NCT03721276

Title of Research Project: Project EQuIP: Empowering Queer Identities in Psychotherapy

Date 07.20.18

Yale University
Yale School of Public Health
Esteem Research Group
Consent for Participation in a Research Project

A Unified Intervention for Sexual Minority Women's Minority Stress, Mental Health, and Associated Health Risks

John Pachankis, PhD

Purpose:

You are invited to participate in Project EQuIP (Empowering Queer Identities in Psychotherapy), a research study that aims to test a type of counseling to improve the mental and behavioral health of sexual minority women. This counseling is a form of cognitive-behavioral therapy that will address your unique experiences with the stressors you might experience in your life, especially those related to being a sexual minority woman. We anticipate that 60 sexual minority women between the ages of 18 and 35 will participate in this study. Should you choose to participate in this study, you may complete the study tasks, outlined in detail below, and receive $225.

Procedures:

1. **Informed Consent:** Today you will review this informed consent form and electronically sign your name. After you consent, you will be re-directed to the first set of at home surveys to complete, which must be completed before your first scheduled appointment with us. You may call us at 646-344-4060 if you have any questions about the consent form. The consent form will also be reviewed with you at your first appointment with a research staff member and again you will be asked to sign your name if you agree to participate in this study once all of your questions have been addressed by the research staff member.

2. **First Appointment:** During the first appointment, a trained research staff member will review the consent form with you and answer any questions you may have, ask you to fill out some surveys, complete computer tasks, and interview you about your past-90-day alcohol use. Some of the surveys will ask you questions about your mental health, substance use, sexual behavior, and stress that you might have experienced because of your sexual orientation and/or gender identity. Our tasks are like brief computer games that give us information on how people think. Additionally, the interview about your recent alcohol use will be video recorded. This is not optional, as we record these videos for quality assurance purposes. However, your face will not be recorded—just your voice will be. At the end of this appointment, you will be randomly assigned to one of two conditions: therapy or waitlist. You will have an equal chance of being randomly assigned to therapy or waitlist. No matter what condition you are assigned to, you will receive therapy. The only difference is that if you are assigned to waitlist, you will be asked to wait 3 months before your first therapy appointment. There are no restrictions when being assigned to waitlist. For example, you are free to participate in other studies or seek out mental health treatment. You will not be re-assessed for eligibility after you sign this consent form. Today's appointment will last about 90 minutes and you will receive $25.

3. **Therapy:** Your role in this study will involve participating in 10, one-hour, weekly, therapy sessions, with a member of our clinical staff. If you miss a session, you can make it up by rescheduling your appointment with the therapist. These 10 therapy sessions must be

completed within three months from your first therapy session. This therapy will address your thoughts, feelings, and behaviors about different stressors in your life, including those related to being a sexual minority woman. These therapy sessions will be video recorded. However, your face will not be recorded—just your voice will be. You will receive $10 at the end of each therapy session.

4. **3-Month and 6-Month Follow-up Appointments**: Regardless of which condition you are assigned to, you will complete in-office surveys and interview appointments at 3 months from now and 6 months from now. The follow-up appointments will be identical to the first appointment. You will receive $25 at your 3-month appointment and another $75 at your 6-month appointment.

Risks and Benefits:
There are no physical risks for participating in this study. As with any research study that collects information about you, there is a risk of breach of confidentiality. However, we will minimize that risk by assigning you a unique study identification number. No identifiers, such as your name, address, email, date of birth, or social security number, will be collected on the survey, interview, or counseling sessions, except your voice in the video recording of the assessments and therapy sessions. A record that will link your unique identification code with your name and contact information will be accessible only to study staff and maintained in a password-protected file on a secure server at our office.

There is a slight chance that you may feel uncomfortable or embarrassed answering some of the questions that may arise in the surveys, interview with the research assistant, or your conversations with the counselor. You have the option of refusing to answer questions by stating "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. John Pachankis, Principal Investigator of the EQuIP study, who is available by phone or in-person at our New York City research center.

It is possible that you may receive benefits from participating in this study. You may learn more about yourself, your mental health, and ways of managing stress and negative emotions. You are also helping Dr. Pachankis and his research team develop a counseling program to improve mental health and reduce alcohol abuse risk for lesbian, bisexual, and queer women, which can benefit other members of the community.

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

- The first in-office interview appointment (baseline): $25
- Ten counseling sessions: $10 per session, equaling a total of $100
- The 3-month in-office interview appointment: $25
- The 6-month in-office interview appointment: $75

There will be no cost to you if you participate in this study. You will be paid the amounts described above after completing each part of the study. 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.

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 law. 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 video files from your interview) 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) during the duration of your participation to minimize breach of confidentiality. However, if you decide to share your study information with people other than our staff, then your privacy might be compromised.

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, as well as on a secure survey website (Qualtrics), to which only Dr. John Pachankis 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, and date of birth). The second will be the information that you provided in your survey and interview appointments, which the study team will review to determine how well this program works and to ensure that our counselors are properly addressing the topics of your discussions. The third will be the digital video recordings from the interview appointments and 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 five 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.

Voluntary Participation:
Your participation in this study is voluntary. You are free to decline to participate, to end your participation at any time for any reason, or to refuse to answer any individual question. Refusing to participate will involve no penalty or loss of benefits or compensation to which you are otherwise entitled or affect your relationship with Yale University, or any other institution or person afflicted with this study.

We may end your participation for a number of reasons: 1) during the course of the study, 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 you are deemed ineligible to move forward with an interview once you have arrived at our office, you will be compensated $10 to cover your travel expenses.

Questions:
If you have any questions about this study or experience a negative reaction that might have been caused by being in this study, please contact the study investigator immediately. You can call or write to him: John Pachankis, PhD (john.pachankis@yale.edu; 203-785-3710). You can also visit our research office in New York: ESTEEM, 220 E. 23rd St. Suite 405, New York, NY 10010.

If you would like to talk with someone other than the researcher to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, 203-785-4688, human.subjects@yale.edu. Additional information is available at http://www.yale.edu/hrpp/participants/index.html.

Agreement to Participate

The following is a list of 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.
- All written and published information will be reported as group data with no reference to my name.
- I have been given the name of the researcher and others to contact.

- I have the right to ask any questions.

I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

_____ _____

(printed name) (date)

_____

(signature)