LGBTQ-affirmative cognitive behavioral group therapy for youth: A pilot study

Protocol Number

2000030664

Protocol Version

10/01/2021

Version #3

Clinical Trials Registration Number (if applicable): NCT05408858

Confidentiality Statement:

Synopsis

Purpose

Lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth experience more mental health problems than their heterosexual and cisgender peers. The purpose of the proposed mixed-methods study is to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive therapy (also known as EQuIP) for youth aged 12-17 years in New York, New Jersey, and Connecticut. This study will be the first to adapt this supportive intervention for youth, and the first to deliver it in a virtual group format. Qualitatively, we will conduct structured post-intervention interviews to assess the feasibility, acceptability, and refinement of the intervention in this population. Quantitatively, we will assess the feasibility and acceptability of the supportive intervention by examining changes from pre- to post-intervention in youth's mental health symptoms, minority stress reactions, and emotional regulation and coping processes.

Objectives

The primary objective of this study is to assess the feasibility, acceptability, and need for refinement of an LGBTQ-affirmative supportive therapy adapted for youth.

The secondary objective of this study is to investigate whether youth's mental health symptoms, minority stress reactions, and emotional regulation and coping difficulties reduce over the course of the intervention.

Study Population

The study population will consist of LGBTQ youth between the ages of 12-17 years who meet *DSM-5* criteria for an internalizing disorder (e.g., anxiety, depression, adjustment), live in New York, New Jersey, or Connecticut, are fluent in English, and have access to an Internet-enabled electronic device that allows for video-conferencing. This population was selected due to the need for additional mental health services as described above.

Number of Participants

20 participants will be enrolled in the study. Participants will be assigned to one of two groups of approximately 10 participants each.

Study Design

This is an open trial pilot intervention study that involves: interviews, online surveys, online group video-conferencing intervention sessions, audio-recording of intervention sessions. The intervention will consist of 10 weekly 90-minute group supportive therapy sessions conducted via Zoom. Study outcomes will be both quantitative (surveys) and qualitative (interviews) in nature.

Study Duration

The entire study, including data analysis, is expected to last from August 2021 until August 2022. Participation for the subjects will begin in August 2021 (i.e., recruitment, pre-intervention assessment). Participants in the first group will begin the 10-week intervention in September-November 2021 and complete their post-intervention assessment in December 2021-January 2022. Participants in the second group will begin the 10-week intervention in February 2022 and complete their post-intervention assessment in May 2021-June 2022. Data analysis is expected to continue through August 2022.

Outcome Variables

Primary Objective:

- Acceptability:
  - *Main outcome*: Client Satisfaction Questionnaire-8 (CSQ-8)
  - *Supportive variables*: Treatment Expectations, Top Problems Assessment, Top Problems Tracking Form, Acceptability of Session Questionnaire, AFFIRM Acceptability Survey, Exit Interview-Acceptability of program format, delivery, and content
- Feasibility:
  - *Main outcome*: Session Attendance
  - *Supportive variables*: Homework Compliance Scale, Feasibility of Session Questionnaire, Feasibility of Program Questionnaire, Exit Interview-Program feasibility
- Need for refinement:
  - *Main outcome*: Exit interview
  - *Supportive variables*: Session Refinement Questions, Program Refinement Questions

Secondary Objective:

- Mental health:
  - *Main outcome*: Revised Children's Anxiety and Depression Scale (RCADS)
  - *Supportive variables*: Depressive Symptom Index - Suicidality Subscale (DSI-SS), Strengths and Difficulties Questionnaire (SDQ), WHO-5 Well-Being Index
- Minority stress reactions:
  - *Main outcome*: Gender Minority Stress and Resilience Scale for Adolescents (GMSR-A) — Internalized Trans/Homophobia subscale
  - *Supportive/related variables*: Rest of GMSR-A, Child Perceived Discrimination Questionnaire (CPDQ), Outness Inventory (OI), Lesbian, Gay, Bisexual Affiliate Stigma Measure (LGB-ASM), Parental Rejection/Acceptance of LGBTQ child
- Emotion regulation & coping:
  - *Main outcome:* Children's Emotion Management Scales (CEMS)

○ *Supportive variables:* Emotion Regulation Questionnaire (ERQ-CA), Child Avoidance Measure (CAMS/CAMP), Children's Automatic Thoughts Scale - N/P version (CATS), Coping with Sexual Orientation-Related Minority Stress, Multidimensional Scale of Perceived Social Support (MSPSS)
Locations/Facilities The study is housed within the Yale School of Public Health's Pachankis lab, located at 220 E. 23rd Street, New York, NY 10010. All study procedures will be conducted online. All assessments will be completed by phone, Zoom, or on Qualtrics. The intervention will be delivered online via Zoom, as will exit interviews.

Abbreviations

Abbreviation	Explanation
LGBTQ	Lesbian, Gay, Bisexual, Transgender, and Queer
CBT	Cognitive-Behavioral Therapy
EQuIP	Empowering Queer Identities in Psychotherapy (name used to refer to LGBTQ-affirmative psychotherapy in recruitment flyers, with participants, etc.)
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th edition

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.
Stigma (also called minority stress)	The unique and chronic negative experiences that LGBTQ 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 and/or cisgender.
Minority stress reactions	The negative effects of anti-LGBTQ stigma on LGBTQ individuals' wellbeing, including their cognitive, emotional, and behavioral wellbeing. Examples of minority stress reactions include internalized stigma (i.e., believing the anti-LGBTQ messages one hears), rejection sensitivity (i.e., heightened perception of rejection as a result of anti-LGBTQ stigma), and identity concealment (i.e., concealing one's LGBTQ identity due to fears of anti-LGBTQ backlash).
EQuIP	Empowering Queer Identities in Psychotherapy (name used to refer to LGBTQ-affirmative psychotherapy in recruitment flyers, with participants, etc.)

Table of Contents

Protocol Revision History

Version Date	Summary of Substantial Changes
October 1, 2021	Changes composition of groups to be based on time of recruitment, rather than based on age, in order to facilitate timely completion of study procedures; Extends study timeframe to allow for second group in spring 2022; Removes exclusion criterion related to current mental health treatment — that is, eligible participants can be in supportive treatment (but not cognitive behavioral therapy) concurrent with their participation in the study.
August 3, 2021	Addresses IRB requested revisions related to: Zoom sessions as supportive vs. treatment; recruitment; inclusion criteria; language related to confidentiality/privacy; provision of earbuds; use of HIPAA compliant Zoom platform; use of pseudonyms in Zoom sessions; use of Secure File Transfer.

1 Background

1.1 Background

Lesbian, gay, bisexual, transgender, and queer (LGBTQ) youth experience mental health challenges, including anxiety, depression, and suicide attempts, at a higher rate than their heterosexual and cisgender peers (Russell & Fish, 2016). For example, LGBTQ youth are two to three times more likely to report a history of suicidality, relative to their heterosexual and cisgender peers (Marshal et al., 2011; Reisner et al., 2015). This phenomenon has been explained through the lens of minority stress theory, which states that *stigma* related to LGBTQ identity (e.g., discrimination, rejection) elicits *minority stress reactions* (e.g., concealment of LGBTQ identity, internalized stigma, rejection sensitivity) which then combines with general life stress to increase an individual's risk of mental illness (Meyer, 2003). Numerous studies have supported the use of this framework in understanding the development and maintenance of excess mental health concerns in LGBTQ youth (Baams et al., 2015; Goldbach et al., 2014; Goldbach & Gibbs, 2017; Paceley et al., 2017). However, to date, only one intervention for older LGBTQ adolescents (aged 15-18) has been developed that attempts to directly reduce youth's maladaptive minority stress reactions, and this intervention has yet to be rigorously tested using a randomized controlled trial (Craig & Austin, 2016). Importantly, no minority stress-focused interventions exist for younger LGBTQ adolescents (e.g., ages 12-14).

To date, the only minority stress reaction-focussed mental health intervention to have been tested in a randomized controlled trial with LGBTQ people is LGBTQ-affirmative cognitive behavioral therapy (CBT), developed over the past seven years by our team with support from the Yale Fund for Lesbian and Gay Studies, the David R. Kessler '55 Resource Fund for LGBTQ Mental Health Research at Yale, and the National Institute of Mental Health. CBT is an evidence-based psychotherapy that focusses on helping clients understand links between their thoughts, emotions, and behaviors, and it has been shown to be effective at treating a wide range of mental health problems in children, adolescents, and adults, including anxiety and depression (Beck & Beck, 2011). LGBTQ-affirmative CBT builds upon a CBT base (Barlow et al., 2018) by adding minority stress reaction-specific education and examples to the intervention in an effort to target the underlying cognitive, affective, and behavioral pathways through which minority stress reactions impair LGBTQ young adults' health. It is a skills-building intervention designed to reduce maladaptive minority stress reactions. This is achieved through the administration of nine modules that focus on motivational enhancement, psychoeducation regarding the nature and emotional impact of minority stress, tracking emotional experiences, mindful awareness and minority stress, cognitive flexibility, countering emotional behaviors, behavioral skills training, emotion exposures, and relapse prevention (Burton et al., 2019).

Results from two randomized controlled trials of LGBTQ-affirmative CBT with gay and bisexual men and sexual minority women demonstrate that this intervention is effective in reducing symptoms of depression and anxiety in young adults, as well as reductions in

alcohol use and HIV-transmission-risk behavior in young men (Pachankis et al., 2015, 2020). Moreover, these studies showed that maladaptive minority stress reactions, like internalized stigma and rejection sensitivity, as well as emotion dysregulation, decreased across the course of LGBTQ-affirmative CBT. Thus, there is evidence that the intervention achieves its goal of addressing underlying minority stress reactions that contribute to mental health problems.

What is less clear, however, is whether this intervention could effectively address minority stress reactions and associated emotional problems in adolescents, as studies to date have focused on LGBTQ young adults aged 18 and over. Adolescence represents an important developmental period for intervention, particularly among LGBTQ individuals. Research shows that LGBTQ adolescents today come out at younger ages than previous generations (Calzo et al., 2011), which has been linked to their high rates of peer victimization (Russell et al., 2014) and family rejection (Newcomb et al., 2019). Critically, these painful experiences occur at an age when adolescents' brains are still developing and thus they do not yet have the cognitive coping abilities that may help buffer LGBTQ adults against the negative minority stress reactions (Russell & Fish, 2019). In addition, numerous mental health conditions (e.g., anxiety, mood disorders) have an average onset during or immediately after adolescence (Kessler & Wang, 2008). Moreover, in episodic disorders like major depression and bipolar disorder, an individual's risk of more episodes increases with each subsequent episode (Kessing et al., 2004). Thus, it is critical that vulnerable populations like LGBTQ youth receive effective mental health interventions early in order to mitigate both current distress and the continuation (and potential worsening) of symptoms into young adulthood.

The purpose of this proposed mixed-methods study is to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive behavior therapy for youth aged 12-17 years in the United States. Importantly, this study proposes to examine LGBTQ-affirmative CBT as a supportive intervention, rather than an individualized treatment, as the anticipated settings in which this program would be implemented are not treatment settings but rather community centers, which tend to provide supportive counseling. Thus, in contrast to treatment in which individual case conceptualizations would be developed for each participant, in this study, participants will all be provided with the same supportive information about minority stress and coping with stigma, with no individual case conceptualization. In addition, parents will only be provided supportive information with suggestions about how to support their child, rather than targeted treatment advice tailored to their specific child.

References:

Baams, L., Grossman, A. H., & Russell, S. T. (2015). Minority stress and mechanisms of risk for depression and suicidal ideation among lesbian, gay, and bisexual youth. *Developmental Psychology*, *51*(5), 688–696. https://doi.org/10.1037/a0038994

Barlow, D. H., Farchione, T. J., Sauer-Zavala, S., Murray Latin, H., Ellard, K. K., Bullis, J. R., Bentley, K. H., Boettcher, H. T., & Cassiello-Robbins, C. (2018). *Unified protocol for transdiagnostic treatment of emotional disorders: Therapist guide* (Second edition). Oxford University Press.

Beck, J. S., & Beck, J. S. (2011). *Cognitive behavior therapy: Basics and beyond* (2nd ed). Guilford Press.

