

NCT04559698

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

Date: 9.23.20

STUDY PROTOCOL

Social Behavioral Template

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

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Confidentiality Statement

Synopsis

Purpose

The purpose of the proposed study is to train mental health providers (MHPs) at lesbian, gay, bisexual, transgender, and queer (LGBTQ) community centers across the United States in evidence-based, LGBTQ-affirmative cognitive-behavioral therapy (CBT). We will assess changes in MHPs' knowledge and clinical skills in providing mental health care for LGBTQ clients from baseline to 3-months post-baseline and 6-months post-baseline using a randomized-waitlist-controlled study design. We will also evaluate the training's feasibility and acceptability.

Objectives

The primary objective of this study is to determine whether the LGBTQ-affirmative CBT training increases LGBTQ and CBT knowledge, clinical skills, and cultural humility among a sample of MHPs from LGBTQ community centers in the United States. The secondary objective is to evaluate the feasibility and acceptability of the 11-weekly 1-hour training seminars.

Study Population

The study population will consist of healthy participants who are 18 year of age or older, fluent in English, and currently in the role of an MHP at an LGBTQ community center in the U.S. engaging in treatment with LGBTQ clients. MHPs from LGBTQ community centers through CenterLink, the coordinating hub of 250+ LGBTQ community centers in the U.S., will specifically be recruited for this study in order to provide evidence-based LGBTQ-affirmative training to MHPs working predominantly with individuals from the LGBTQ community.

Number of Participants

We plan to enroll at least 76 participants ($n = 38$ per group). Our team's prior pilot studies assessing the efficacy of LGBTQ-affirmative health trainings have demonstrated moderate-to-large effect sizes in improving healthcare providers' LGBTQ-affirmative clinical skills and willingness to provide LGBTQ-affirmative clinical care ($d = 0.66-1.20$; Lelutiu-Weinberger, Clark, & Pachankis, in preparation; Lelutiu-Weinberger & Pachankis, 2017; White Hughto, Clark, et al., 2017). Based on the most conservative effect size drawn from our team's previous LGBTQ-affirmative training studies for healthcare providers ($d = 0.66$), we conducted a power analysis for an independent samples t -test used to compare the mean of a continuous measurement in two samples. We set the threshold probability for rejecting the null hypothesis (type I error rate) to α (two-tailed) = 0.05. Power to detect Type I error was fixed at a standard level of $1 - \beta = 0.80$ (type II error rate). Given these parameters, we require 38 participants per group ($N = 76$) to retain statistical power. We expect to enroll at minimum 38 participants per group; due to the high need and reach of our recruitment partner (i.e., CenterLink, the coordinating hub of 250+ LGBTQ community centers in the U.S.), we expect to enroll at least 100 participants which will allow for adequate statistical power even with 20% attrition.

Study Design

The proposed prospective study will follow a 2-arm waitlist randomized-controlled trial (RCT) design where one group of MHPs will be randomized to receive the intervention training (i.e., the immediate training group) in LGBTQ-affirmative CBT, and the second group of MHPs will be randomized to a waitlist control group. The training will be conducted online via Zoom for 1-hour per week over two separate 11-week courses (i.e., the first 11 weeks for the immediate training group, and the second 11 weeks for the waitlist control group). A team of four clinical and counseling psychologists (the PI, two postdoctoral psychologists, and one associate research scientist) will lead the training. All trainers have participated in the development, research, and implementation of the LGBTQ-affirmative CBT treatment.

To assess intervention efficacy, participants will be assessed at three time-points: baseline, 3-months post-baseline, and 6-months post-baseline. Participants randomized to the immediate training group will be scheduled to receive the first iteration of the 11-week LGBTQ-affirmative CBT training (scheduled for October 30, 2020 – January 29, 2021, excluding holidays of November 27, December 25, and January 1). Participants randomized to the waitlist control group will receive one e-mail per month to remind them of their upcoming training and 3-month post-baseline assessment, and will then be scheduled for the second iteration of the 11-week LGBTQ-affirmative CBT training (March 5, 2021 – May 21, 2021, excluding the holiday of April 9). Participants randomized to the immediate training group will receive the training between their baseline and 3-month post-baseline assessments. Participants randomized to the waitlist control group will receive the training between their 3-month post-baseline and 6-month post-baseline assessments.

The proposed mixed-methods study will consist of quantitative self-report measures, as well as a qualitative self-assessment of participants' LGBTQ-affirmative CBT clinical skills. All study measures will be administered online via the secure Yale Qualtrics survey software.

Study Duration

The entire study, including data analysis, is expected to last until July 2021. Participation for the subjects will begin at the beginning of October 2020 (i.e., recruitment for the intervention training at an optional informational webinar). Subjects in the immediate training group will begin the 11-week training on October 30, 2020, finish the training on January 29, 2021, and complete their 6-months post-baseline measures in mid-May 2021. The waitlist control group will remain on the waitlist until the immediate training group completes the training. Then, starting on March 5, 2021, the waitlist control group will receive the same 11-week training. Their participation will end upon completion of the training and the 6-months post-baseline measures in mid-May 2021. Data analysis is expected to continue to July 2021.

Outcome Variables

The following are the outcome variables and associated measures that will be administered at all three time points (i.e., baseline, 3-months post-baseline, and 6-months post-baseline) in the study, unless otherwise noted:

- LGBTQ Clinical Skills Competency
 - Sexual Orientation Counselor Competency Scale (SOCCS) – Clinical Skills subscale

- Deliberate Practice of LGBTQ-Affirmative CBT Skills
- Cultural Humility
 - Multidimensional Cultural Humility Scale (MCHS)
- Content Knowledge, Familiarity, and Use of Minority Stress & CBT
 - Minority Stress Content Knowledge Quiz
 - CBT/LGBTQ-Affirmative CBT Content Knowledge Quiz
 - Familiarity and Use of LGBTQ-Affirmative CBT Skills Questionnaire
- Acceptability of LGBTQ-affirmative CBT Training
 - Acceptability of LGBTQ-affirmative CBT Training Questionnaire (*only* administered immediately after the training)
 - Training in LGBTQ-Affirmative CBT – Session Feedback Forms (administered immediately after each training session)

Locations/Facilities

The training and online surveys will be completed from the participants' electronic devices (e.g., phones, tablets, or computers). All trainings will be conducted via the PI or postdoctoral researchers' Yale-affiliated Zoom videoconferencing accounts and require a passcode to enter. All measures will be conducted utilizing the secure Yale Qualtrics online survey software.

Abbreviations

Abbreviation	Explanation
CBT	Cognitive-Behavioral Therapy
LGBTQ	Lesbian, gay, bisexual, transgender, and queer
MCHS	Multidimensional Cultural Humility Scale
MHP	Mental health provider
RCT	Randomized-controlled trial
SOCCS	Sexual Orientation Counselor Competency Scale

Glossary of Terms

Glossary	Explanation
Cognitive-Behavioral Therapy (CBT)	A short term, structured, problem-solving form of evidence-based psychotherapy based on a framework focused on the relationship between thoughts, feelings, and behaviors.
Minority stress	The unique and chronic stress (or stigma) that sexual minority individuals experience because of the inferior social status that social structures, institutions, policies, and social interactions communicate about individuals who do not identify as heterosexual.

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Protocol Revision History

Include the IRB approved protocol version number and date for each revision of the protocol. All version history should remain in the table and never be deleted. The oldest IRB approved version of the protocol should be listed on the top row. The most recent IRB approved version should be listed on the bottom row.

