, Suite 316, New Haven, CT, 06510.

You have rights as a research volunteer. Taking part in this study is voluntary. If you do not take part, you will neither incur a penalty nor lose benefits. You may stop participating in the study at any point, but will only receive compensation for the parts that you have completed. Ending your participation in this study or choosing not to participate is completely voluntary and will not affect benefits that you are otherwise entitled to.

The alternative to participation in this study is not to participate.

Withdrawing from the Study

If you do decide to participate in this study, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments.

The researchers may also withdraw your participation for a number of reasons: 1) during the course of the survey, assessments, or counseling sessions, it becomes clear that you do not meet study eligibility criteria, 2) if physical or psychological problems arise which would interfere with your participation in the study, 3) if we

feel that it is in the best interests of your health or psychological well-being, or 4) if we believe that you are providing inaccurate or false information. If we do dismiss you from the study, you will still receive partial compensation for the parts you have completed.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with *the Fair Haven Community Health Center. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.*

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to *John Pachankis, PhD* at the Yale University School of Public Health, Suite 316, 60 College Street, New Haven, CT 06510.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

INFORMED CONSENT SIGNATURE PAGE

The following is a list key information pieces you have received about this research study. If you have any questions about any of these items, please ask the person who is discussing the study with you for more information before agreeing to participate. Please verify you understand the following items:

- What the study is about.
- What I must do when I am in the study.
- The possible risks and benefits to me.
- Who to contact if I have questions or if there is a research related injury.
- Any costs and payments.
- I can discontinue participating in the study at any time without penalty.
- Other choices.
- I have been given the name of the researcher and others to contact.
- I have the right to ask any questions.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____

Signature of Principal Investigator Date

or

_____ _____

Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203-432-5919

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator*, John Pachankis, PhD [203-785-3710]*. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Subjects Committee (HSC) at (203) 785-4688