Burton, C. L., Wang, K., & Pachankis, J. E. (2019). Psychotherapy for the spectrum of sexual minority stress: Application and technique of the ESTEEM treatment model. *Cognitive and Behavioral Practice*, *26*(2), 285–299. https://doi.org/10.1016/j.cbpra.2017.05.001

Calzo, J. P., Antonucci, T. C., Mays, V. M., & Cochran, S. D. (2011). Retrospective recall of sexual orientation identity development among gay, lesbian, and bisexual adults. *Developmental Psychology*, *47*(6), 1658–1673. https://doi.org/10.1037/a0025508

Craig, S. L., & Austin, A. (2016). The AFFIRM open pilot feasibility study: A brief affirmative cognitive behavioral coping skills group intervention for sexual and gender minority youth. *Children and Youth Services Review*, *64*, 136–144. https://doi.org/10.1016/j.childyouth.2016.02.022

Goldbach, J. T., & Gibbs, J. J. (2017). A developmentally informed adaptation of minority stress for sexual minority adolescents. *Journal of Adolescence*, *55*, 36–50. https://doi.org/10.1016/j.adolescence.2016.12.007

Goldbach, J. T., Tanner-Smith, E. E., Bagwell, M., & Dunlap, S. (2014). Minority stress and substance use in sexual minority adolescents: A meta-analysis. *Prevention Science*, *15*(3), 350–363. https://doi.org/10.1007/s11121-013-0393-7

Kessing, L. V., Hansen, M. G., Andersen, P. K., & Angst, J. (2004). The predictive effect of episodes on the risk of recurrence in depressive and bipolar disorders—A life-long perspective. *Acta Psychiatrica Scandinavica*, *109*(5), 339–344. https://doi.org/10.1046/j.1600-0447.2003.00266.x

Kessler, R. C., & Wang, P. S. (2008). The descriptive epidemiology of commonly occurring mental disorders in the United States. *Annual Review of Public Health*, *29*(1), 115–129. https://doi.org/10.1146/annurev.publhealth.29.020907.090847

Marshal, M. P., Dietz, L. J., Friedman, M. S., Stall, R., Smith, H. A., McGinley, J., Thoma, B. C., Murray, P. J., D'Augelli, A. R., & Brent, D. A. (2011). Suicidality and depression disparities between sexual minority and heterosexual youth: A meta-analytic review. *The Journal of Adolescent Health: Official Publication of the Society for Adolescent Medicine*, *49*(2), 115–123. https://doi.org/10.1016/j.jadohealth.2011.02.005

Meyer, I. H. (2003). Prejudice, social stress, and mental health in lesbian, gay, and bisexual populations: Conceptual issues and research evidence. *Psychological Bulletin*, *129*(5), 674–697. https://doi.org/10.1037/0033-2909.129.5.674

Newcomb, M. E., LaSala, M. C., Bouris, A., Mustanski, B., Prado, G., Schrager, S. M., & Huebner, D. M. (2019). The influence of families on LGBTQ youth health: A call to action for innovation in research and intervention development. *LGBT Health*, *6*(4), 139–145. https://doi.org/10.1089/lgbt.2018.0157

Paceley, M. S., Goffnett, J., & Gandy-Guedes, M. (2017). Impact of victimization, community climate, and community size on the mental health of sexual and gender minority youth. *Journal of Community Psychology*, 658–671. https://doi.org/10.1002/jcop.21885

Pachankis, J. E., Hatzenbuehler, M. L., Jonathon, H., Safren, S. A., & Parsons, J. T. (2015). LGB-affirmative cognitive-behavioral therapy for young adult gay and bisexual men: A randomized

controlled trial of a transdiagnostic minority stress approach. *Journal of Consulting and Clinical Psychology*, *83*(5), 875–889.

Pachankis, J. E., McConocha, E. M., Clark, K. A., Wang, K., Behari, K., Fetzner, B. K., Brisbin, C. D., Scheer, J. R., & Lehavot, K. (2020). A transdiagnostic minority stress intervention for gender diverse sexual minority women's depression, anxiety, and unhealthy alcohol use: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *88*(7), 613–630. https://doi.org/10.1037/ccp0000508

Reisner, S. L., Vetters, R., Leclerc, M., Zaslow, S., Wolfrum, S., Shumer, D., & Mimiaga, M. J. (2015). Mental health of transgender youth in care at an adolescent urban community health center: A matched retrospective cohort study. *Journal of Adolescent Health*, *56*(3), 274–279. https://doi.org/10.1016/j.jadohealth.2014.10.264

Russell, S. T., & Fish, J. N. (2016). Mental health in lesbian, gay, bisexual, and transgender (LGBT) youth. *Annual Review of Clinical Psychology*, *12*(1), 465–487. https://doi.org/10.1146/annurev-clinpsy-021815-093153

Russell, S. T., & Fish, J. N. (2019). Sexual minority youth, social change, and health: A developmental collision. *Research in Human Development*, *16*(1), 5–20. https://doi.org/10.1080/15427609.2018.1537772

Russell, S. T., Toomey, R. B., Ryan, C., & Diaz, R. M. (2014). Being out at school: The implications for school victimization and young adult adjustment. *American Journal of Orthopsychiatry*, *84*(6), 635–643. https://doi.org/10.1037/ort0000037

1.2 Prior Experience (if applicable)

LGBTQ-affirmative CBT has been previously developed and tested by the current research team. In the pilot testing of the intervention among a sample of gay and bisexual men (Pachankis et al., 2015), the intervention 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 intervention 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. The research team has also tested LGBTQ-affirmative CBT among gender diverse, sexual minority women (see IRB protocol: 2000020997; Pachankis, McConocha, et al., 2020). Compared to waitlist, participants experienced significantly reduced depression and anxiety symptoms, and marginally reduced alcohol use.

Since these studies, the research team has been in the process of testing the efficacy of the intervention among gay and bisexual men in an RCT against community mental health intervention and voluntary testing and counselling for HIV (see IRB protocol: 1509016430), as well as for an online platform (see IRB protocol: 2000025803).

References:

Pachankis, J. E., Hatzenbuehler, M. L., Rendina, H. J., Safren, S. A., & Parsons, J. T. (2015). LGB-affirmative cognitive-behavioral therapy for young adult gay and bisexual men: A randomized controlled trial of a transdiagnostic minority stress approach. *Journal of consulting and clinical psychology*, *83*(5), 875.

Pachankis, J. E., McConocha, E. M., Clark, K. A., Wang, K., Behari, K., Fetzner, B. K., ... & Lehavot, K. (2020). A transdiagnostic minority stress intervention for gender diverse sexual minority women's depression, anxiety, and unhealthy alcohol use: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *88*(7), 613.

2 Rationale/Significance

2.1 Rationale and Study Significance

LGBTQ youth experience more mental health problems than their heterosexual and cisgender peers. This phenomenon has been linked to LGBTQ youth's experiences with stigma (e.g., discrimination on the basis of sexual orientation and/or gender identity) and associated minority stress reactions. However, to date, no interventions for LGBTQ youth as young as 12 years of age exist that are designed to specifically address these unique forms of stress. Further, the one group-based intervention for LGBTQ adolescents (aged 15-18) that exists, has not been delivered remotely via video conference, limiting the accessibility of this intervention to this vulnerable population.

This study will be the first to adapt the LGBTQ-affirmative CBT intervention developed by our team for youth, and the first to deliver it in a virtual group format. By focusing the present investigation on assessing the feasibility, acceptability, and need for refinement of this intervention, we plan to improve the developmental appropriateness of the intervention for 12-17 year-olds, in anticipation of a larger future efficacy trial.

2.2 Risks

The study participants are at minimal risk of harm as a result of participation in the proposed research study. Risks to potential study participants will be mitigated from the first contact with participants, as described in detail in the recruitment and informed consent section below. Although unlikely, one risk of the proposed study is that participants will experience emotional discomfort as a result of completing the assessments or the intervention. Breach of participants' confidentiality presents another possible risk. Breach of confidentiality can also occur if participants in this group-based intervention disclose information about other participants to outside parties. The research team's strategies to protect against these risks are described below.

Recruitment and Informed Consent: The research team has conducted a number of studies involving young LGBTQ people, which have involved asking participants to complete potentially sensitive interviews and self-report measures. Thus, we have extensive protocols in place for all aspects of the study. All team members will complete IRB (re)certification as required. All team members will receive training in issues pertinent to research among LGBTQ people prior to any contact with participants or data. No identifying information is collected prior to the moment at which a participant provides informed consent.

Participants will be recruited into the study through online advertisements. The online advertisements will direct parents/legal guardians of potential youth participants to an online screening survey, where parents/legal guardians will be prompted to provide consent for answering screener questions, as well as permission for their child to participate in the screening process. At the end of the parent's screening survey, they will be prompted to enter an email address to which a link to the youth screening survey will be sent. Youth

participants will then be prompted to provide active assent for answering the screening questions.

If determined eligible for the study, research team members will email both parent/guardian and child a copy of the full consent, assent, and parental permission forms and schedule a call to discuss the study. During the call, a study team member will review key points of the study and participation requirements with the youth participant and their parent/caregiver, and clarify any questions the pair may have. The team member will ensure that the participant and their parent understand the risks associated with the disclosure of information that could indicate imminent threat to self or others. Verification of comprehension of informed consent will be accomplished by asking participants and parents to recall central points in the consent process; points of confusion will be clarified. Once participants and parents have fully understood the requirements of the study, they will be asked to verbally consent and assent to participation during the call, and then to sign the consent and assent forms electronically. A youth's parent or parent/caregiver must provide parental permission for their child to participate and the youth must assent to participate in order for the youth to be enrolled in the study. Study team members will be instructed to contact the PI, Dr. John Pachankis, or lead postdoctoral associate, Dr. Ilana Seager van Dyk, if they are unsure about any participant's capacity to consent. Participants will again see the consent form at the beginning of the pre-intervention assessment survey and again before their first group therapy session.

There is a potential risk that engagement in this study could inadvertently reveal youth's sexual orientation and/or gender identity to their parent or parent/caregiver, by virtue of the need for parental permission for the youth to participate. In order to mitigate this risk, only youth who indicate that their parent is aware of their LGBTQ status and that they are comfortable with their parent knowing that they are participating in this study will be eligible. All of the study recruitment materials make it clear to potential participants that parent/guardian consent will be required, in order to ensure that all potential participants are fully aware of this in advance, and can thus choose whether or not to participate accordingly. For parents/guardians who express concern about their child's sexual orientation/gender identity to study staff, a resource list will be provided that lists helpful books, websites, and support groups.

Protection Against Emotional Discomfort. It is possible that participants may experience emotional discomfort in responding to assessments, or while discussing challenging experiences in intervention sessions. While every possible step will be taken to minimize such risk, consent documentation will make it clear that if participants have any concerns about any aspect of the study they may refuse to continue with the study at any time, without penalty. In addition, we will remind participants during the course of their assessments that they can refuse to answer any questions and may discontinue participation at any time. Research team members will receive training from a licensed clinical psychologist in appropriate response practices in instances of participant distress. This training will address the appropriate handling of imminent threats and provision of referrals to free counseling services in less imminent clinical situations.

During the course of the study, there is possibility that participants may report suicidality, homicidality, emotional distress, violent/aggressive or disruptive behavior, intoxication, and/or suspected abuse or maltreatment. Our lab's clinical protocol has successfully guided reporting of such instances in our other online-based clinical trials (see IRB #2000025803 and #2000029433). Our Clinical Protocol, attached to this application, will guide this training and its implementation during instances of participant distress.

Protection Against Breach of Confidentiality. The primary potential risk to participants is breach of confidentiality. Breaches of confidentiality will occur if a participant reports a clear intention to harm themselves or another person. Health care professionals are required by state law to report suspected cases of abuse or neglect. Breach of confidentiality can also occur if participants in this group-based intervention disclose information about participants to outside parties. Participants will agree in their signed consent forms that any information shared during group sessions may not be discussed outside of the intervention. During the consent process, we will indicate that youth will be able to pick a username that they will be known by during the Zoom sessions. This can be any name they want, including their affirmed first name (last names will not be allowed, nor will any other names that clearly identify the youth; e.g., phone number or address). The goal of using a username is to protect their privacy, so youth will be informed that using their legal name introduces some risk to their confidentiality. Youth will be kept in the Zoom waiting room until their study username is displayed. Youth will be reminded of their study username by email a few days before the first session, and will be provided instructions about how to change their username. Moreover, participants will be reminded at the beginning of each session to keep all information shared during the group intervention sessions private; that is, the session therapist will ask all group members to not disclose any other participant's information outside of the group setting. Participants will also be told, however, that this protection cannot be guaranteed by the group leader. Participants will be notified on the consent form and at the start of each session that by participating in the study they acknowledge the risk that other participants will become aware of any information they disclose during the group intervention sessions and might disclose such information to others outside of the study. The likelihood that any additional breaches of confidentiality would occur is minimal, as steps will be taken to guard against this risk. All study team members will undergo rigorous training in maintaining participants' confidentiality and will be in possession of valid Collaborative Institutional Training Initiative (CITI) certificates. Further, immediately upon providing consent, all participants will be assigned an identification number. Only one database will contain participant information with a link to identification numbers and no data will be stored on this file. This database will be stored on Yale's HIPAA-compliant Secure Box server and will be password protected. This information will not be stored with any participant data and no other identifying information will appear on any form. All contact with participants will be made by counselors and research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants.

2.3 Anticipated Benefits

The disproportionate mental health burden experienced by LGBTQ young people is a clear public health concern. All participants in the present study will be exposed to information about how stressful LGBTQ-specific experiences (e.g., discrimination, coming out) are associated with mental health difficulties. We anticipate that participants will acquire knowledge and skills and will receive support needed to improve their capacity for managing emotional distress like anxiety and/or depression.