Version Date	Summary of Substantial Changes
9/22/2020	Original IRB approval
9/23/2020	- Updated inclusion criteria

1 Background

1.1 Background

Given their disproportionate exposure to stigma-related stressors, including institutional and interpersonal discrimination, and unique developmental challenges across the lifespan, individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ) experience disproportionately high rates of stress-sensitive mental health conditions (Bränström, van der Star, & Pachankis, 2020; Rice, Vasilenko, Fish, & Lanza, 2019). At least in part for these reasons, LGBTQ individuals also seek treatment for mental health conditions at higher rates than the general population (Cochran, Björkenstam, & Mays, 2017). Despite high rates of treatment utilization among LGBTQ individuals, research finds a large remaining unmet mental health treatment need among this population (Burgess, Lee, Tran, & van Ryn, 2008). Transgender individuals appear to be at particularly high risk of unfulfilled mental health care needs (Shipherd, Green, & Abromovitz, 2010; Steele et al., 2017).

The LGBTQ community has historically demonstrated strong activism and community organizing to address the barriers faced to mental health care. Since the 1970s, LGBTQ community activism has largely been centered around ensuring sufficient health and mental health services for this population (Martos, Wilson, & Meyer, 2017). Many of these services were and remain heavily focused on HIV prevention and care and are embedded within LGBTQ community centers (Herek & Greene, 1995). In fact, LGBTQ community centers often led the front lines against the HIV/AIDS epidemic. Still, even before the HIV/AIDS epidemic, LGBTQ community centers were initially established to raise consciousness about the need for LGBTQ visibility and empowerment, advocate for LGBTQ rights, and provide other needed supports and connectedness among SGM people unavailable in general-population settings. From the beginning then, services offered at LGBTQ community centers had an explicit focus on identity-affirming mental health support (Silverstein, 1997). With greater visibility of SGM people throughout the 1970s and 1980s and political realizations that non-pathologizing, identity-affirming care would have to come from within the LGBTQ community itself, the role of LGBTQ community centers in supporting LGBTQ mental health became even more imperative and persists today (D'Emilio 2012; Mail & Lear, 2006).

Today, LGBTQ community centers continue to respond to the increasingly prominent fact that the mental health disparity facing the LGBTQ population represents one of its most pressing contemporary challenges (Bromberg, Paltiel, Busch, & Pachankis, 2020). Of the more than 250 LGBTQ community centers in the US, about 40% provide mental health services, primarily counseling, peer-led programs, and support groups, free of the discrimination that many SGM might experience or anticipate experiencing in other settings (Movement Advancement Project and CenterLink, 2018). Most centers are located in urban areas and coastal states characterized by low structural stigma toward SGM people; thirteen U.S. states do not have an LGBTQ center, posing access barriers to SGM living in many high-stigma, rural locations (Martos et al., 2017). At the same time, because LGBTQ community centers often offer free or heavily-subsidized mental health services, they are ideally suited to increase access to services among those who might not otherwise receive such care, including those with lower incomes and LGBTQ people of color (Matos, Fingerhut, Wilson, & Meyer, 2019).

Based on a recent study that surveyed 60 directors of LGBTQ community centers across the U.S. (Pachankis, Clark, Jackson, Pereira, & Levine, under review), these center directors perceive a high need for mental health care in their LGBTQ communities and strive to meet that need; for most centers, however, the perceived need outweighs their current resources.

Most center directors reported having few mental health staff; still, most reported providing support groups and individual psychotherapy, delivered by social workers and mental health counselors. Further, most center directors report providing general evidence-based care, such as CBT, and report that their mental health staff has received training in evidence-based practice. Most centers also reported high interest in their staff receiving training in the specific type of evidence-based, LGBTQ-affirmative care that has only recently become available following successful RCTs (e.g., Pachankis et al., 2020). In general, there is currently a high demand for and willingness among LGBTQ community center directors to provide evidence-based training for their providers. At this time, we seek to build upon our team's previous work (further described in Section 1.2) to now disseminate our LGBTQ-affirmative CBT to reach young LGBTQ people across the U.S. The purpose of this project is to test the effectiveness of a training for MHPs in LGBTQ-affirmative CBT to disseminate the treatment to LGBTQ young people nationwide.

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1.2 Prior Experience (if applicable)

The LGBTQ-affirmative CBT treatment for the proposed training has been previously developed and tested by the current research team. In the pilot testing of the treatment among a sample of gay and bisexual men (Pachankis et al., 2015), the treatment significantly reduced depressive, alcohol use problems, sexual compulsivity, and past-90-day condomless sex with casual partners, as well as improved condom use self-efficacy. The treatment yielded moderate and marginally significant improvements compared to a waitlist group in anxiety symptoms and past-90-day heavy drinking. Effects were generally maintained at follow-up.

Since the pilot, the research team has been in the process of testing the efficacy of the treatment among gay and bisexual men in an RCT against Community Mental Health Treatment and Voluntary Testing and Counselling for HIV (see IRB protocol: 1509016430). The research team has also adapted the LGBTQ-affirmative CBT treatment for gender diverse, sexual minority women (see IRB protocol: 2000020997; Pachankis, McConocha, et al., 2020), as well as for an online platform (see IRB protocol: 2000025803).

In addition to the extensive experience with developing and implementing LGBTQ-affirmative treatment, the research team has previous experience specifically designing and implementing trainings based on the LGBTQ-affirmative treatment developed within the lab. These trainings have been designed and implemented in high stigmatizing settings, such as U.S. prisons (Hughto & Clark, 2019; Hughto, Clark, Altice, Reisner, Kershaw, & Pachankis, 2017), as well as internationally, including in Romania (Lelutiu-Weinberger & Pachankis, 2017; 2018; 2019).

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2 Rationale/Significance

2.1 Rationale and Study Significance

LGBTQ community centers, specifically mental health providers (MHPs) within these centers, provide mental health services to treatment-seeking LGBTQ clients across the U.S. However, it is unknown to what extent MHPs in LGBTQ community centers are trained to provide LGBTQ-affirmative, evidence-based treatment (e.g., cognitive-behavioral therapy; CBT). Our team developed the first LGBTQ-affirmative CBT that demonstrated feasibility, acceptability, and efficacy in reducing LGBTQ young people's symptoms of depression, anxiety, and substance use (Pachankis et al., 2015). With the ultimate goal of disseminating this high-quality, LGBTQ-affirmative mental health treatment to LGBTQ individuals across the U.S., we have developed a training for MHPs on delivering our team's evidence-based, LGBTQ-affirmative CBT.

The proposed research study, including MHPs at LGBTQ community centers nationwide, will assess to what extent such a training can improve MHPs LGBTQ-affirmative clinical knowledge and skills. If successful, we can disseminate evidence-based, LGBTQ-affirmative CBT to high-need LGBTQ individuals seeking mental health treatment at LGBTQ community centers across the U.S.

2.2 Risks

The risks associated with participation in this study will be minimal. Two primary risks are risk of emotional discomfort and breach of confidentiality.

First, due to the research topic, there is the potential risk of anxiety or discomfort when reporting opinions, feedback, and beliefs during the training sessions. In particular, there is the risk that participants will feel embarrassed or uncomfortable while discussing topics for which they have limited knowledge, particularly in front of other MHPs. In addition, it is possible that participants may feel uncomfortable answering survey questions about their knowledge, particularly when they lack training in a specific area related to LGBTQ mental health and/or CBT. However, these risks are minimal.

