NCT04559698

Title of Research Project: Assessing mental health providers' clinical knowledge and skills via an online training on LGBTQ-affirmative cognitive-behavioral therapy

Date: 9.17.20

INFORMATION SHEET FOR PARTICIPATION IN A RESEARCH STUDY YALE INITIATIVE FOR LGBTQ MENTAL HEALTH

Study Title:

Assessing mental health providers clinical knowledge and skills via an online training on LGBTQ-affirmative cognitive-behavioral therapy

Principal Investigator (the person who is responsible for this research):

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Research Study Summary:

We are asking you to join an LGBTQ-affirmative cognitive-behavioral therapy (CBT) training and associated research study. The purpose of this research study is to train mental health providers at LGBTQ community centers across the United States in evidence-based, LGBTQ-affirmative CBT, as well as to assess whether the training increases LGBTQ-affirmative CBT clinical skills, content knowledge in minority stress and CBT, and cultural humility among mental health providers. The research study is funded through the David Kessler, M.D. '55 Resource Fund for LGBTQ Mental Health at Yale University. The American Psychological Association's Division 44 is providing continuing education (CEs) credits for those who are eligible and choose to participate in this training.

Study activities will include attending an 11-week training with each session lasting 1 hour over Zoom and completing a feedback form after completing each training session. The training will be held online for one hour at 9am PST/12 pm EST every Friday in two waves: the first will take place from October 30, 2020 to January 29, 2021 (excluding November 27, December 25, and January 1 due to holidays), and the second wave will take place from March 5, 2021 to May 21, 2021 (excluding April 9 due to a holiday). Because we are interested in whether the training is effective, participants will be randomized to either the first wave of training or a waitlist control group. Participants in the waitlist control group will receive the training during the second wave.

Study activities will also include completing self-report questionnaires on LGBTQ clinical skills, content knowledge in minority stress and CBT, cultural humility, and participant demographics. The majority of questionnaires will be based on Likert-type scales or multiple-choice items. One survey will ask participants to watch two brief clips of fictional clients and type a response of how they would respond to this client. Study measures will be administered at three time points: baseline, 3-months post-baseline, and 6-months post-baseline. At each time point, the study measures will be emailed to participants for completion. The measures at each time point should take approximately 30 minutes for participants to complete. Your involvement time in total, including the training and study questionnaires, will require approximately 13 hours.

We do not expect any physical risks from taking part in this study. There is the potential risk of anxiety or discomfort when reporting opinions, feedback, and beliefs during the training sessions. There is the risk that participants will feel embarrassed or uncomfortable while discussing topics for which they have limited knowledge. It is also possible that participants may feel uncomfortable answering survey questions about

their LGBTQ and CBT knowledge. However, these risks are minimal. To minimize the risk of participants experiencing emotional disturbance as a result of the surveys or training, participants may discontinue participation at any time. Participants experiencing mild distress when completing the study questionnaires may take a break or complete them at a later date. In the unlikely event that a participant experiences considerable distress, the research team will make referrals as needed for clinical services.

There is also the possible risk of loss of confidentiality. The principal investigator and his research team have been involved with numerous local, national, and international studies involving human subjects and have considerable experience implementing measures to protect confidentiality. All possible measures will be taken to protect information provided through surveys, and confidentiality will be respected. All data collected will identify participants by a unique code. A master link file will connect participant email addresses to their study code number. The link file will be password protected and only accessible to the principal investigator.

The study may have some benefits to you. As a result of this study, you may increase your knowledge and clinical skills related to minority stress and evidence-based CBT interventions for LGBTQ clients. The proposed study could also lead to future trainings in evidence-based LGBTQ-affirmative mental health care, which would ultimately benefit LGBTQ clients nationwide by increasing accessibility to evidence-based treatment. Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your affiliated LGBTQ community center.

If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, we will continue with the study procedures described in this form.

Are there any costs to participation? Will I be paid for participation?

You will not have to pay for taking part in this study. Participants will be compensated \$50 for completing each set of surveys at the three time points, for a total possible compensation of \$150.

How will you keep my data safe and private?

All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

To best ensure confidentiality, all data will be collected via the secure Yale Qualtrics server. You will be assigned a unique code number that will link your data collected across the study. A master link file will connect your email address to your study code number. The link file will be password protected and only accessible to the PI. All

materials will be stored on password protected folders on Yale Secure Box that requires dual-factor authentication to access. De-identified survey data will only be downloaded, organized, and stored on a password-protected computer.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission. We will not share any of your information with other researchers for future research studies, even if we remove all identifiers such as your name.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your affiliated LGBTQ community center. You do not give up any of your legal rights by giving online consent to participate. You can contact the research team at esteem@yale.edu at any time to withdraw from the study and to request that your data is destroyed.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand. If you have questions later or if you have a research-related problem, you can call the Principal Investigator at (203) 785-3710 or email the research team at esteem@yale.edu.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

After reading about the study, please choose one of the following responses:

- YES. I have read the above information. The study has been explained to me.
 My questions have been answered. I VOLUNTARILY AGREE to be in this study.
- YES. I agree to participate in the online training, but I do NOT agree to take part in the measures associated with the research study.
- NO. I do NOT agree to participate in the online training and associated research study.