Benefits to society in general are also anticipated through the dissemination of intervention findings. Results will better inform mental health professionals' efforts to provide effective, tailored interventions with LGBTQ youth. Further, study findings could inform local and national public health agencies about potentially effective outreach and prevention strategies that can be delivered to LGBTQ youth who experience stress-sensitive mental health disorders, such as depression and anxiety. This project will also lay the groundwork for larger future studies examining the efficacy of this intervention with LGBTQ youth. In sum, the potential benefits outweigh the potential risks to subjects, which are minimal.

3 Study Purpose and Objectives

3.1 Purpose

LGBTQ youth experience more mental health problems than their heterosexual and cisgender peers. The purpose of the proposed mixed-methods study is to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive behavior therapy for youth aged 12-17 years in New York, New Jersey, and Connecticut. This study will be the first to adapt the randomized controlled trial tested LGBTQ-affirmative CBT intervention for youth, and the first to deliver it in a virtual group format. Qualitatively, we will conduct structured post-intervention interviews to assess the feasibility, acceptability, and refinement of the intervention in this population. Quantitatively, we will assess the feasibility and acceptability of the intervention through analysis of indices like number of sessions attended, number of homework assignments completed, weekly satisfaction ratings, and a post-intervention feedback survey. We will also examine changes from pre- to post-intervention in youth's mental health symptoms, minority stress reactions, and emotional regulation and coping difficulties. These pilot data will be used to estimate the sample sizes needed for a future, larger trial of this intervention, as well as areas in which the intervention could be refined.

3.2 Hypothesis

We predict that LGBTQ-affirmative cognitive behavioral therapy for youth will be acceptable and feasible (as measured by both qualitative and quantitative data) to both youth and their parents/guardians. Further, we anticipate that youth will exhibit increases in adaptive coping and decreases in anxiety and depression symptoms, and maladaptive minority stress reactions from pre- to post-intervention (although we do not necessarily expect statistically significant changes from pre- to post-assessment given the small sample size).

3.3 Objectives

The primary objective of this study is to assess the feasibility, acceptability, and need for refinement of an LGBTQ-affirmative cognitive behavioral therapy adapted for youth.

The secondary objective of this study is to investigate whether youth's mental health symptoms, minority stress reactions, and emotional regulation and coping difficulties decrease over the course of the intervention.

4 Study Design

This mixed methods prospective study is designed to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive behavior therapy for youth aged 12-17 years in New York, New Jersey, and Connecticut. To achieve this goal, two 10-week LGBTQ-affirmative CBT groups with LGBTQ youth will be conducted.

The study population will consist of participants with internalizing disorders of mild to moderate severity who identify as LGBTQ, are 12-17 years of age, are fluent in English, and who live in New York, New Jersey, or Connecticut. Parents/legal guardians of these youth will also participate in screening, pre-intervention and post-intervention assessments.

First, participants and their parents will complete an online screening survey, followed by a semi-structured diagnostic interview (K-SADS) with a trained clinical psychology postdoctoral fellow, to assess their eligibility for the study. Additional details about the recruitment process are provided in 5.4. Once eligible, participants will undergo the informed consent process for the study with trained study staff via Zoom or phone with the youth and their parent/caregiver (described in 5.5). Next, youth and their parent/caregiver will complete the pre-intervention survey within 2 weeks of the first intervention session. This consists of a number of measures to assess constructs relevant to the primary and secondary objectives of the study (see 4.2 for full list of measures). Youth will then be assigned to one of two intervention groups based on the timing of their enrollment (i.e., participants who enroll in fall 2021 will be assigned to the first group, participants who enroll in winter/spring 2022 will be assigned to second group).

The intervention itself will consist of 10 weekly, 90-minute group sessions, delivered remotely via Zoom. The intervention will be delivered by Dr. Seager van Dyk, who has experience counseling LGBTQ teenagers and who has received training in the intervention from the PI (who developed LGBTQ-affirmative CBT), with support from the study team. Intervention sessions and associated home practice will cover the following topics (additional details are provided in the Session Outlines document uploaded in IRES):

- Building and keeping motivation
- Introduction to LGBTQ-related stress
- Getting to know your emotions
- Introduction to emotional behaviors and behavioral experiments
- Awareness of physical sensations and introduction to flexible thinking
- Being flexible in your thinking
- Awareness of emotional experiences
- Assertiveness
- Situational exposures
- Reviewing accomplishments and looking ahead

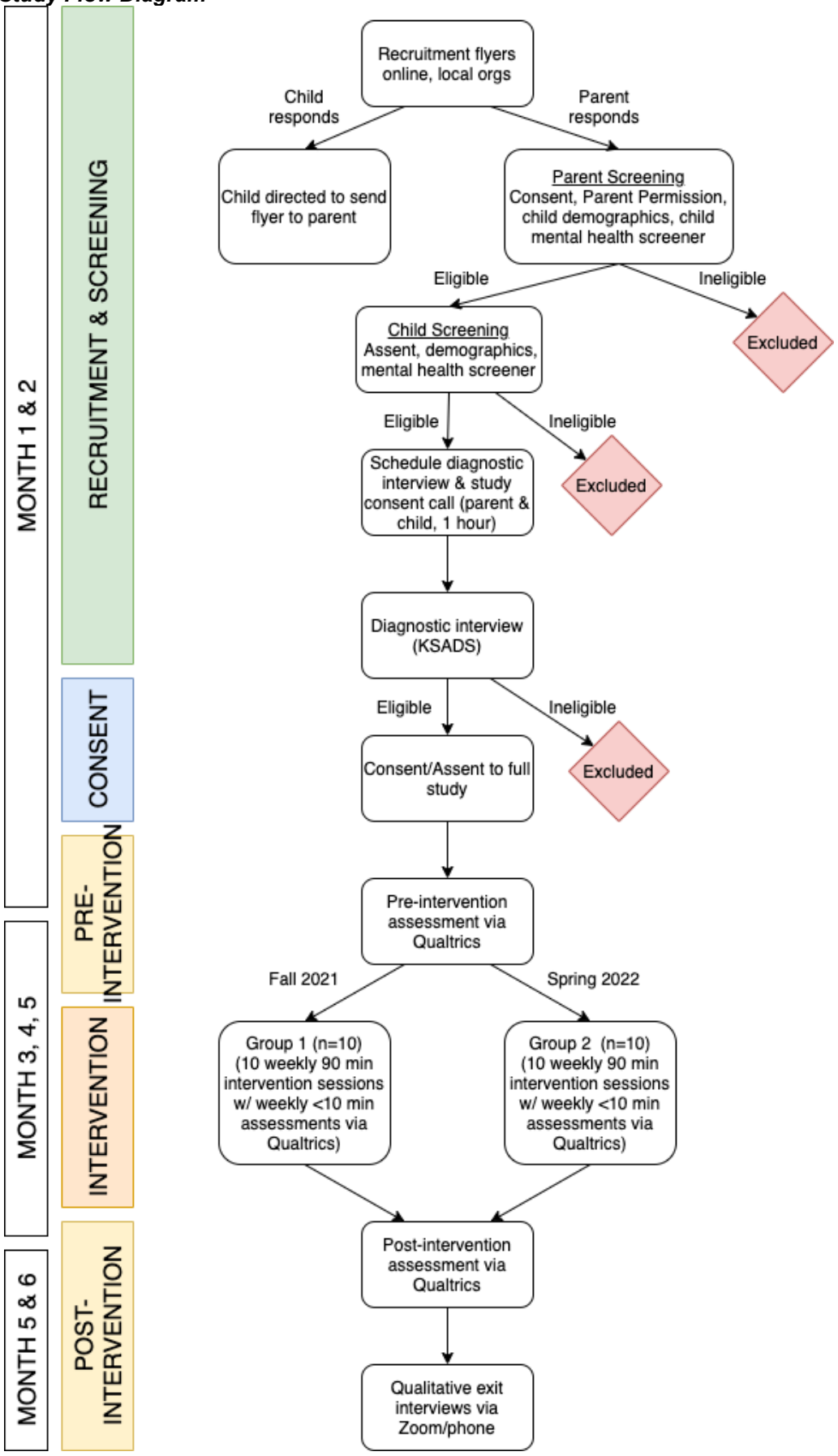
Participants will be taught intervention content through a range of teaching modalities including use of the Zoom whiteboard feature, videos, interactive activities, worksheets, and

group discussion. All sessions will be audio-recorded for supervision purposes, and audio recordings will be saved in a secure Yale Box folder.

Following each intervention session, participants will be sent a brief survey to evaluate the acceptability, feasibility, and need for refinement of each intervention session. Participants will also complete brief mental health measures each week to address the study's secondary objective. Participants will be asked to submit an electronic copy (e.g., PDF, photo) of any completed home practice assignments to the study team via Yale's Secure File Transfer, in order to evaluate the acceptability of these assignments. Study staff will de-identify all home practice materials before saving them in a secure Yale Box folder with the participant's study ID number.

Post-intervention assessment measures will be sent to youth participants and their parent/caregiver immediately following the last intervention session, and will be available for three weeks (see 4.2 for full list of measures). After the post-intervention assessment is complete, youth will be invited to complete an exit interview via Zoom/phone to assess the feasibility, acceptability, and refinement.

Study Flow Diagram



4.1 Study Duration

The entire study, including data analysis, is expected to last from August 2021 until August 2022. Participation for the subjects will begin in August 2021 (i.e., recruitment, pre-intervention assessment). Participants in the first group will begin the 10-week intervention in September-November 2021 and complete their post-intervention assessment in December 2021-January 2022. Participants in the second group will begin the 10-week intervention in February 2022 and complete their post-intervention assessment in May 2021-June 2022. Data analysis is expected to continue through August 2022.

4.2 Outcome Variables/Endpoints

The following are the outcome variables and associated measures that will be administered at each time point (i.e., screening, pre-intervention, weekly assessments, and post-intervention) in the study:

* = Main outcome variable; all others are supportive variables

Screening:

- Mental health: Revised Children's Anxiety and Depression Scale (RCADS)*, Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), Depressive Symptom Index - Suicidality Subscale (DSI-SS), Youth Psychosis At-Risk Questionnaire - Brief (YPARQ-B), Brief Child Mania Rating Scale - Parent Version (CMRS-P), Child & Adolescent Intellectual Disability Screening Questionnaire (CAIDS-Q)

Pre-intervention:

- Acceptability: Treatment Expectations
- Mental health: Revised Children's Anxiety and Depression Scale (RCADS)*, Depressive Symptom Index - Suicidality Subscale (DSI-SS), Strengths and Difficulties Questionnaire (SDQ), WHO-5 Well-Being Index, CRAFFT 2.1, Autism Quotient-10 (AQ-10)
- Minority stress reactions: Gender Minority Stress and Resilience Scale for Adolescents (GMSR-A)*, Outness Inventory (OI)
- Stigma exposure: Gender Minority Stress and Resilience Scale for Adolescents (GMSR-A), Child Perceived Discrimination Questionnaire (CPDQ), Lesbian, Gay, Bisexual Affiliate Stigma Measure (LGB-ASM), Parental Rejection/Acceptance of LGBTQ child
- Emotion regulation & coping: Children's Emotion Management Scales (CEMS)*, Emotion Regulation Questionnaire (ERQ-CA), Child Avoidance Measure (CAMS/CAMP), Children's Automatic Thoughts Scale - N/P version (CATS), Coping with Sexual Orientation-Related Minority Stress

Weekly:

- Acceptability: Top Problems Assessment (Session 1 only), Top Problems Tracking Form, Client Satisfaction Questionnaire-8 (Session 5 only)*, Acceptability of Session Questionnaire
- Feasibility: Session Attendance*, Homework Compliance Scale, Feasibility of Session Questionnaire
- Need for refinement: Session Refinement Questions
- Mental health: Revised Children's Anxiety and Depression Scale (RCADS-Short form)*, Depressive Symptom Index - Suicidality Subscale (DSI-SS)

Post-intervention:

- Acceptability: Top Problems Tracking Form, Client Satisfaction Questionnaire-8 (CSQ-8)*, AFFIRM Acceptability Survey, Exit Interview-Acceptability of program format, delivery, and content
- Feasibility: Feasibility of Program Questionnaire, Exit Interview-Program feasibility
- Need for refinement: Program Refinement Questions, Exit Interview-Program need for refinement*
- Mental health: Revised Children's Anxiety and Depression Scale (RCADS)*, Depressive Symptom Index - Suicidality Subscale (DSI-SS), Strengths and Difficulties Questionnaire (SDQ), WHO-5 Well-Being Index, CRAFFT 2.1
- Minority stress reactions: Gender Minority Stress and Resilience Scale for Adolescents (GMSR-A)*, Outness Inventory (OI)
- Stigma exposure: Gender Minority Stress and Resilience Scale for Adolescents (GMSR-A), Child Perceived Discrimination Questionnaire (CPDQ), Lesbian, Gay, Bisexual Affiliate Stigma Measure (LGB-ASM), Parental Rejection/Acceptance of LGBTQ child
- Emotion regulation & coping: Children's Emotion Management Scales (CEMS)*, Emotion Regulation Questionnaire (ERQ-CA), Child Avoidance Measure (CAMS/CAMP), Children's Automatic Thoughts Scale - N/P version (CATS), Coping with Sexual Orientation-Related Minority Stress, Multidimensional Scale of Perceived Social Support (MSPSS)

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

4.2.1 Primary Outcome Variables/Endpoints

Acceptability:

- *Client Satisfaction Questionnaire-8 (CSQ-8)*. The CSQ-8 (Larsen et al., 1979) is a well-validated, 8-item self-report questionnaire designed to assess patient/client satisfaction with services received. Both the adolescent self-report and the parent report of child services versions of the CSQ-8 will be used in this study. Items are scored on a 4-point scale, where higher scores indicate more satisfaction. The CSQ-8 has demonstrated excellent internal consistency in prior studies (α = 0.93; Larsen et al., 1979).