To minimize the risk of participants experiencing emotional disturbance as a result of the surveys or intervention training, participants will be informed via the informed consent that the study may elicit emotional discomfort and that they may discontinue participation at any time. Participants experiencing mild distress during the assessments may take a break or complete the assessment at a later date. In the unlikely event that a participant experiences

considerable distress, we will make a referral (if needed) for clinical assessment and/or counseling. Of note, given that all participants will be MHPs connected with LGBTQ community centers, it is likely that they will already be knowledgeable about mental health services available in their area. In the event that a participant discloses abuse or intent to harm oneself or others, the PI will report disclosures of abuse or intent to harm to the appropriate authorities immediately. Clinically trained staff members, including the PI, Dr. John Pachankis, a licensed clinical psychologist, will be on call for emergency consultation. In the unlikely event that such an incident should occur, we will notify the Yale IRB within 5 days hours, and appropriate measures will be taken, including necessary reporting to the IRB.

Second, as with any study, there is a risk of inadvertent breach of confidentiality. The PI 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. Specifically, to maximize privacy and ensure confidentiality, participant names will not be recorded during the online surveys. The only exception will be during the initial online screener, which will ask for participants' name, email address, age, degree, provider title, and name of their LGBTQ community center. The purpose of this initial online screener is to collect contact information to inform potential participants about the training, as well as to determine eligibility for the training and associated research study. Data from the initial online screener will not be merged or included with subsequent data collected during the study. For all surveys, participants will be told that they are not obligated to answer any question they do not wish to. Beginning at the baseline assessments, 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 PI.

2.3 Anticipated Benefits

As a result of this study, participating MHPs at LGBTQ community centers across the U.S. might increase their knowledge and clinical skills related to minority stress and evidence-based CBT interventions for LGBTQ clients. If successful, the proposed study could lead to future trainings in evidence-based LGBTQ-affirmative mental health care, which would ultimately benefit LGBTQ clients by increasing accessibility to evidence-based treatment.

3 Study Purpose and Objectives

3.1 Purpose

The purpose of the proposed study is to train mental health providers (MHPs) at lesbian, gay, bisexual, transgender, and queer (LGBTQ) community centers across the United States in evidence-based, LGBTQ-affirmative cognitive-behavioral therapy (CBT). We will assess changes in MHPs' knowledge and clinical skills in providing mental health care for LGBTQ clients from baseline to 3-months post-baseline and 6-months post-baseline using a randomized-waitlist-controlled study design. We will also evaluate the training's feasibility and acceptability.

3.2 Hypothesis

Hypotheses for the proposed study include:

1. Participants will demonstrate improvement in their knowledge and clinical skills related to LGBTQ-affirmative CBT treatment immediately following the training and—for the immediate training group—at 6-months post-baseline. Participants will

demonstrate these improvements via increases in LGBTQ clinical skills competency, cultural humility, and content knowledge, familiarity, and use of minority stress and CBT in their treatment with LGBTQ clients.

2. At 3-months post-baseline, participants in the immediate training group in comparison to participants in the waitlist control group will exhibit greater improvement in knowledge and clinical skills related to LGBTQ-affirmative CBT treatment, as evidenced by increases in LGBTQ clinical skills competency, cultural humility, and content knowledge, familiarity, and use of minority stress and CBT in their treatment with LGBTQ clients.

3.3 Objectives

Primary Objective

The primary objective of this study is to determine whether the LGBTQ-affirmative CBT training increases LGBTQ and CBT knowledge, clinical skills, and cultural humility among a sample of MHPs from LGBTQ community centers in the United States.

Second Objective

The secondary objective of this study is to evaluate the feasibility and acceptability of the 11-week training in LGBTQ-affirmative CBT.

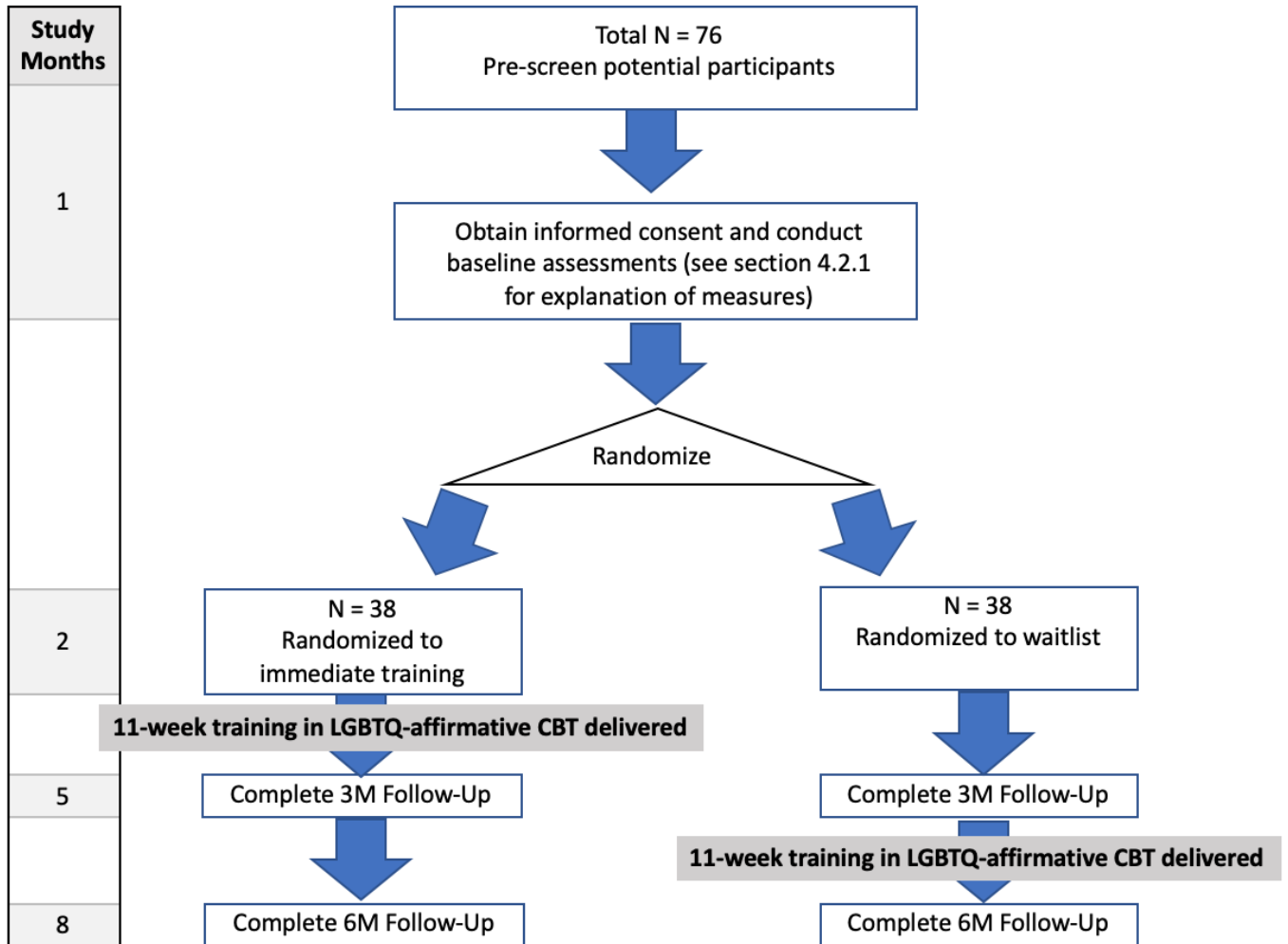
4 Study Design

The proposed prospective study will follow a 2-arm waitlist RCT design where one group of MHPs will be randomized to receive the intervention training (i.e., the immediate training group) in LGBTQ-affirmative CBT, and the second group of MHPs will be randomized to a waitlist control group. The training will be conducted online via Zoom for 1-hour per week over two separate 11-week courses (i.e., the first 11 weeks for the immediate training group, and the second 11 weeks for the waitlist control group). A team of four clinical and counseling psychologists (the PI, two postdoctoral psychologists, and one associate research scientist) will lead the training. All trainers have participated in the development, research, and implementation of the LGBTQ-affirmative CBT treatment.