Feasibility:

- *Session Attendance*. Session attendance will be tracked by the study therapist(s) each week to examine the feasibility of weekly sessions.

Need for refinement:

- *Exit Interview*. The need to refine the intervention will also be assessed qualitatively during a post-intervention exit interview with each youth participant. Questions will probe participants' suggestions for improving the intervention, as well as the parts of the intervention that they felt most helpful, among other topics.

Mental health:

- *Revised Children's Anxiety and Depression Scale (RCADS).* The RCADS (Chorpita et al., 2000; Ebesutani et al., 2010) is a 47-item questionnaire assessing symptoms of depression and anxiety in youth aged 6-18 years. Both the parent-report and the child self-report versions of this scale will be used in this study. In addition to a Total Internalizing Scale and a Total Anxiety Scale, the RCADS includes six subscales: separation anxiety disorder (SAD), social phobia (SP), generalized anxiety disorder (GAD), panic disorder (PD), obsessive compulsive disorder (OCD), and major depressive disorder (MDD). Items are rated on a 4-point Likert-scale from 0 ("never") to 3 ("always"). Previous studies have showed the RCADS has good internal consistency (αs = 0.73-0.82; Chorpita et al., 2000).

Minority stress reactions:

- *Gender Minority Stress and Resilience Measure for Adolescents (GMSR-A).* The GMSR-A (Hidalgo et al., 2019) is a 59-item youth-report questionnaire that assesses experiences of both distal (discrimination, rejection, victimization, non-affirmation) and proximal minority stress (internalized transphobia, negative expectations for the future, and non-disclosure of gender identity/history), as well as resilience (pride, community connectedness) among gender minority adolescents aged 12-18 years. Three subscales (discrimination, rejection, victimization) are rated using a count (yes/no) of items, while the remaining six subscales are scored using a 5-point scale, where 0 = Strongly Disagree and 4 = Strongly Agree. Prior research demonstrated good internal consistency for the GMSR-A and its subscales (αs = 0.80-0.95; Hidalgo et al., 2019). For the purposes of this study, the wording of items will be modified slightly to apply to both sexual and gender minority youth (e.g., "I have been rejected at school or work because of my gender identity or expression" was changed to "I have been rejected at school or work because of my LGBTQ identity"). The primary outcome related to minority stress reactions for this study will be the Internalized trans/homophobia subscale of this questionnaire.

Emotion regulation & coping:

- *Children's Emotion Management Scales (CEMS).* The CEMS (Zeman et al., 2001; Zeman et al., 2010) is a 33-item measure assessing youth's responses to

experiences of sadness (12 items), anger (11 items), and worry (10 items). Within each emotion scale, there are three subscales, including: inhibition, dysregulation, and regulation coping. Both the parent-report and the youth self-report versions of this scale will be used in this study. Participants are asked to indicate the degree to which each item applies to them using a 3-point scale, where 1 = Hardly ever, 2 = Sometimes, and 3 = Often. The CEMS has been validated for use with youth aged 7-17 years and prior studies show that its subscales have adequate internal consistency (αs = 0.62-0.77; Zeman et al., 2001; Zeman et al., 2010).

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

Acceptability:

- *Treatment Expectations*. The Treatment Expectations measure (Lewin et al., 2011) is a single-item measure of participants' confidence that the treatment they are about to receive will help them with their problems. Participants rate the question "how sure are you that doing this treatment will help you with your problems (including your anxiety and/or depression)?" on a 7-point scale, where 1 = Not sure at all and 7 = Extremely sure. This scale was adapted from Lewin et al. (2011), who used the scale in a sample of youth aged 8-17 years. The single item format is consistent with prior treatment expectations work (e.g., Borkovec & Nau, 1972; Vogel et al., 2006)
- *Top Problems Assessment / Top Problems Tracking Form*. The Top Problems assessment (Weisz et al., 2011) is an idiographic measure used to identify and track child- and parent-reported target problems for psychological treatment over time. Youth are asked to identify the three main problems that they are experiencing in their life at the beginning of treatment, along with a behaviorally specific goal for addressing each of the identified problems. Then, throughout the course of treatment, youth provide weekly ratings of each problem's severity on a Likert-type scale from 0 to 8, where 0 = total problem remission and 8 = extreme problem severity. The Top Problems assessment has been used in prior trials of the Unified Protocols for the Treatment of Emotional Disorders in Children and Adolescents (one of the treatments upon which the current intervention is based) (Milgram et al., 2021). For the purposes of this study, only child-reported target problems will be identified and tracked as parents will not be actively involved in the weekly intervention sessions.
- *Acceptability of Session Questionnaire*. The Acceptability of Session Questionnaire (Heck, 2015) is a 10-item adolescent self-report questionnaire that will be used in this study to assess the acceptability of each intervention session. This scale was originally developed to assess a minority stress-informed mental health promotion program for LGBTQ high school students (Heck, 2015). For this study, five additional items were added to assess the acceptability of intervention components that are unique to this intervention (e.g., home practice tasks, group member support). The Heck (2015) study did not report psychometric properties of the scale.

- *AFFIRM Acceptability Survey*. The AFFIRM Acceptability Survey (Craig & Austin, 2016) is a 17-item youth-report questionnaire originally designed to assess the acceptability of the CBT-based AFFIRM intervention with LGBTQ young people. Items were slightly modified for this study to omit the word "AFFIRM" and replace it with "this intervention." Items address topics like intervention usefulness, relevance to participants' lives, and overall satisfaction, and are rated on a 4-point scale, where 1 = Strongly Disagree and 4 = Strongly Agree. The Craig & Austin (2016) study did not report psychometric properties of the scale.
- *Exit Interview*. The acceptability of the intervention will also be assessed qualitatively during a post-intervention exit interview with each youth participant. Questions will address the acceptability of the intervention format, delivery modality, and the content.

Feasibility:

- *Homework Compliance Scale*. The Homework Compliance Scale (Primakoff, Epstein, & Covi, 1986) is a single-item rating scale that asks therapists to assess the degree to which a client completed assigned cognitive therapy homework. A 6-point scale is employed, where 1 = the patient did not attempt the assigned homework and 6 = the patient did more of the assigned homework than was requested. In this study, therapist(s) will review homework with participants at the beginning of each session, and participants will also be asked to submit their homework assignment electronically to facilitate scoring. Therapists will provide a homework compliance score for each participant every session.
- *Feasibility of Session Questionnaire*. This is a novel 5-item measure that assesses barriers to intervention engagement that youth may encounter, including difficulty accessing a device for the session, finding a private place from which to attend the session, technical difficulties, and homework incompletion. Participants will be asked to complete these questions after each session, and will rate items using a dichotomous yes/no response.
- *Feasibility of Program Questionnaire*. This is a novel 4-item measure that is designed to assess parent/caregiver barriers to intervention engagement. This scale will be administered to parents/caregivers during the post-intervention assessment to capture feasibility of the intervention as a whole. Due to the broader scope of these questions (full intervention) relative to the youth items (individual sessions), items will be rated on a 4-point scale, where 1 = Disagree/Never and 4 = Agree/Always.
- *Exit Interview*. The feasibility of the intervention will also be assessed qualitatively during a post-intervention exit interview with each youth participant. Questions will address the feasibility of session attendance (e.g., acquisition of an electronic device), session length, and home practice exercises, among other topics.

Need for refinement:

- *Session Refinement Questions*. This is a novel 3-item measure that asks youth participants to describe their most favorite and least favorite aspects of a given intervention session, and to provide suggestions for ways to improve the session so that it is more helpful for LGBTQ youth. Youth participants will be asked to complete these questions after each session, and data will be analyzed qualitatively at the end of the intervention.
- *Program Refinement Questions*. This is a novel 11-item measure for parents/caregivers that has two goals. First, parents/caregivers are asked to provide feedback on the parent/caregiver handouts that they receive electronically after each intervention session. Second, parents/caregivers are asked several questions that assess interest in a potential parent/caregiver group for future iterations of the intervention. In prior studies with the Unified Protocol for Adolescents, a parent group has been a component of the intervention model (Ehrenreich-May et al., 2017). However, since no studies have examined intervention preferences among parents of LGBTQ youth, parents' answers to these questions will guide the study team as we seek to develop a parent group in the future.
- *Exit Interview*. The need to refine the intervention will also be assessed qualitatively during a post-intervention exit interview with each youth participant. Questions will probe participants' suggestions for improving the intervention, as well as the parts of the intervention that they felt most helpful, among other topics.

Mental health:

- *Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS*). The KSADS (Kaufman et al., 1997, 2016) is a well-validated semi-structured diagnostic interview designed to identify DSM-5 mental disorders in youth. It has demonstrated excellent test-retest reliability in prior work (κ¬=0.77-1.00; Kaufman et al., 1997). The KSADS will be used in this study to determine whether youth are eligible for the study (inclusion: meet criteria for a DSM-5 internalizing disorder; exclusion: meet criteria for psychotic or bipolar spectrum diagnosis, active suicidality and/or homicidality, significant cognitive impairment, significant developmental or behavior disorder (if impairing youth's ability to participate in group therapy)
- *Depressive Symptom Index - Suicidality Subscale (DSI-SS)*. The DSI-SS (Joiner, Pfaff, & Acres, 2002; Metalsky & Joiner, 1997) is a 4-item self-report questionnaire that assesses the frequency and intensity of suicidality in the past two weeks. Items are scored on a 0-3 scale, where higher scores indicate more suicidal thoughts and impulses. Previous studies with the DSI-SS have revealed strong internal consistency (α = 0.90; Joiner, Pfaff, & Acres, 2002).
- *Strengths and Difficulties Questionnaire (SDQ)*. The SDQ (Goodman, 1997; Goodman et al., 1998) is a 25-item questionnaire that assesses a broad range of psychological attributes of youth aged 3-17 years. Both the parent-report and the adolescent self-report versions of this scale will be used in this study. The measure

consists of five, five-item subscales measuring emotional difficulties, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behavior. Participants are asked to rate whether each item is not true, somewhat true, or certainly true for them over the past six months. Previous studies with the SDQ have revealed good internal consistency (α = 0.73; Goodman, 2001).

- *WHO-5 Well-Being Index (WHO-5)*. The WHO-5 (Psychiatric Research Unit, 1998) is a brief, 5-item self-report questionnaire that measures subjective well-being. It is derived from longer, 10- and 28-item versions of the same scale (Bech et al., 1996). Participants are asked to rate how well each of the items applies to them over the past 14 days on a scale from 0 = none of the time to 5 = all of the time. It has been widely used and deemed valid in a range of countries and contexts (Topp et al., 2015), and in youth as young as 9 years. The WHO-5 has demonstrated good internal consistency in adolescent samples (α = 0.82; de Wit et al., 2007).
- *CRAFFT 2.1.* The CRAFFT 2.1 (The Center for Adolescent Behavioral Health Research, 2020) is a 9-item youth-report screening tool for risky substance use in 12-21 year olds. Participants are asked to report on the frequency (# of days) of alcohol, marijuana, and other substance use in the past year, as well as high-risk behaviors (e.g., riding in a car driven by someone under the influence, use of substances to relax). Prior research indicates that the CRAFFT has good sensitivity in identifying both alcohol (0.79) and drug use (0.86) in adolescents (The Center for Adolescent Behavioral Health Research, 2020), and good predictive validity (Shenoi et al., 2019).
- *Youth Psychosis At-Risk Questionnaire - Brief (YPARQ-B)*. The YPARQ-B (Ord et al., 2004) is a 28-item youth-report questionnaire that assesses psychotic symptoms in adolescents as young as 12. It is an abbreviated version of the original 92-item scale by the same name (Ord et al., 2004). Participants are asked to indicate whether each item applies to them (“yes”) or not (“no”), or if they are “undecided.” The YPARQ-B has shown strong internal consistency in prior studies (α = 0.94; Fonseca-Pedrero et al., 2017), and high sensitivity (1.00) and specificity (0.80) (Kline et al., 2015). In this project, the YPARQ-B will be used to determine eligibility. Potential participants will be deemed ineligible if their score is 13 or above.
- *Brief Child Mania Rating Scale - Parent Version (CMRS-P).* The brief CMRS-P (Henry et al., 2008) is a 10-item parent-report questionnaire that assesses manic symptoms in youth aged 9-17 years. It is an abbreviated version of the original 21-item scale by the same name (Pavuluri et al., 2006). The brief CMRS-P has shown excellent internal consistency (α = 0.91), and strong sensitivity and specificity for differentiating mania from ADHD (0.84 and 0.92 respectively) and from healthy controls (0.90 and 0.96 respectively) (Henry et al., 2008). In this project, the CMRS-P will be used to determine eligibility. Potential participants will be deemed ineligible if their score is 10 or above.
- *Child & Adolescent Intellectual Disability Screening Questionnaire (CAIDS-Q).* The CAIDS-Q (McKenzie et al., 2012) is a 7-item, parent-report questionnaire that

screens for intellectual disability and related adaptive functioning difficulties in youth aged 8-18. Participants are asked to indicate whether each item (e.g., “can the child/adolescent read?”) applies to their child (“yes”) or not (“no”). Prior studies have demonstrated strong internal consistency of the CAIDS-Q (α = 0.88), and high sensitivity (0.96) and specificity (0.85) for differentiating intellectual disability from healthy controls (McKenzie et al., 2012). In this project, the CAIDS-Q will be used to determine eligibility. Potential participants will be deemed ineligible if their score is 64 or above.

- *Autism Quotient-10 (AQ-10).* The AQ-10 (Allison et al., 2012) is brief, 10-item screening tool for assessing symptoms of autism spectrum disorders (ASD). In this study, we will use the adolescent version of the scale, which asks parents to rate the degree to which each item applies to their teenager on a 4-point scale from Definitely Agree to Definitely Disagree. Prior studies with this scale have demonstrated good internal consistency (α = 0.89) and high sensitivity (0.93) and specificity (0.95) when differentiating between youth with ASD and healthy controls (cut point = 6) (Allison et al., 2012). In this study, the AQ-10 will be used to help characterize the sample, especially given the documented increased frequency of ASD traits in gender diverse youth (Warrier et al., 2020). We do not anticipate changes in these traits over the course of the trial, and thus will only administer this questionnaire at pre-intervention.

<u>Minority stress reactions:</u>

- *Gender Minority Stress and Resilience Measure for Adolescents (GMSR-A).* The GMSR-A (Hidalgo et al., 2019) is a 59-item youth-report questionnaire that assesses experiences of both distal (discrimination, rejection, victimization, non-affirmation) and proximal minority stress (internalized transphobia, negative expectations for the future, and non-disclosure of gender identity/history), as well as resilience (pride, community connectedness) among gender minority adolescents aged 12-18 years. Three subscales (discrimination, rejection, victimization) are rated using a count (yes/no) of items, while the remaining six subscales are scored using a 5-point scale, where 0 = Strongly Disagree and 4 = Strongly Agree. Prior research demonstrated good internal consistency for the GMSR-A and its subscales (αs = 0.80-0.95; Hidalgo et al., 2019). For the purposes of this study, the wording of items will be modified slightly to apply to both sexual and gender minority youth (e.g., “I have been rejected at school or work because of my gender identity or expression” was changed to “I have been rejected at school or work because of my LGBTQ identity”). Pertinent subscales include: internalized transphobia, negative expectations for the future, and non-disclosure of gender identity/history, resilience, and community connectedness.

- *Outness Inventory (OI)*. The OI (Mohr & Fassinger, 2000) is an 11-item self-report measure that assesses the extent to which sexual minority individuals are open about their sexual orientation with various people in their lives (e.g., family, friends, strangers). For this study, the wording of the item anchors were modified slightly to apply to LGBTQ identity more broadly. In addition, two items related to the school

environment (school peers, teachers) were added, given the age of the sample. Items are rated on a 7-point scale, where 1 = person definitely does NOT know about my LGBTQ identity and 7 = person definitely knows about my LGBTQ identity and it is openly talked about. Prior studies have shown strong internal consistency for the OI total score (α = 0.94), as well as subscales pertaining to family (α = 0.91), world (α = 0.91), and religion (α = 0.96) (Wilkerson et al., 2016).

Stigma exposure:

- *GMSR-A* (as described in minority stress reactions section). Pertinent subscales include: discrimination, rejection, victimization, non-affirmation.
- *Child Perceived Discrimination Questionnaire (CPDQ)*. The CPDQ (LaFont et al., 2018) is a 16-item youth-report scale designed to measure youth experiences of discrimination as perpetrated by their peers (8 items) and by adults (8 items). Items are rated for their frequency of occurrence using a 5-point scale, where 1 = Never and 5 = Very Often. The instructions for this scale were modified slightly for this study to pertain specifically to discrimination that youth perceive to be related to their LGBTQ identity. Prior investigations have shown the CPDQ has strong internal consistency (αs = 0.90-0.92).
- *Lesbian, Gay, Bisexual Affiliate Stigma Measure (LGB-ASM).* The LGB-ASM (Robinson, 2014) is a 17-item self-report measure that assesses stigma experiences of individuals who are affiliated (e.g., friends, family) with LGBTQ people. In addition to a total score, the LGB-ASM includes subscales measuring public discrimination/rejection-related affiliate stigma, vicarious affiliate stigma, and public shame affiliate stigma. Items are scored on a 6-point scale from 1 = Strongly Disagree to 6 = Strongly Agree. Prior studies demonstrate good internal consistency for the total scale (α = 0.87) and the subscales (αs = 0.84-0.89) (Robinson, 2014). For this study, the wording of each item was slightly modified to pertain to parents' feelings on behalf of their LGBTQ child.
- *Parental Rejection/Acceptance of LGBTQ Child*. The Parental Rejection/Acceptance of LGBTQ Child scale (Pachankis et al., 2018) is a brief, 4-item scale that assesses LGBTQ individuals' perceived parental rejection and acceptance. Participants are asked to rate the degree to which their mother (or closest female guardian) and their father (or closest male guardian) is accepting of their sexual orientation and gender identity, using a 6-point scale where 1 = completely accepting and 6 = completely rejecting. For the purposes of this study, matching items were created for parents to self-report their degree of acceptance of their LGBTQ child.

Emotion regulation & coping:

- *Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA)*. The ERQ-CA (Gross & John, 2003; Gullone & Taffe, 2012) is a 10-item youth-report questionnaire assessing the use of emotion regulation strategies in youth aged 9-18. The scale is comprised of two subscales: cognitive reappraisal (6 items), and

expressive suppression (4 items). Items are rated on 5-point scale, where 1 = Strongly Disagree and 5 = Strongly Agree. Prior studies with youth demonstrate good internal consistency for the cognitive reappraisal subscale (α = 0.83) and adequate internal consistency for the expressive suppression subscale (α = 0.75) (Gullone & Taffe, 2012).

- *Child Avoidance Measure - Self Report (CAMS) and Parent Report (CAMP).* The CAMS/CAMP (Whiteside et al., 2013) is an 8-item youth- and parent-report scale that assesses behavioral avoidance related to anxiety and worry in youth aged 9-18. Both the parent-report and the youth self-report versions of this scale will be used in this study. Participants are asked to rate the frequency with which they (or their child) engage in each behavioral avoidance strategy using a 4-point scale, where 0 = Almost Never and 3 = Almost Always. Prior studies demonstrate good internal consistency for both the youth self-report (α = 0.86-0.89) and the parent-report (α = 0.90-0.91) versions of the scale (Whiteside et al., 2013).
- *Children's Automatic Thoughts Scale - Negative/Positive version (CATS)*. The CATS-N/P (Schniering & Rapee, 2002; Hogendoorn et al., 2010) is a 50-item youth-report scale that assesses negative and positive self-statements in youth aged 8-18 years. The CATS-N/P is an extension of the original 40-item CATS (Schniering & Rapee, 2002) that solely assessed negative thoughts. The CATS-N/P has five subscales: automatic thoughts related to physical threat, social threat, personal failure, and hostility, and positive automatic thoughts. Items are rated for their frequency on a 5-point scale, where 0 = Not at all and 4 = All the time. Prior studies demonstrate excellent internal consistency for the total negative thoughts score (α = 0.94-0.95), physical threat subscale (α = 0.84-0.85), social threat subscale (α = 0.89-0.92), personal failure subscale (α = 0.87-0.92), hostility subscale (α = 0.83-0.85), and positive thoughts score (α = 0.86) (Schniering & Rapee, 2002; Hogendoorn et al., 2010).
- *Coping with Sexual Orientation-Related Minority Stress*. The Coping with Sexual Orientation-Related Minority Stress scale (Toomey et al., 2018) is a 10-item youth self-report questionnaire designed to assess sexual minority adolescents' strategies for coping with minority stress. The scale consists of three subscales: LGBT-specific coping (3 items), alternative seeking (3 items), and cognitive strategies (4 items). Although this scale was not initially created for use with gender minority youth, all items are written to be inclusive (i.e., use of "LGBT") and capture coping strategies that gender minorities may also use in the face of gender-related minority stress (e.g., "looking for services for LGBT youth," "imagining a better future for yourself"). Items are scored on a 5-point scale, where 0 = Never and 4 = Very Often. Prior studies demonstrate that the three subscales have good internal consistency ($\alpha_{\text{LGBT coping}}$ = 0.82; $\alpha_{\text{alternative-seeking}}$ = 0.79; $\alpha_{\text{cognitive strategies}}$ = 0.78; Toomey et al., 2018).
- *Multidimensional Scale of Perceived Social Support (MSPSS)*. The MSPSS (Zimet et al., 1988; Canty-Mitchell & Zimet, 2000) is a 12-item self-report scale that measures

perceived social support from family, friends, and significant others. Originally an adult scale, the MSPSS has been successfully adapted for use with adolescents (Canty-Mitchell & Zimet, 2000). Participants are asked to rate how much they agree with each statement using a 7-point scale, where 1 = Very Strongly Disagree and 7 = Very Strongly Agree. Previous studies have found strong internal consistency for the MSPSS total score (α = 0.93), as well as the family (α = 0.91), friends (α = 0.89), and significant other (α = 0.91) subscales (Canty-Mitchell & Zimet, 2000).

Other:

In addition to the above measures, we will collect several measures to better characterize our sample and their current context.

- *Demographics*: Both youth and parent/caregiver will be asked demographic questions about factors like age, sex, gender, sexual orientation, race, ethnicity, family income, employment, family structure, living situation, education, religion, and other related constructs.
- *Gender Unicorn*: Youth will be asked to rate their gender identity, gender expression, sex assigned at birth, physical attraction, and emotional attraction using the Gender Unicorn worksheet (see Measure Packet). Each scale will be rated from 0-10.
- *General Parent-Child Relationship Characteristics*. As parents/caregivers will be provided with parent/caregiver handouts throughout the intervention, we wanted to better characterize our youth participants' contact with their parent/caregivers as part of this study. This novel 14-item measure assesses parents' frequency of contact with their child, sense of connection with their child, as well as their experience of their child's LGBTQ identity. All items will be administered to parents/caregivers at pre-intervention, but only Q6 (which assesses the degree to which the parent views the child's LGBTQ identity as real and valid) will be readministered at the post-intervention timepoint.
- *Family Assessment Device (FAD) — General Functioning Subscale*. To characterize the youth's family environment, both youth and parent/caregiver will be asked to complete the general functioning FAD subscale (Epstein et al., 1983; Byles et al., 1988). The subscale includes 12 items that all assess aspects of adaptive and maladaptive family functioning. Items are scored on a 4-point scale from 1 = Strongly Agree to 4 = Strongly Disagree. Prior studies with this measure have demonstrated good internal consistency (α = 0.86; Byles et al., 1988).