To assess intervention efficacy, participants will be assessed at three time-points: baseline, 3-months post-baseline, and 6-months post-baseline. Participants randomized to the immediate training group will be scheduled to receive the first iteration of the 11-week LGBTQ-affirmative CBT training (scheduled for October 30, 2020 – January 29, 2021, excluding holidays of November 27, December 25, and January 1). Participants randomized to the waitlist control group will receive one e-mail per month to remind them of their upcoming training and 3-month post-baseline assessment, and will then be scheduled for the second iteration of the 11-week LGBTQ-affirmative CBT training (March 5, 2021 – May 21, 2021, excluding the holiday of April 9). Participants randomized to the immediate training group will receive the training between their baseline and 3-month post-baseline assessments. Participants randomized to the waitlist control group will receive the training between their 3-month post-baseline and 6-month post-baseline assessments.

The proposed mixed-methods study will consist of quantitative self-report measures, as well as a qualitative self-assessment of participants' LGBTQ-affirmative CBT clinical skills. All study measures will be administered online via the secure Yale Qualtrics survey software.

Flow Diagram for the Waitlist-Controlled Randomized Trial Design



4.1 Study Duration

The entire study, including data analysis, is expected to last until July 2021. Participation for the subjects will begin at the beginning of October 2020 (i.e., recruitment for the intervention training at an optional informational webinar). Subjects in the immediate training group will begin the 11-week training on October 30, 2020, finish the training on January 29, 2021, and complete their 3-months post-baseline measures in mid-April 2021. The waitlist control group will remain on the waitlist until the immediate training group completes the training. Then, starting on March 5, 2021, the waitlist control group will receive the same 11-week training. Their participation will end upon completion of the training and the 6-months post-baseline measures in mid-May 2021. Data analysis is expected to continue to July 2021.

4.2 Outcome Variables/Endpoints

The following are the outcome variables and associated measures that will be administered at all three time points (i.e., baseline, 3-months post-baseline, and 6-months post-baseline) in the study, unless otherwise noted:

- LGBTQ Clinical Skills Competency
 - Sexual Orientation Counselor Competency Scale (SOCCS) – Clinical Skills subscale
 - Deliberate Practice of LGBTQ-Affirmative CBT Skills
- Cultural Humility
 - Multidimensional Cultural Humility Scale (MCHS)
- Content Knowledge, Familiarity, and Use of Minority Stress & CBT
 - Minority Stress Content Knowledge Quiz
 - CBT/LGBTQ-Affirmative CBT Content Knowledge Quiz
 - Familiarity and Use of LGBTQ-Affirmative CBT Skills Questionnaire
- Acceptability of LGBTQ-affirmative CBT Training
 - Acceptability of LGBTQ-affirmative CBT Training Questionnaire (*only* administered immediately after the training)
 - Training in LGBTQ-Affirmative CBT – Session Feedback Forms (administered immediately after each training session)

See Sections 4.2.1 and 4.2.2. for further explanations of each measure.

4.2.1 Primary Outcome Variables/Endpoints

The following are the primary outcome variables and associated measures that will be administered at all three time points (i.e., baseline, 3-months post-baseline, and 6-months post-baseline) in the study:

- LGBTQ Clinical Skills Competency
 - Sexual Orientation Counselor Competency Scale (SOCCS) – Clinical Skills subscale – 11-items from a psychometrically validated measure, based on a 7-point Likert scale assessing the extent to which respondents endorse clinical competence as related to their skills in working with clients of diverse sexual identities. For the present study, items have been adapted to specifically assess competence in clinical skills based on an LGBTQ-affirmative CBT framework.
 - Deliberate Practice of LGBTQ-Affirmative CBT Skills: 2 brief video clips (less than 1 minute each) of fictional clients will be presented. Participants will be asked to write a brief paragraph describing what clinical approaches they would use in their clinical treatment in order to address the challenges

discussed by the fictional client. These written responses will be used to assess participants' LGBTQ-affirmative CBT skills.

- Cultural Humility
 - Multidimensional Cultural Humility Scale (MCHS) – a 15-item self-report psychometrically validated measure assessing the extent to which respondents endorse an ability to maintain an other-oriented, interpersonal stance in relation to cultural identities most salient to clients. For the present study, items were adapted to specifically assess cultural humility as related to working with LGBTQ clients.
- Content Knowledge, Familiarity, and Use of Minority Stress & CBT
 - Minority Stress Content Knowledge Quiz – 10 multiple choice items developed by the researchers for the purpose of this study to assess respondents' content knowledge of minority stress
 - CBT/LGBTQ-Affirmative CBT Content Knowledge Quiz – 10 multiple choice items developed by the researchers for the purpose of this study to assess respondents' content knowledge of CBT/LGBTQ-affirmative CBT
 - Familiarity and Use of LGBTQ-Affirmative CBT Skills Questionnaire – 14 items rated on a 5-point Likert scale that was developed by the researchers for the purposes of this study assessing respondents' familiarity with and use of LGBTQ-affirmative CBT skills

4.2.2 Secondary and Exploratory Outcome Variables/Endpoints (if applicable)

The following are the secondary outcome variables and associated measures that will be administered in the study:

- Acceptability of LGBTQ-affirmative CBT Training
 - Acceptability of LGBTQ-affirmative CBT Training Questionnaire (*only* administered immediately after the training) – Participants will be asked to report how many of the 11 training sessions they attended. Participants will then be asked 2 qualitative questions in regard to which of the 11 training sessions they found most and least helpful. Participants will also be asked 7 questions based on a 5-point Likert scale regarding their interest and perceived benefit from the training. All items were self-developed by the researchers for the purpose of this study.
 - Training in LGBTQ-Affirmative CBT – Session Feedback Forms (administered immediately after each training session) – Participants will be asked at the end of each training session to complete an online feedback form about the session, including providing feedback in regard to participants' satisfaction with the instruction, team members leading the training, and learning activities. This feedback form was developed by the researchers for the purpose of this study.

5 Study Participants

5.1 Study Population

The study population will consist of healthy participants who are 18 year of age or older, fluent in English, and currently in the role of an MHP at an LGBTQ community center in the

U.S. engaging in treatment with LGBTQ clients. MHPs from LGBTQ community centers will specifically be recruited for this study in order to provide evidence-based LGBTQ-affirmative training to MHPs working predominantly with individuals from the LGBTQ community.

5.2 Number of Participants

We plan to enroll at least 76 participants ($n = 38$ per training group). Our team's prior pilot studies assessing the efficacy of LGBTQ-affirmative health trainings demonstrated moderate-to-large effect sizes in improving healthcare providers' LGBTQ-affirmative clinical skills and willingness to provide LGBTQ-affirmative clinical care ($d = 0.66-1.20$; Lelutiu-Weinberger, Clark, & Pachankis, in preparation; Lelutiu-Weinberger & Pachankis, 2017; White Hughto, Clark, et al., 2017). Based on the most conservative effect size drawn from our team's previous LGBTQ-affirmative training studies for healthcare providers ($d = 0.66$), we conducted a power analysis for an independent samples t -test used to compare the mean of a continuous measurement in two samples. We set the threshold probability for rejecting the null hypothesis (type I error rate) to α (two-tailed) = 0.05. Power to detect Type I error was fixed at a standard level of $1 - \beta = 0.80$ (type II error rate). Given these parameters, we require 38 participants per group ($N = 76$) to retain statistical power. We expect to enroll at minimum 38 participants per group; due to the high need and reach of our recruitment partner (i.e., CenterLink, the coordinating hub of 250+ LGBTQ community centers in the U.S.), we expect to enroll at least 100 participants which will allow for adequate statistical power even with 20% attrition.