References

Allison, C., Auyeung, B., & Baron-Cohen, S. (2012). Toward Brief "Red Flags" for Autism Screening: The Short Autism Spectrum Quotient and the Short Quantitative Checklist in 1,000 Cases and 3,000 Controls. *Journal of the American Academy of Child & Adolescent Psychiatry*, *51*(2), 202-212.e7. https://doi.org/10.1016/j.jaac.2011.11.003

Bech, P., Gudex, C., & Johansen, S. (1996). The WHO (Ten) Weil-Being Index: Validation in Diabetes. *Psychotherapy and Psychosomatics*, *65*(4), 183–190. https://doi.org/10.1159/000289073

Borkovec, T. D., & Nau, S. D. (1972). Credibility of analogue therapy rationales. *Journal of Behavior Therapy and Experimental Psychiatry*, *3*(4), 257–260. https://doi.org/10.1016/0005-7916(72)90045-6

Byles, J., Byrne, C., Boyle, M. H., & Offord, D. R. (1988). Ontario Child Health Study: Reliability and Validity of the General Functioning Subscale of the McMaster Family Assessment Device. *Family Process*, *27*(1), 97–104. https://doi.org/10.1111/j.1545-5300.1988.00097.x

Canty-Mitchell, J., & Zimet, G. D. (2000). Psychometric Properties of the Multidimensional Scale of Perceived Social Support in Urban Adolescents. *American Journal of Community Psychology*, *28*(3), 391–400. https://doi.org/10.1023/A:1005109522457

Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., & Francis, S. E. (2000). Assessment of symptoms of DSM-IV anxiety and depression in children: A revised child anxiety and depression scale. *Behaviour Research and Therapy*, *38*(8), 835–855. https://doi.org/10.1016/S0005-7967(99)00130-8

Craig, S. L., & Austin, A. (2016). The AFFIRM open pilot feasibility study: A brief affirmative cognitive behavioral coping skills group intervention for sexual and gender minority youth. *Children and Youth Services Review*, *64*, 136–144. https://doi.org/10.1016/j.childyouth.2016.02.022

de Wit, M., Pouwer, F., Gemke, R. J. B. J., Delemarre-van de Waal, H. A., & Snoek, F. J. (2007). Validation of the WHO-5 Well-Being Index in Adolescents With Type 1 Diabetes. *Diabetes Care*, *30*(8), 2003–2006. https://doi.org/10.2337/dc07-0447

Ebesutani, C., Bernstein, A., Nakamura, B. J., Chorpita, B. F., & Weisz, J. R. (2010). A Psychometric Analysis of the Revised Child Anxiety and Depression Scale—Parent Version in a Clinical Sample. *Journal of Abnormal Child Psychology*, *38*(2), 249–260. https://doi.org/10.1007/s10802-009-9363-8

Ehrenreich-May, J., Rosenfield, D., Queen, A. H., Kennedy, S. M., Remmes, C. S., & Barlow, D. H. (2017). An initial waitlist-controlled trial of the unified protocol for the treatment of emotional disorders in adolescents. *Journal of Anxiety Disorders*, *46*, 46–55. https://doi.org/10.1016/j.janxdis.2016.10.006

Epstein, N. B., Baldwin, L. M., & Bishop, D. S. (1983). The McMaster Family Assessment Device. *Journal of Marital and Family Therapy*, *9*(2), 1710180. https://doi.org/10.1111/j.1752-0606.1983.tb01497.x

Fonseca-Pedrero, E., Ortuño-Sierra, J., Chocarro, E., Inchausti, F., Debbané, M., & Bobes, J. (2017). Psychosis risk screening: Validation of the youth psychosis at-risk questionnaire - brief in a community-derived sample of adolescents: Validation of the Y-PARQ-B. *International Journal of Methods in Psychiatric Research*, *26*(4), e1543. https://doi.org/10.1002/mpr.1543

Goodman, R., Meltzer, H., & Bailey, V. (1998). The strengths and difficulties questionnaire: A pilot study on the validity of the self-report version. *European Child & Adolescent Psychiatry*, *7*(3), 125–130. https://doi.org/10.1007/s007870050057

Goodman, Robert. (1997). The strengths and difficulties questionnaire: A research note. *Journal of Child Psychology and Psychiatry*, *38*(5), 581–586. https://doi.org/10.1111/j.1469-7610.1997.tb01545.x

Gross, J. J., & John, O. P. (2003). Individual differences in two emotion regulation processes: Implications for affect, relationships, and well-being. *Journal of Personality and Social Psychology*, *85*(2), 348–362. https://doi.org/10.1037/0022-3514.85.2.348

Gullone, E., & Taffe, J. (2012). The Emotion Regulation Questionnaire for Children and Adolescents (ERQ–CA): A psychometric evaluation. *Psychological Assessment*, *24*(2), 409–417. https://doi.org/10.1037/a0025777

Heck, N. C. (2015). The potential to promote resilience: Piloting a minority stress-informed, GSA-based, mental health promotion program for LGBTQ youth. *Psychology of Sexual Orientation and Gender Diversity*, *2*(3), 225–231. https://doi.org/10.1037/sgd0000110

Henry, D. B., Pavuluri, M. N., Youngstrom, E., & Birmaher, B. (2008). Accuracy of brief and full forms of the child mania rating scale. *Journal of Clinical Psychology*, *64*(4), 368–381. https://doi.org/10.1002/jclp.20464

Hidalgo, M. A., Petras, H., Chen, D., & Chodzen, G. (2019). The Gender Minority Stress and Resilience Measure: Psychometric validity of an adolescent extension. *Clinical Practice in Pediatric Psychology*, *7*(3), 278–290. https://doi.org/10.1037/cpp0000297

Hogendoorn, S. M., Wolters, L. H., Vervoort, L., Prins, P. J. M., Boer, F., Kooij, E., & de Haan, E. (2010). Measuring negative and positive thoughts in children: An adaptation of the Children's Automatic Thoughts Scale (CATS). *Cognitive Therapy and Research*, *34*(5), 467–478. https://doi.org/10.1007/s10608-010-9306-2

Joiner, T. E., Pfaff, J. J., & Acres, J. G. (2002). A brief screening tool for suicidal symptoms in adolescents and young adults in general health settings: Reliability and validity data from the Australian National General Practice Youth Suicide Prevention Project. *Behaviour Research and Therapy*, *40*(4), 471–481. https://doi.org/10.1016/S0005-7967(01)00017-1

Kaufman, J., Birmaher, B., Axelson, D., Perepletchikova, F., Brent, D., & Ryan, N. (2016). *Kiddie Schedule for Affective Disorders and Schizophrenia (KSADS-PL) DSM-5*.

Kaufman, J., Birmaher, B., Brent, D., Rao, U. M. A., Flynn, C., Moreci, P., Williamson, D., & Ryan, N. (1997). Schedule for affective disorders and schizophrenia for school-age children-present and lifetime version (K-SADS-PL): Initial reliability and validity data. *Journal of the American Academy of Child & Adolescent Psychiatry*, *36*(7), 980–988.

Kline, E., Thompson, E., Demro, C., Bussell, K., Reeves, G., & Schiffman, J. (2015). Longitudinal validation of psychosis risk screening tools. *Schizophrenia Research*, *165*(2–3), 116–122. https://doi.org/10.1016/j.schres.2015.04.026

LaFont, S. R., Brondolo, E., Dumas, A. K., Lynk, N. C., & Gump, B. B. (2018). The development and initial validation of the child perceived discrimination questionnaire. *International Journal of Culture and Mental Health*, *11*(2), 208–219. https://doi.org/10.1080/17542863.2017.1356337

Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., & Nguyen, T. D. (1979). Assessment of client/patient satisfaction: Development of a general scale. *Evaluation and Program Planning*, *2*(3), 197–207. https://doi.org/10.1016/0149-7189(79)90094-6

Lewin, A. B., Peris, T. S., Lindsey Bergman, R., McCracken, J. T., & Piacentini, J. (2011). The role of treatment expectancy in youth receiving exposure-based CBT for obsessive compulsive disorder. *Behaviour Research and Therapy*, *49*(9), 536–543. https://doi.org/10.1016/j.brat.2011.06.001

McKenzie, K., Murray, G., Murray, A., Delahunty, L., Hutton, L., Murray, K., & O'Hare, A. (2019). Child and Adolescent Intellectual Disability Screening Questionnaire to identify children with intellectual disability. *Developmental Medicine & Child Neurology*, *61*(4), 444–450. https://doi.org/10.1111/dmcn.13998

McKenzie, K., Paxton, D., Murray, G., Milanesi, P., & Murray, A. L. (2012). The evaluation of a screening tool for children with an intellectual disability: The Child and Adolescent Intellectual Disability Screening Questionnaire. *Research in Developmental Disabilities*, *33*(4), 1068–1075. https://doi.org/10.1016/j.ridd.2012.01.015

Metalsky, G. I., & Joiner, Jr., T. E. (1997). The Hopelessness Depression Symptom Questionnaire. *Cognitive Therapy and Research*, *21*(3), 359–384. https://doi.org/10.1023/A:1021882717784

Milgram, L., Tonarely, N. A., & Ehrenreich-May, J. (2021). Youth Top Problems and Early Treatment Response to the Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents. *Child Psychiatry & Human Development*. https://doi.org/10.1007/s10578-021-01151-4

Mohr, J., & Fassinger, R. (2000). Measuring dimensions of lesbian and gay male experience. *Measurement and Evaluation in Counseling and Development*.

Ord, L. M., Myles-Worsley, M., Blailes, F., & Ngiralmau, H. (2004). Screening for prodromal adolescents in an isolated high-risk population. *Schizophrenia Research*, *71*(2–3), 507–508. https://doi.org/10.1016/j.schres.2004.03.014

Pachankis, J. E., Sullivan, T. J., & Moore, N. F. (2018). A 7-year longitudinal study of sexual minority young men's parental relationships and mental health. *Journal of Family Psychology*, *32*(8), 1068–1077. https://doi.org/10.1037/fam0000427

Pavuluri, M. N., Henry, D. B., Devineni, B., Carbray, J. A., & Birmaher, B. (2006). Child Mania Rating Scale: Development, Reliability, and Validity. *Journal of the American Academy of Child & Adolescent Psychiatry*, *45*(5), 550–560. https://doi.org/10.1097/01.chi.0000205700.40700.50

Primakoff, L., Epstein, N., & Covi, L. (1986). Homework compliance: An uncontrolled variable in cognitive therapy outcome research. *Behavior Therapy*, *17*(4), 433–446. https://doi.org/10.1016/S0005-7894(86)80073-9

Robinson, M. (2014). *The Development of the Lesbian, Gay, Bisexual Affiliate Stigma Measure*. https://doi.org/10.7916/D8445JNP

Schniering, C. A., & Rapee, R. M. (2002). Development and validation of a measure of children's automatic thoughts: The children's automatic thoughts scale. *Behaviour Research and Therapy*, *40*(9), 1091–1109. https://doi.org/10.1016/S0005-7967(02)00022-0

Shenoi, R. P., Linakis, J. G., Bromberg, J. R., Casper, T. C., Richards, R., Mello, M. J., Chun, T. H., Spirito, A., & PEDIATRIC EMERGENCY CARE APPLIED RESEARCH NETWORK. (2019). Predictive Validity of the CRAFFT for Substance Use Disorder. *Pediatrics*, *144*(2), e20183415. https://doi.org/10.1542/peds.2018-3415

The Center for Adolescent Behavioral Health Research. (2020). *The CRAFFT 2.1 manual*. Boston Children's Hosptial.

Toomey, R. B., Ryan, C., Diaz, R. M., & Russell, S. T. (2018). Coping With Sexual Orientation–Related Minority Stress. *Journal of Homosexuality*, *65*(4), 484–500. https://doi.org/10.1080/00918369.2017.1321888

Topp, C. W., Østergaard, S. D., Søndergaard, S., & Bech, P. (2015). The WHO-5 Well-Being Index: A Systematic Review of the Literature. *Psychotherapy and Psychosomatics*, *84*(3), 167–176. https://doi.org/10.1159/000376585

Vogel, P. A., Hansen, B., Stiles, T. C., & Götestam, K. G. (2006). Treatment motivation, treatment expectancy, and helping alliance as predictors of outcome in cognitive behavioral treatment of OCD. *Journal of Behavior Therapy and Experimental Psychiatry*, *37*(3), 247–255. https://doi.org/10.1016/j.jbtep.2005.12.001

Warrier, V., Greenberg, D. M., Weir, E., Buckingham, C., Smith, P., Lai, M.-C., Allison, C., & Baron-Cohen, S. (2020). Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals. *Nature Communications*, *11*(1), 3959. https://doi.org/10.1038/s41467-020-17794-1

Weisz, J. R., Chorpita, B. F., Frye, A., Ng, M. Y., Lau, N., Bearman, S. K., Ugueto, A. M., Langer, D. A., Hoagwood, K. E., & The Research Network on Youth Mental Health. (2011). Youth top problems: Using idiographic, consumer-guided assessment to identify treatment needs and to track change during psychotherapy. *Journal of Consulting and Clinical Psychology*, *79*(3), 369–380. https://doi.org/10.1037/a0023307

Whiteside, S. P. H., Gryczkowski, M., Ale, C. M., Brown-Jacobsen, A. M., & McCarthy, D. M. (2013). Development of child- and parent-report measures of behavioral avoidance related to childhood anxiety disorders. *Behavior Therapy*, *44*(2), 325–337. https://doi.org/10.1016/j.beth.2013.02.006

World Health Organization: Regional Office for Europe. (1998). *Well-Being measures in primary health care: The DepCare Project*.

Zeman, J. L., Cassano, M., Suveg, C., & Shipman, K. (2010). Initial Validation of the Children's Worry Management Scale. *Journal of Child and Family Studies*, *19*(4), 381–392. https://doi.org/10.1007/s10826-009-9308-4

Zeman, J., Shipman, K., & Penza-Clyve, S. (2001). Development and initial validation of the Children's Sadness Management Scale. *Journal of Nonverbal Behavior*, *25*(3), 187–205. https://doi.org/10.1023/A:1010623226626

Zimet, G. D., Dahlem, N. W., Zimet, S. G., & Farley, G. K. (1988). The Multidimensional Scale of Perceived Social Support. *Journal of Personality Assessment*, *52*(1), 30–41. https://doi.org/10.1207/s15327752jpa5201_2

5 Study Participants

5.1 Study Population

The study population will consist of participants with internalizing disorders of mild to moderate severity who identify as LGBTQ, are 12-17 years of age, are fluent in English, and who live in New York, New Jersey, or Connecticut. Parents/legal guardians of these youth will also participate in pre-intervention and post-intervention assessments.

This intervention, and the treatments on which this intervention is based, was developed for the treatment of internalizing disorders, and thus eligible participants must meet criteria for anxiety, depression, or another internalizing disorder. Participants with severe internalizing disorders will be provided with referral information and excluded due to safety concerns and the need for more intensive intervention services.

This age group was selected due to the lack of interventions that have been adapted and tested for LGBTQ youth in adolescence, particularly in the 12-14 years age group. Moreover, this is a period during which internalizing psychopathology may emerge, making youth in this age range important targets for intervention.

These three US states were selected to allow for regional and geographic similarities between participants' locations (and thus potentially increase group rapport), to facilitate logistical aspects of the study (e.g., same time zone for all participants), and to aid in risk mitigation as needed, given the clinical nature of the sample (i.e., team has greater familiarity with local emergency services in these states). This geographic restriction might limit the generalizability of this intervention to LGBTQ adolescents in other parts of the US and world; however, as the goal of this pilot is to examine the feasibility and acceptability of the intervention in a small sample of diverse LGBTQ youth, we believe that this geographic restriction allows for diversity in participants while also limiting logistical barriers and mitigating risk.

5.2 Number of Participants

A total of 20 LGBTQ youth (aged 12-17 years) and their parents will be selected to participate in this study.

Given the numerous inclusion criteria, we anticipate needing to screen up to 100 participants in order to reach our target enrollment.

5.3 Eligibility Criteria

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

- 12-17 years old
- Self-identify as LGBTQ (any diverse sexual orientation and/or gender identity)
- Live in New York, New Jersey, or Connecticut
- Fluent in English

- Meet diagnostic criteria for a DSM-5 internalizing disorder (any depressive, anxiety, obsessive-compulsive, or adjustment disorder)
- Have consistent, weekly access to an Internet-enabled electronic device that allows for video-conferencing
- Availability to attend 10 weekly 90 minute intervention sessions in summer 2021
- Access to a quiet, private place for intervention sessions
- Provision of informed consent from parent/guardian and assent from the youth

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

- Evidence of any psychotic or bipolar spectrum diagnosis
- Active suicidality and/or homicidality (defined as active intent or concrete plan, as opposed to passive ideation) or psychiatric hospitalization within the past 6 months
- Significant cognitive impairment (as determined by an intellectual disability screener [CAIDS-Q]) or significant developmental disorder (if impairing youth's ability to participate in group therapy)
- Significant behavior disorder (e.g., oppositional defiant disorder, conduct disorder) if impairing youth's ability to participate in group therapy
- Received any cognitive-behavioral therapy treatment in the past 12 months
- Unstable psychotropic medications (defined as changes to antidepressant dosage in the past 3 months, or changes to a benzodiazepine dosage in the past month)

The virtual group sessions will exclude non-English speaking participants due to the need for participants to understand both the group facilitator and each other. As existing research highlights transportation as a key barrier to accessing services for economically disadvantaged LGBTQ youth (Zullo, Seager van Dyk, et al., 2021), the virtual format of the sessions could make the study more accessible to these youth. However, as participants will require a video-conferencing capable electronic device in order to participant, some economically disadvantaged potential participants will be excluded. Future trials might consider the addition of video-enabled e-tablets for youth and families without access.

5.4 Recruitment Procedures

Recruitment strategy: Potential participants will be identified through responses to study advertisements posted widely online. Advertisements will be shared through social media (e.g., Facebook, Instagram, Twitter), our lab's website, online search engines (e.g., Google Ads), and emails to local LGBTQ-related organizations, clinics, and listservs (e.g., Yale Gender Clinic, Kaleidoscope). Advertisements will attempt to target both eligible LGBTQ youth and their parent/caregivers, and will include a link to a Qualtrics-hosted screening survey (separate links for youth and parent/caregivers), as well as basic information about the study design. Advertisements will refer to the intervention and study as "EQuIP (Empowering Queer Identities in Psychotherapy)" to 1) be consistent with previous studies of this intervention that also used this branding, and 2) aid potential participants in remembering the name of the study during the recruitment process.

Screening: Once potential participants navigate to the screening survey on Qualtrics, they will view one of two screens.

- If the potential participant is a youth, they will be notified that their parent or parent/caregiver must provide parental permission/consent in order for them to proceed. Youth will also be informed that during the consent process, their parent/caregiver will learn that this study is for LGBTQ youth, so that youth can make an informed decision about whether to share the link with their

parent/caregiver (particularly if their parent does not know about their LGBTQ status). They will be instructed to share the link to the parent/caregiver screening survey with their parent/caregiver at this time if they would like to continue with the screening process.

- If the potential participant is a parent/caregiver, they will be asked to confirm that they have the legal right to consent for their child's participation in research studies and/or medical/psychological care. If the participant confirms, they will view an online consent form and parental permission form for the screening process (details provided in section 5.5).

If the parent/caregiver provides informed consent and parental permission for the screening process, they will then be asked to provide information about their child to assess eligibility, including the child's age, pertinent demographics, residency in New York, New Jersey, or Connecticut, availability to participate in study procedures, and mental health symptoms. If the parent/caregiver's responses to screening questions suggest their child is NOT eligible for the study, they will be thanked for their time and the survey will discontinue. If the parent/caregiver's responses to screening questions suggest their child may be eligible for the study, they will be asked to provide both their own contact information (name, email address, phone number, physical address), as well as contact information for their child. The parent/caregiver will be directed to a separate online survey to provide this contact information for themselves and their child. A link to the youth version of the screening survey will be subsequently emailed to the youth.

When the youth navigates to the screening survey, they will view an assent form for the screening process (details provided in section 5.5). If youth provide informed assent, they will be asked to complete questions to assess eligibility, including their LGBTQ status, pertinent demographics, availability to participate in study procedures, and mental health symptoms. Once youth complete this survey, they will be informed that based on their survey responses either 1) they are ineligible for the study, or 2) they may be eligible for the study, pending a phone screen with a study team member.

Study team members will review responses to the screening survey to identify potentially eligible participants. If a youth appears to meet study criteria (as documented in Section 5.3), including mental health symptoms on the RCADS-P or -C with a T-score of 65 or more (suggesting they likely meet diagnostic criteria for a DSM-5 internalizing disorder), the study team member will reach out to the child and their parent (by phone and/or email) to schedule a one-hour call (Zoom or phone) for a brief diagnostic interview with Dr. Seager van Dyk (postdoctoral fellow).

During the one-hour call, Dr. Seager van Dyk will administer relevant modules from the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), in order to confirm the youth meets diagnostic criteria for a DSM-5 internalizing disorder. If the youth does not meet diagnostic criteria for a DSM-5 internalizing disorder, the youth and parent will be informed that they do not meet eligibility criteria for the study, provided with a list of LGBTQ resources (including mental health resources) for youth, and the call will be concluded. If the youth does meet diagnostic criteria for a relevant disorder, the study team member will spend the rest of the call conducting the consent/assent process (described in Section 5.5).

5.5 Consent/Assent Procedures/HIPAA Authorization

Consent, assent, and parental permission will be obtained online via the secure Yale Qualtrics survey software. As such, a waiver of documentation of consent is planned for this

study. The PI will be responsible for ensuring that online consent, assent, and parental permission has been obtained appropriately.

Given the sensitivity associated with disclosing LGBTQ status to parents/caregivers, particularly among youth who rely on their parent/caregivers for basic necessities (e.g., shelter, clothing, food), as well as the high likelihood of some youth selectively disclosing their LGBTQ status to one parent/caregiver but not the other (as is developmentally appropriate), we will only require one parent/caregiver to provide parental permission for their child to participate in this study. However, if any parent/caregiver with the appropriate legal authority requests that the child be removed from the study, their wishes will be respected.

Screening: As previously described, potential participants will first complete an initial screening to determine their eligibility for the study. Before potential youth participants provide any information, they will be directed to send their parent/caregiver a link to a consent and parental permission form (hosted online via Qualtrics). Parents/caregivers will be first asked the following question:

- Do you have the legal right to consent for your child's participation in research studies and/or medical/psychological care? (i.e., parental rights, guardianship rights).
    - YES, I confirm I have the legal right to provide consent for my child.
    - NO, I do NOT have the legal right to provide consent for my child.

If the parent/caregiver selects YES, they will view an online consent form and parental permission form for the screening process. Parents/caregivers will be informed on the consent and parental permission forms about all steps of the screening process (caregiver and youth questionnaires, as well as a phone or Zoom call to determine eligibility), as well as related risks and benefits. Parents/caregivers will be informed that participation in the screening process does not guarantee inclusion in the intervention study, and that they have the option to participate or decline participation in the study (see attachments on IRES for online consent form). Parents/caregivers will be informed that both youth and parent/caregiver participation is required during the screening process (i.e., if the parent/caregiver elects not to provide parental permission for their child to participate in the screening but consents for their own participation, the screening will not proceed because youth input is vital for determining eligibility). Parents/caregivers will be provided with the PI's contact information and directed to call or email the PI if they have any questions or concerns. Parents/caregivers will be informed that participation is voluntary and that they may withdraw from the study at any time, without penalty. A copy of the informed consent document will be given to the parent/caregiver for their records. Parents/caregivers will be required to check two of the following boxes before moving on to the rest of the screening questions:

- On the consent form screen:
    - 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.
    - NO. I do NOT agree to participate in this online study.
- On the parental permission form screen:
    - YES. I have read the above information. The study has been explained to me. My questions have been answered. I VOLUNTARILY AGREE to provide permission for my child to be in this study.
    - NO. I do NOT agree to provide permission for my child to be in this study.

If the parent/caregiver's responses to screening questions suggest their child may be eligible for the study, they will be asked to provide both their own contact information (name, email address, phone number, physical address), as well as contact information for their child. The parent/caregiver will be directed to a separate online survey to provide this contact information for themselves and their child. A link to the youth version of the screening survey will be subsequently sent to the youth. Assent will be obtained. A written explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Youth will be provided the same information as was given to parent/caregivers during the consent/parental permission process, using developmentally appropriate language.

Intervention Study: As described above, if youth are determined during the screening process to be eligible for the study, study team members will obtain informed consent, assent, and parental permission during a call (Zoom or phone) with both the youth and parent/caregiver. The study team member will review the consent, assent, and permission forms with the youth, along with the main study components (e.g., assessment timepoints, format of the intervention, timing of the intervention sessions). Copies of the consent, assent, and permission forms will be provided electronically to the youth and parent during the meeting for them to review in detail.

Potential participants will be informed on these forms that the youth will receive $30 for completing the pre-intervention survey, $5 for each weekly survey they complete after each intervention session (up to a total of 10 sessions = $50), $30 for completing the post-intervention survey, and $30 for completing a post-intervention one-hour exit interview (total = $140). In addition, parent/caregivers will be informed that they will receive $30 for completing the parent/caregiver version of the pre-intervention survey, and $30 for completing the parent/caregiver version of the post-intervention survey (total = $60). 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."

Youth and parents/caregivers will be given the opportunity to ask questions, and risks and benefits of participation will be reviewed. They will be provided with the PI's contact information and directed to call or email the PI if they have any questions or concerns. Youth and parent/caregivers will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records.

Once potential participants have made a decision with regard to their participation in the study, they will be asked to provide verbal consent, assent, and parental permission to the study member conducting the consent process. The study member will document the date and time of consent, assent, and permission. In addition, youth and parent/caregiver will be provided with a link to a Qualtrics survey containing the consent, assent, and parental permission forms, where they will be asked to select from the following options:

- On the consent and assent form screens:
  - 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.
  - NO. I do NOT agree to participate in this study.
- On the parental permission form screen:
  - YES. I have read the above information. The study has been explained to me. My questions have been answered. I VOLUNTARILY AGREE to provide permission for my child to be in this study.
  - NO. I do NOT agree to provide permission for my child to be in this study.

Upon providing consent/permission/assent for the study, participants will be asked if they have access to headphones/ear buds or the equivalent for use during the Zoom sessions. If not, the study team will mail headphones/ear buds to the participant to ensure that all participants have the ability to participate while maintaining both their confidentiality and that of the other participants. During the consent process, we will also indicate that youth will be able to pick a username that they will be known by during the Zoom sessions. This can be any name they want, including their affirmed first name (last names will not be allowed, nor will any other names that clearly identify the youth; e.g., phone number or address). The goal of using a username is to protect their privacy, so youth will be informed that using their legal name introduces some risk to their confidentiality. Youth will be kept in the Zoom waiting room until their study username is displayed. Youth will be reminded of their study username by email a few days before the first session, and will be provided instructions about how to change their username.