5.3 Eligibility Criteria

In order to be eligible for inclusion in the study, an individual must meet all of the following criteria:

- 18+ years old
- Fluent in English
- Mental health provider (including, but not limited to licensed practicing counselors, licensed clinical social workers, licensed marital and family therapists, clinical/counseling psychologists, pre-doctoral psychology interns, third-year or greater graduate practicum students/externs)
- Currently practicing within, or in collaboration with, an LGBTQ community center that is coordinated by CenterLink, the coordinating hub for LGBTQ community centers in the U.S.

Any individual who meets any of the following criteria will be excluded from participation in this study:

- Individuals unwilling or unable to give informed consent at the time of participation and/or not fitting the eligibility criteria outlined above

5.4 Recruitment Procedures

Recruitment of MHPs will be coordinated in collaboration with Deborah Levine, Director of LGBTQ YouthLink at CenterLink, which is the coordinating hub for over 250 LGBTQ community centers in the U.S. Specifically, a recruitment e-flyer (see attached e-flyer) will be sent by Ms. Levine to executive directors at CenterLink community centers throughout the U.S., who will then be asked to send the e-flyer to eligible staff members within their centers. The recruitment e-flyer includes dates/times of the trainings, information regarding the research design (i.e., immediate training group and waitlist control group), as well as information about receiving continuing education credits for participating in the training. Interested participants will be directed to click on a QR code on the recruitment flyer that will direct them to complete an initial online screener (see attached initial online screener) that will ask for their name, email address, age, degree, provider title, and name of their CenterLink community center.

5.5 Consent/Assent Procedures/HIPAA Authorization

Consent will be obtained online via the secure Yale Qualtrics survey software. As such, a waiver of documentation of consent is planned for this study. As previously described, participants will first complete an initial online screener (see attachments on IRES for initial online screener) to express their interest in the training and/or an informational webinar via Zoom on October 2 at 9am PST / 12pm EST to learn more about the training. No research data will be collected at the informational webinar. The initial online screener will also be used to determine eligibility for the training and associated research study. Upon receiving email addresses from interested participants, the research team will contact eligible participants with an anonymized link directing them to the study consent form two weeks prior to the first training session. Any ineligible participants will be contacted and informed of the reason for their ineligibility in this study.

At this point, participants will review the online consent form and have the option to participate or decline participation in the study (see attachments on IRES for online consent form). MHPs will still have the option to receive the training whether or not they consent to and complete the assessment measures. For MHPs who want to attend the training, but do not want to participate in the study, the online consent form will end and no data will be collected from these providers due to them not consenting to participate in the study.

Participants will be informed on the consent forms that they will receive \$50 for completing the baseline measures, \$50 for completing the 3-month post-baseline measures, and \$50 for completing the 6-months post-baseline measures (total = \$150). All study payments will be in the form of e-mailed Amazon gift cards or Venmo payments. Venmo payments will be sent to participants from the private @Yale-Study account and will be accompanied with the text "Thank you for your participation."

Participants will be provided with the PI's contact information and directed to call or email the PI if they have any questions or concerns. The PI will be responsible for ensuring that online consent has been obtained.

Potential participants will be required to check one of the following boxes before moving on to the baseline assessment measures part of the research study:

- 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.

6 Study Methods/Procedures

6.1 Study Procedures

A 3-time point longitudinal design will be used for both the immediate training group and waitlist control group with assessment measures administered at each time point (T1: baseline; T2: 3-months post-baseline; T3: 6-months post-baseline). As previously discussed, interested participants will complete an initial online screener. Data collected on this brief online screener will be used to determine eligibility based on the previously listed inclusion criteria, as well as to collect email addresses to contact participants about the training. Data from the initial online screener will not be merged or included with subsequent data collected during the study.

Participants will be contacted via email approximately two weeks prior to the start of the training and informed via the online consent about the research study, including risks and benefits of the study. Participants will still have the option to participate in the training and receive continuing education credits whether or not they consent to and complete the research study measures. The 11 training sessions in terms of content will be no different for those who consent to participate in the study compared to those who choose not to participate in the study. For those who do not provide consent to the study, no data will be collected from these individuals at the three time-point surveys. For those who do provide consent, participants will complete the baseline surveys (T1) via a web-based survey link to the secure Yale Qualtrics survey software. Participants will be told that they do not have to answer any question they do not wish to. Participants will be assigned a unique code number. The use of the unique code will permit linkage of the data being collected across three time points in the study. 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 PI. All materials will be stored on a password-protected digital folder. Data will be organized in Microsoft Excel, SPSS files, or SAS files and stored on a password-protected computer.

The PI and three postdoctoral psychologists will lead the 11-week LGBTQ-affirmative CBT training (scheduled for October 30, 2020 – January 29, 2021, excluding holidays of November 27, December 25, and January 1) for participants randomized to the immediate training group (see Table 1 in Section 11.1 with more information regarding the content of each of the training sessions). At 3-months post-baseline (i.e., following the immediate training group's completion of the training), the 3-months post-baseline measures will be sent to participants in both the immediate training group and waitlist control group. Participants randomized to the waitlist control group will subsequently receive the second iteration of the 11-week LGBTQ-affirmative CBT training (scheduled for March 5, 2021 – May 21, 2021, excluding the holiday of April 9). At 6-months post-baseline (i.e., following the waitlist control group's completion of the training), the 6-months post-baseline measures will be sent to participants in both the immediate training group and waitlist control group.

See Table 2 in Section 11.2 for a Visit Schedule Table with study procedures listing the points of data collection.

6.1.1 Data Collection

All data collection will occur online via the secure Yale Qualtrics survey software. Data collection will begin with the initial online screener that potential participants will be able to access via a QR code on recruitment e-flyer that will be sent by directors of LGBTQ community centers.

Baseline assessment measures will be sent via email one month prior to the first iteration of the training. The 3-months post-baseline measures will be sent after January 29, 2021 (i.e., after the last session of the training for the immediate training group). The 6-months post-baseline measures will be sent after May 21, 2021 (i.e., after the last session of the training for the waitlist control group). Participants will have a two-week window to complete the study measures at each time point. None of the study measures require licensure for their administration. All measures can be found in the "Measures Packet" uploaded with the study protocol.

At baseline, all participants will be given a unique code that will serve as their study ID for the duration of the study. The use of the unique code will permit linkage of the data being collected across the three time points in the study. 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 PI. All materials will be stored on password protected folders on Yale Secure Box that requires dual-factor authentication to access.

6.2 Method of Assignment/Randomization (if applicable)

Participants who are confirmed to be eligible via the online screener and provide informed consent to take part in the study will then be randomized via the randomizer feature of Qualtrics, which will be programmed to evenly assign participants to the immediate training group or the waitlist control group. Our team has successfully used the Qualtrics randomizer for previous waitlist-randomized-controlled trial (e.g., see Pachankis et al., 2020).

6.3 Adverse Events Definition and Reporting

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related. An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

This proposed study presents minimal risks to the participants, and as such, adverse events are not anticipated. In the unlikely event that such events occur, the PI will apprise fellow investigators and study personnel of all adverse events, such as loss of confidentiality, that occur during the conduct of this research project via email as they are reviewed.

6.4 Reaction Management

Participants experiencing mild distress during the assessments or training can take a break or complete the assessment at a later date. In the unlikely event that a participant experiences considerable distress, we will make a referral (if needed) for clinical assessment and/or counseling. Participants will be given the names and office phone numbers of the PI and the IRB managers of research and compliance. Of note, given that all participants will be MHPs connected with LGBTQ community centers, it is probable that they will already be knowledgeable about mental health services in their area. In the event that a participant discloses abuse or intent to harm oneself or others, the PI will report disclosures of abuse or intent to harm to the appropriate authorities immediately. Identified clinically trained staff members, including Dr. John Pachankis, a licensed clinical psychologist, will be on call for emergency consultation. In the unlikely event that such an incident should occur, we will notify the Yale IRB within 5 days and appropriate measures will be taken, including necessary reporting to the IRB.

6.5 Withdrawal Procedures

Of the participants who are eligible and consent to the research study, participants will be able to withdraw from the study at any point. The online consent form will clearly state the voluntary nature of the study and possibility of withdrawal at any point. Additionally, participants will have the option of having their data destroyed.

6.6 Locations/Facilities

The training and online surveys will be completed from the participants' electronic devices (e.g., phones, tablets, or computers). All trainings will be conducted via the PI or postdoctoral researchers' Yale-affiliated Zoom videoconferencing accounts and require a passcode to enter. All measures will be conducted utilizing the secure Yale Qualtrics online survey software.

7 Statistical Design

7.1 Sample Size Considerations

Our team's prior pilot studies assessing the efficacy of LGBTQ-affirmative health trainings have demonstrated moderate-to-large effect sizes in improving healthcare providers' LGBTQ-affirmative clinical skills and willingness to provide LGBTQ-affirmative clinical care ($d = 0.66-1.20$) (Lelutiu-Weinberger & Pachankis, 2017, Lelutiu-Weinberger, Clark & Pachankis, in preparation; White Hughto, Clark, et al., 2017). Based on the most conservative effect size drawn from our team's previous LGBTQ-affirmative training studies for healthcare providers ($d = 0.66$), we conducted a power analysis for an independent samples t -test used to compare the mean of a continuous measurement in two samples. We set the threshold probability for rejecting the null hypothesis (type I error rate) to α (two-tailed) = 0.05. Power to detect Type I error was fixed at a standard level of $1 - \beta = 0.80$ (type II error rate). Given these parameters, we require 38 participants per group ($N = 76$) to retain statistical power. We expect to enroll at minimum 38 participants per group; due the high need and reach of our recruitment partner (i.e., CenterLink, the coordinating hub of the United States 250+ LGBTQ community centers), we expect to enroll at least 100 participants which will allow for adequate statistical power even with 20% attrition.

7.2 Planned Analyses

We will assess training efficacy using an intent-to-treat analysis including all eligible cases. First, to determine randomization effectiveness, differences in baseline demographic characteristics will be assessed between the immediate training and waitlist control conditions using t -tests for continuous measures and chi-square tests for categorical measures. Any differences in baseline demographic characteristics between the groups will be retained as covariates in subsequent analyses. Dependent variables, all of which are assessed as continuous outcomes documenting domains of Clinical Knowledge and Skills of LGBTQ-affirmative CBT, will be assessed for normality using skewness and kurtosis thresholds of ± 2 . If any continuous outcomes are found to be non-normally distributed, we will transform these variables for further statistical tests and reassess skewness and kurtosis after transformation.

In a first set of analyses, we will use linear mixed models with maximum likelihood estimation and we expect to utilize a compound symmetry covariance structure (although final covariance structure will selected based on fit criteria, i.e., lowest Akaike information criterion [AIC]) to test the Condition \times Time interaction for all training outcomes). To do so, we will limit the data to baseline (time = 0) and 3 months post-baseline assessment (time = 1) and examined the Condition \times Time interaction effect of receiving immediate training (condition = 1) versus receiving the 3-month waitlist (condition = 0). Thus, the estimate of interest compared pre-training to immediate post-training outcomes in the immediate training group to pre-waitlist and immediate post-waitlist outcomes in the waitlist control group. Effect sizes (d) for linear mixed models will be calculated as mean pre–post change in the immediate training group minus the mean pre-post change in the waitlist control group, divided by the pooled baseline standard deviation.

In a second set of analyses, we will conduct a pooled analysis whereby data from all participants will be pooled to examine change in outcomes from immediate pre-training to post-training using paired t -tests (i.e., baseline to 3 months post-baseline for the immediate training group and 3-months post-baseline to 6-months post-baseline for the waitlist-control group). Pooled analyses are useful in waitlist-controlled studies (where all participants ultimately receive the intervention) to assess the pre-post effect of the intervention in a larger sample than the condition \times time analyses allow. Effect sizes (d) for pooled analyses will be calculated as $2t/\sqrt{df}$.

Finally, we will assess the longer-term persistence of observed intervention effects by limiting analyses to 3-months post-baseline (time = 1) and 6-months post-baseline (time = 2) among participants in the immediate training condition (condition = 1), the only participants to have completed assessments 3-months after receiving the training. Specifically, we will examine the significance of changes between time points for all outcomes across self-report and deliberate practice of Clinical Knowledge and Skills of LGBTQ-affirmative CBT. Results will be evaluated at $p < .05$. We will report means, standard errors, and 95% confidence intervals.

7.2.1 Secondary Objective Analyses (if applicable)

Feasibility of the training will be assessed in terms of training attendance. Acceptability will be assessed in terms of responses to the Acceptability of LGBTQ-affirmative CBT Training Questionnaire that all participants will complete at their immediate post-training time point (3-month post-baseline for the immediate training group and 6-month post-baseline for the waitlist control group). Acceptability analyses will include descriptive statistics including means and medians for quantitative responses. For the qualitative free-response data that will be collected on the acceptability questionnaire, thematic analysis will be used to identify patterns of responses and emergent codes will be categorized into larger themes (Braun & Clarke, 2006).

7.2.2 Analysis of Subject Characteristics (if applicable)

In the baseline assessment, we will collect demographic data including age, race/ethnicity, sex, gender identity, sexual orientation, education level, degree/provider title, and number of years working in mental health generally, as well as number of years working specifically in LGBTQ-focused mental health. Subject characteristics will be reported descriptively utilizing means and standard deviations for continuous variables and proportions for categorical variables.

7.2.3 Interim Analysis (if applicable)

N/A

7.3 Data Relevance

In this study our primary objective is to measure whether a training in LGBTQ-affirmative practice increases MHPs clinical knowledge and skills of LGBTQ-affirmative CBT. The data that we will collect in this study is highly relevant to our primary objective. We will measure self-reported clinical knowledge and skills across several domains including sexual orientation counselor competency, cultural humility, LGBTQ-affirmative CBT skills, minority stress understanding, and LGBTQ-affirmative CBT content understanding. In addition to this self-report data, we will also obtain deliberate practice of LGBTQ-affirmative CBT skills that will include open-ended response to clinical vignettes that will then be coded on a continuous scale. Finally, in alignment with our secondary objective to assess training feasibility and acceptability, we will assess the acceptability of the training through quantitative and qualitative survey items. All data collected as part of this study is highly relevant to our research questions.

7.4 Data Coding

Data will be scored based on each measure's pre-specified ratings scale (see Measures packet). Outcomes utilized in statistical analyses will be continuous sum or mean scores, as applicable.

7.5 Data Analysis Tools

Data will be managed and analyzed utilizing SPSS and SAS version 9.4.

7.6 Data Monitoring

N/A

7.7 Handling of Missing Data

We will assess the LGBTQ-affirmative CBT training efficacy using an intent-to-treat analysis including all eligible cases; therefore, cases with missing data on outcomes will be dropped.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality and privacy is strictly held in confidence by the participating investigators and their staff. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. All research activities will be conducted in as private a setting as possible. Representatives of the Institutional Review Board (IRB) may inspect all documents and records required to be maintained by the investigator for the participants in this study.

To maximize privacy and ensure confidentiality, participant names, which will only be recorded during the initial online screener, will be kept separate from all other data collection surveys. All data will be collected via the secure Yale Qualtrics server. Participants will be assigned a unique code number at baseline for their surveys. The use of the unique code will permit linkage of the data being collected across the three time points in the study. 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 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 be downloaded and organized in SPSS files or SAS files and stored on a password-protected computer. Taken together, these measures are anticipated to be highly effective in protecting the privacy and confidentiality of participants and have proven successful in other studies that the PI and his research team have implemented.

The study participants' contact information will be held securely during the study. At the end of the study, all records will continue to be kept in a secure location for three years. After three years, all records for the study will be destroyed.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on a secure Yale Secure Box folder only accessible by the research study team members. This will not include the participants' identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived on a secure Yale Box folder.

8.2 Data Quality Assurance

All three-time point survey measures will be administered via the secure Yale Qualtrics server using contact lists to accurately and consistently administer surveys to participants. A similar system will be used to administer the feedback forms to participants after each session. All research assistants part of this study will be trained by one of the postdoctoral researchers on the study team on these study procedures.

8.3 Data or Specimen Storage/Security

Participant names, which will only be recorded during the initial online screener, will be kept separate from all other data collection surveys. All data will be collected via the secure Yale Qualtrics server. Participants will be assigned a unique code number for their surveys. The use of the unique code will permit linkage of the data being collected across the three time points in the study. 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 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 be downloaded and organized in SPSS or SAS files and stored on a password-protected computer.

Study participant research data will be transmitted to and stored on a Yale Secure Box folder only accessible by the research study team members. This will not include the participant's identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived on a secure Yale Box folder.

8.4 Study Records

Study records will consist of surveys and other study measures. The PI will be responsible for maintaining the study documentation, which will be maintained on a Yale Secure Box folder.

8.5 Access to Source

Source data will consist of surveys and other study measures that will all be administered online via the secure Yale Qualtrics server. All source data will be electronic (i.e., no surveys with handwritten responses). Research data will only be accessible on a Yale Secure Box folder by the research study team members.

8.6 Retention of Records

At the end of the study, all records will continue to be kept in a Yale Secure Box folder. After three years, all records for the study will be destroyed.

8.7 Data and Safety Monitoring Plan

The principal investigator is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews quarterly (or weekly during collection periods of baseline and post-training data). During the review process the principal investigator will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment.

The principal investigator and the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected) and possibly, probably, or definitely related) or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the Principal Investigator becoming aware of the event to the IRB (using the appropriate forms from the website) and any appropriate funding and regulatory agencies. The principal investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project via email as they are reviewed. The protocol's research monitor, Yale University, and decision-making bodies will be informed of adverse events, such as loss of confidentiality, within 5 days of the event becoming known to the principal investigator.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.

Study closure will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

9.2 Research Personnel Training

Drs. Pachankis, Jackson, Soulliard, and Seager van Dyk will be primarily responsible for the preparation of training materials and leading the training sessions. All members of the research team who will take part in delivery of the clinical training hold doctoral-level degrees in clinical or counseling psychology. Dr. Soulliard and Kriti Behari (senior research assistant) will be responsible for online administration of the study measures, as well as the cleaning and organizing of the study data. Drs. Clark and Layland will be primarily responsible for data analysis. Dr. Pachankis will be responsible as the PI for oversight of the previously mentioned responsibilities.

9.3 Study Monitoring

The study will be monitored internally by the study team members on a weekly basis.

9.4 Unanticipated Problems and Protocol Deviations

A protocol deviation is any noncompliance with the protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the principal investigator to identify and report deviations within 5 working days of identification of the protocol deviation. All deviations must be addressed in study source documents and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by via email.

The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs will be reported to the IRB within 5 of the investigator becoming aware of the event.

9.5 Study Discontinuation

The research team will discuss discontinuation of the study in the event that participants in the first training group (i.e., the immediate training group) endorse significantly worse outcomes (e.g., reduced LGBTQ clinical skills competency) compared to the waitlist control group.

9.6 Study Completion

Data collection for the study will end in mid-May 2021. Data analysis is expected to continue to July 2021. The study is anticipated to be completed upon the writing of a manuscript for publication by September 2021.

9.7 Conflict of Interest Management Plan

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

All investigators will follow the applicable conflict of interest policies.

9.8 Funding Source

The study is internally funded from the David R. Kessler M.D. '55 funds provided to the PI of this study.

9.9 Publication Plan

Upon the completion of data analysis by July 2021, the research team anticipates submitting a manuscript for publication by September 2021. It will be the PI's primary responsibility for publishing the study results.

10 Appendices

Appendix #	Title	Section	Topic
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11 List of Tables

11.1 Table 1 – Summary of Training Sessions for LGBTQ-Affirmative CBT Treatment for Immediate Training Group / Waitlist Control Group

Date & Module Title	Objectives & Learning Activities
<p><u>October 30, 2020/</u> <u>March 5, 2021</u></p> <p>Introduction: Orientation to the Treatment</p>	<p><i>Objective:</i></p> <ul style="list-style-type: none"> ○ Describe the history and development of LGBTQ-affirmative CBT ○ Explain the rationale behind LGBTQ-affirmative CBT ○ Identify how concepts from LGBTQ-affirmative psychotherapy and CBT can be combined <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Introductions (5 minutes) ○ History of team’s development of LGBTQ-affirmative CBT (10 minutes) ○ Overview of LGBTQ-affirmative CBT (20 minutes) ○ Description (i.e., structure, format) of training (15 minutes) ○ Q&A (10 minutes)
<p><u>November 6, 2020/</u> <u>March 12, 2021</u></p> <p>Module 1: Motivation Enhancement for Treatment Engagement</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Define the concept of minority stress ○ Explain the use of motivational interviewing skills and discuss its importance to treatment outcomes ○ Describe the importance of assisting LGBTQ clients in setting specific goals to reduce the impact of minority stress <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on minority stress and its relationship to mental health (15 minutes) ○ Group discussion of examples of minority stress expressed by LGBTQ clients (10 minutes) ○ Presentation on motivational interviewing and setting treatment goals (15 minutes) ○ Group discussion of how to utilize motivational interviewing at the beginning of treatment (10 minutes) ○ Q&A (10 minutes)
<p><u>November 13, 2020/</u> <u>March 19, 2021</u></p> <p>Module 2: Nature and Emotional Impact of Minority Stress</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Describe how to assist clients in identifying early and current experiences of minority stress ○ Summarize the sources of minority stress faced by LGBTQ clients ○ Describe how sources of minority stress may contribute to clients’ experiences of anxiety and depression <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on the emotional impact of minority stress among LGBTQ clients (20 minutes) ○ Group discussion on examples of minority stress’ emotional impact on LGBTQ clients (10 minutes) ○ Introduce the Monitoring LGBTQ-Related Stress

	<p>Worksheet with a focus on Antecedents (20 minutes)</p> <ul style="list-style-type: none"> ○ Q&A (10 minutes)
<p><u>November 20, 2020/ March 26, 2021</u></p> <p>Module 3: Tracking Emotional Experiences</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ List the three components of emotional experiences ○ Identify common emotional experiences endorsed by LGBTQ clients as related to minority stress ○ Summarize the role of antecedents, responses, and consequences (ARC) of minority stress <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on the three components of emotional experiences (i.e., thoughts, behaviors, and bodily sensations) (15 minutes) ○ Group discussion on ways to present the three components of emotional experiences to LGBTQ clients (10 minutes) ○ Introduce the tracking of Responses and Consequences on the Monitoring LGBTQ-Related Stress Worksheet (15 minutes) ○ Examples of Monitoring LGBTQ-Related Stress Worksheet (ARC) Worksheets completed by LGBTQ clients (10 minutes) ○ Q&A (10 minutes)
<p><u>December 4, 2020/ April 2, 2021</u></p> <p>Module 4: Mindful Awareness & Minority Stress</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Recognize the concept and practice of nonjudgmental emotion awareness ○ Demonstrate the clinical use of present-focused, mindful awareness of minority stress reactions with LGBTQ clients ○ Describe how mood-induction exercises can promote mindful awareness for LGBTQ clients <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on emotion awareness and mindfulness in the context of minority stress (20 minutes) ○ Engage attendees in an emotion awareness exercise (5 minutes) ○ Group discussion of the emotion awareness exercise (10 minutes) ○ Engage attendees in a mood-induction exercise (5 minutes) ○ Group discussion of the mood-induction exercise (10 minutes) ○ Q&A (10 minutes)
<p><u>December 11, 2020/ April 16, 2021</u></p> <p>Module 5: Cognitive Flexibility</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Describe the relationship between thoughts and emotions ○ Define the concepts of cognitive flexibility, including cognitive appraisals and cognitive reappraisals ○ Summarize thinking traps as related to LGBTQ clients and minority stress ○ Identify ways to assist LGBTQ clients in engaging in cognitive flexibility <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on cognitive flexibility, including cognitive

	<p>appraisals, thinking traps, and cognitive reappraisals (20 minutes)</p> <ul style="list-style-type: none"> ○ Group discussion of the ambiguous picture exercise (5 minutes) ○ Group discussion on the use of the Downward Arrow Technique Worksheet (10 minutes) ○ Group discussion on Identifying and Evaluating Automatic Thoughts Worksheet (10 minutes) ○ Q&A (10 minutes)
<p><u>December 18, 2020/ April 23, 2021</u></p> <p>Module 6: Countering Emotional Behaviors</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Identify and summarize the four main types of emotion-driven behaviors ○ Identify common examples of helpful and unhelpful emotion-driven behaviors reported by LGBTQ clients ○ Describe the paradoxical effects of emotion avoidance ○ Describe how to engage clients in the process of alternative actions <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on emotion-driven behaviors, including helpful and unhelpful emotional behaviors (15 minutes) ○ Group discussion on common unhelpful emotion-driven behaviors endorsed by LGBTQ clients (10 minutes) ○ Presentation on alternative action and how to address resistance from LGBTQ clients to alternative action (10 minutes) ○ Group discussion on ways to support LGBTQ clients' in engaging in alternative actions (15 minutes) ○ Q&A (10 minutes)
<p><u>January 8, 2021/ April 30, 2021</u></p> <p>Module 7: Behavioral Skills Training</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Describe the concept of assertiveness in the context of minority stress ○ Discuss strategies to assist LGBTQ clients in identifying and challenging unassertive thoughts ○ Identify ways to assist LGBTQ clients with contextual challenges related to assertiveness <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on assertiveness training in the context of minority stress (15 minutes) ○ Group discussion on assertiveness training exercises for LGBTQ clients (10 minutes) ○ Review the Assertiveness Bill of Rights (10 minutes) ○ Group discussion on navigating challenges related to assertiveness (e.g., deciding in what situations to be assertive) (15 minutes) ○ Q&A (10 minutes)
<p><u>January 15, 2021/ May 7, 2021</u></p> <p>Module 8: Emotion Exposures</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Summarize the intervention of emotion exposures and how they can support lasting change ○ Describe how bodily sensations relate to emotions and minority stress ○ Identify different ways to design and types of emotion exposures for LGBTQ clients

	<p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on emotion exposures, including exposure hierarchies (15 minutes) ○ Review the Symptom Induction Test Worksheet (10 minutes) ○ Presentation on ways to design, prepare for, and engage in emotion exposure for LGBTQ clients (15 minutes) ○ Group discussions on ways to address resistance or non-compliance from LGBTQ clients in completing emotion exposures (10 minutes) ○ Q&A (10 minutes)
<p><u>January 22, 2021/ May 14, 2021</u></p> <p>Module 9: Relapse Prevention</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Describe overall points from treatment to summarize with LGBTQ clients ○ Describe skills from the LGBTQ-affirmative CBT treatment to discuss with LGBTQ clients for coping with minority stressors ○ Identify ways to engage LGBTQ clients in a dialogue about long-term goals in order to continue challenging minority stressors <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Presentation on termination and relapse prevention in LGBTQ-Affirmative CBT (15 minutes) ○ Group discussion on strategies related to discussing long-term goals and relapse prevention with LGBTQ clients (20 minutes) ○ Review of Self-Affirmative Exercise (15 minutes) ○ Q&A (10 minutes)
<p><u>January 29, 2021/ May 21, 2021</u></p> <p>Conclusion: Wrap-up/Feedback on Training</p>	<p><i>Objectives:</i></p> <ul style="list-style-type: none"> ○ Summarize challenges of implementing LGBTQ-affirmative CBT ○ Develop a plan for continued practice and implementation of LGBTQ-affirmative CBT in real-world clinic practice ○ Uncover barriers and facilitators of applying LGBTQ-affirmative CBT in attendees' affiliated community centers <p><i>Learning Activities:</i></p> <ul style="list-style-type: none"> ○ Group discussion on remaining challenges about implementing LGBTQ-affirmative CBT (20 minutes) ○ Group discussion in order to request feedback from attendees about the training (30 minutes) ○ Final thoughts (10 minutes)

11.2 Table 2 – Visit Schedule Table of Study Measures and Training

	<i>Pre-training: Online consent for initial screening</i>	<i>Pre-training: Information Session</i>	<i>Visit 1: Baseline surveys (T1) (Day 1 ± 14)</i>	<i>Visit 2: 11-Week Training (for immediate training group) (Days 14 to 91)</i>	<i>Visit 3: 3-month post-baseline surveys (Day 91 ± 14)</i>	<i>Visit 4: 11-Week Training (for waitlist control group) (Day 105 to 182)</i>	<i>Visit 5: 6-month post-baseline surveys (Day 182 ± 196)</i>
Informed Consent	X		X				
Demographics			X				
Randomization			X				
Outcome Measures							
LGBTQ Clinical Skills Competency							
SOCCS			X		X		X
<i>Deliberate Practice of LGBTQ-Affirmative CBT Skills</i>			X		X		X
Cultural Humility							
MCHS			X		X		X
Content Knowledge, Familiarity, and Use of Minority Stress & CBT							
<i>Minority Stress Content Knowledge Quiz</i>			X		X		X
<i>CBT/LGBTQ-Affirmative CBT Content Knowledge Quiz</i>			X		X		X
<i>Familiarity and Use of LGBTQ-Affirmative CBT Skills Questionnaire</i>			X		X		X
Acceptability of LGBTQ-affirmative CBT Training							
<i>Acceptability of LGBTQ-affirmative CBT Training Questionnaire</i>					X (immediate training group)		X (waitlist control group)
<i>Training in LGBTQ-Affirmative CBT – Session Feedback Forms</i>							
Intervention training (or waitlist control) – LGBTQ-affirmative CBT				X		X	
Adverse Event Reporting			X	X	X	X	X