Youth participants who reach the age of majority (18 years) during the course of the study: Participants must be 12-17 years of age to participate in the intervention phase of the study (see eligibility criteria). However, if participants turn 18 during the post-intervention assessment phase, they will be reconsented to the study using the appropriate consent form before assessments are completed. Specifically, a study team member will arrange a phone or Zoom call with the participant to review the consent form, provide copies of the consent form to the participant, and answer any questions the participant may have. As during the previous consent process, they will be asked to provide verbal consent (which the team member will document) as well as indicate their consent in an online version of the consent form (hosted on Qualtrics) using the options provided above. If the participant decides not to reconsent to the study, they will no longer be contacted for assessments.

6 Study Methods/Procedures

6.1 Study Procedures

This mixed methods prospective study is designed to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive behavior therapy for youth aged 12-17 years in New York, New Jersey, and Connecticut. To achieve this goal, two 10-week LGBTQ-affirmative CBT groups with LGBTQ youth will be conducted (content of the intervention is described further in Section 4, Study Design).

The study population will consist of participants with internalizing disorders of mild to moderate severity who identify as LGBTQ, are 12-17 years of age, are fluent in English, and who live in New York, New Jersey, or Connecticut. Parents/legal guardians of these youth will also participate in screening, pre-intervention and post-intervention assessments.

Recruitment: Potential participants will be identified through responses to study advertisements posted widely online. Advertisements will be shared through social media (e.g., Facebook, Instagram, Twitter), our lab's website, online search engines (e.g., Google Ads), and emails to local LGBTQ-related organizations, clinics, and listservs (e.g., Yale Gender Clinic, Kaleidoscope). Advertisements will attempt to target both eligible LGBTQ youth and their parent/caregivers, and will include a link to a Qualtrics-hosted screening survey (separate links for youth and parent/caregivers), as well as basic information about the study design.

Screening: Once potential participants navigate to the screening survey on Qualtrics, they will view one of two screens.

- If the potential participant is a youth, they will be notified that their parent or parent/caregiver must provide parental permission/consent in order for them to proceed. Youth will also be informed that during the consent process, their parent/caregiver will learn that this study is for LGBTQ youth, so that youth can make an informed decision about whether to share the link with their parent/caregiver (particularly if their parent does not know about their LGBTQ status). They will be instructed to share the link to the parent/caregiver screening survey with their parent/caregiver at this time if they would like to continue with the screening process.
- If the potential participant is a parent/caregiver, they will be asked to confirm that they have the legal right to consent for their child's participation in research studies and/or medical/psychological care. If the participant confirms, they will view an online consent form and parental permission form for the screening process (details provided in section 5.5).

If the parent/caregiver provides informed consent and parental permission for the screening process, they will then be asked to provide information about their child to assess eligibility, including the child's age, pertinent demographics, residency in New York, New Jersey, or Connecticut, availability to participate in study procedures, and mental health symptoms. If the parent/caregiver's responses to screening questions suggest their child is NOT eligible for the study, they will be thanked for their time and the survey will discontinue. If the parent/caregiver's responses to screening questions suggest their child may be eligible for the study, they will be asked to provide both their own contact information (name, email address, phone number, physical address), as well as contact information for their child. The parent/caregiver will be directed to a separate online survey to provide this contact information for themselves and their child. A link to the youth version of the screening survey will be subsequently sent to the youth.

When the youth navigates to the screening survey, they will view an assent form for the screening process (details provided in section 5.5). If youth provide informed assent, they will be asked to complete questions to assess eligibility, including their LGBTQ status, pertinent demographics, availability to participate in study procedures, and mental health symptoms. Once youth complete this survey, they will be informed that based on their survey responses either 1) they are ineligible for the study, or 2) they may be eligible for the study, pending a phone screen with a study team member.

Study team members will review responses to the screening survey to identify potential participants. If a potential youth participant appears to meet study criteria (as documented in Section 5.3), including mental health symptoms on the RCADS-P or -C with a T-score of 65 or more (suggesting they likely meet diagnostic criteria for a DSM-5 internalizing disorder), the study team member will reach out to the child and their parent (by phone and/or email) to schedule a one-hour call (Zoom or phone) for a brief diagnostic interview with Dr. Seager van Dyk (lead postdoctoral associate).

During the one-hour call, Dr. Seager van Dyk will administer relevant modules from the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), in order to confirm the youth meets diagnostic criteria for a DSM-5 internalizing disorder. If the youth does not meet diagnostic criteria for a DSM-5 internalizing disorder, the youth and parent will be informed that they do not meet eligibility criteria for the study, provided with a list of LGBTQ resources (including mental health resources) for youth, and the call will be concluded. If the youth does meet diagnostic criteria for a relevant disorder, the study team member will spend the rest of the call conducting the consent/assent process (described in Section 5.5).

Pre-intervention assessment: Within two weeks of the first intervention session, youth and their parent/caregiver will be sent a link to the pre-intervention assessment survey via Qualtrics. This consists of a number of measures to assess constructs relevant to the primary and secondary objectives of the study (see 4.2 for full list of measures). Youth will then be assigned to one of two intervention groups based on the timing of their enrollment (i.e., participants who enroll in fall 2021 will be assigned to the first group, participants who enroll in winter/spring 2022 will be assigned to second group).

Intervention: Each week for ten weeks, youth participants will attend a 90-minute group therapy session via Zoom. Participants will be taught intervention content (see Session Outlines document uploaded in IRES for more details) through a range of teaching modalities including use of the Zoom whiteboard feature, videos, interactive activities, worksheets, and group discussion. The intervention will be delivered by Dr. Seager van Dyk, who has experience counseling LGBTQ teenagers and who has received training in the intervention from the PI (who developed LGBTQ-affirmative CBT), with support from the study team. To ensure fidelity to the intervention model, Dr. Seager van Dyk will engage in clinical supervision with the PI throughout the course of the intervention, and any inadequate fidelity to the intervention model will be addressed during these supervision meetings. All sessions will be audio-recorded for supervision purposes, and audio recordings will be saved in a secure Yale Box folder. Due to the need for clinical supervision given the pilot nature of this intervention, audio recording will be a mandatory aspect of the study. Participants and their parent/caregiver will be informed of this requirement during the informed consent process.

Weekly assessments: Following each intervention session, youth participants will be sent a brief survey to evaluate the acceptability, feasibility, and need for refinement of each intervention session. Participants will also complete brief mental health measures each week to address the study's secondary objective. Participants will be asked to submit an electronic copy (e.g., PDF, photo) of any completed home practice assignments to the study team via Yale's Secure File Transfer, in order to evaluate the acceptability of these assignments. Study staff will de-identify all home practice materials before saving them in a secure Yale Box folder with the participant's study ID number. For the first two weekly assessments, a study team member will call the youth participant to ensure that they understand all the survey questions and to ensure that responses via both modalities (i.e., phone, online survey) are consistent.

Post-intervention assessment: Post-intervention assessment measures will be sent to youth participants and their parent/caregiver immediately following the last intervention session, and will be available for three weeks (see 4.2 for full list of measures).

Exit interview: Once all other study tasks are complete, exit interviews will be conducted with youth via Zoom/phone to assess the feasibility, acceptability, and need for refinement of the intervention. See Measure Packet uploaded in IRES for exit interview content.

Unscheduled visits: We do not anticipate any unscheduled intervention visits outside of the regularly scheduled group therapy sessions. However, in the event that participants indicate suicidality on any of the assessment surveys, the clinical protocol for our lab will be initiated (as described in 6.4), which requires a study team member to reach out to the participant via phone or Zoom to complete a safety assessment. In addition, if a youth participant does not show up to their scheduled visit, a study team member will contact the participant and/or their parent/legal guardian by phone/Zoom to assess barriers to attendance

Visit Schedule

C = Child P = Parent T = Therapist	**Screening surveys** Day -14 to 0	**Diagnostic interview / Consent Call** Day 1	**Pre-intervention** Day 14 ± 7	**Session 1** Day 28 ± 7	**Session 2** Day 35 ± 7	**Session 3** Day 42 ± 7	**Session 4** Day 49 ± 7	**Session 5** Day 56 ± 7	**Session 6** Day 63 ± 7	**Session 7** Day 70 ± 7	**Session 8** Day 77 ± 7	**Session 9** Day 84 ± 7	**Session 10** Day 91 ± 7	**Post-intervention** Day 91 ± 21	**Exit interview** Day 98 ± 42
Consent / Assent / Permission	C, P	C, P													
Background Information															
Demographics	C, P														
Gender Unicorn			C											C	
Parent-Child Relationship			P											P*	
FAD			C, P											C, P	
Acceptability															
Treatment Expectations			C												
Top Problems Assessed				C											
Top Problems Tracking					C	C	C	C	C	C	C	C	C	C	
CSQ-8								C						C, P	
Acceptability of session				C	C	C	C	C	C	C	C	C	C		
AFFIRM Acceptability														C, P	
Format/delivery/content															C
Feasibility															
Session Attendance				T	T	T	T	T	T	T	T	T	T		
Homework Compliance				T	T	T	T	T	T	T	T	T	T		
Feasibility of Session				C	C	C	C	C	C	C	C	C	C		
Feasibility of Program														P	C
Need for Refinement															
Session Refinement				C	C	C	C	C	C	C	C	C	C		

Program Refinement														P	C
Mental Health															
KSADS		C, P													
RCADS - Long	C, P		C, P											C, P	
RCADS - Short				C	C	C	C	C	C	C	C	C	C		
DSI-SS		C	C	C	C	C	C	C	C	C	C	C	C	C	
SDQ			C, P											C, P	
WHO-5 Well-Being Index			C											C	
CRAFFT 2.1			C											C	
AQ-10			P												
YPARQ-B	C														
CMRS-P	P														
CAIDS-Q	P														
Minority Stress															
GMSR-A			C											C	
CPDQ			C											C	
Outness Inventory (OI)			C											C	
LGB-ASM			P											P	
Parent Rejection			C, P											C, P	
Emotional Regulation & Coping															
CEMS			C, P											C, P	
ERQ-CA			C											C	
CAMS/CAMP			C, P											C, P	
CATS			C											C	
Minority Stress Coping			C											C	
MSPSS			C											C	

Note. *Question 6 only. Parent-Child Relationship = General Parent-Child Relationship Questions. FAD = Family Assessment Device — General Functioning subscale. CSQ-8 = Client Satisfaction Questionnaire-8. KSADS = Kiddie Schedule for Affective Disorders and Schizophrenia. RCADS = Revised Children's Anxiety and Depression Scale. DSI-SS = Depressive Symptom Index - Suicidality Subscale. SDQ = Strengths and Difficulties Questionnaire. AQ-10 = Autism

Quotient-10. YPARQ-B = Youth Psychosis At-Risk Questionnaire – Brief. CMRS-P = Brief Child Mania Rating Scale - Parent Version. CAIDS-Q = Child & Adolescent Intellectual Disability Screening Questionnaire. GMSR-A = Gender Minority Stress and Resilience measure – Adolescent. CPDQ = Child Perceived Discrimination Questionnaire. LGB-ASM = Lesbian, Gay, Bisexual Affiliate Stigma Measure. Parent Rejection = Parental Rejection/Acceptance of LGBTQ child. CEMS = Children's Emotion Management Scales. ERQ-CA = Emotion Regulation Questionnaire for Children and Adolescents. CAMS/CAMP = Child Avoidance Measure Self / Parent. CATS = Children's Automatic Thoughts Scale - N/P version. Minority Stress Coping = Coping with Sexual Orientation-Related Minority Stress. MSPSS = Multidimensional Scale of Perceived Social Support.

6.1.1 Data Collection

All survey-based data collection will occur online via the secure Yale Qualtrics survey software. Such data collection will begin with the initial online screening surveys, to be completed by both parent/caregiver and the potential youth participant. Specific details about the contents of the screening surveys are provided elsewhere in this document; briefly, questions pertaining to the inclusion and exclusion criteria for this study will be asked in order to determine eligibility for the study. In addition, identifiable contact information (including parent/caregiver and youth name, email address, physical address and phone number) will be collected in these screening surveys in order to facilitate contacting participants for the diagnostic interview stage of the screening process. If, after the parent/caregiver completes their screening survey, it is clear that their child will not be eligible for the study, no contact information will be requested, in order to maximize potential participant confidentiality.

After participants have completed the screening surveys through Qualtrics, a study team member will reach out potentially eligible participants (by phone and/or email) to schedule a one-hour call (Zoom or phone) for a brief diagnostic interview with Dr. Seager van Dyk (lead postdoctoral associate). Dr. Seager van Dyk will administer relevant modules from the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS), in order to confirm the youth meets diagnostic criteria for a DSM-5 internalizing disorder. Administration of the K-SADS requires advanced training, which Dr. Seager van Dyk received from a doctoral-level supervisor in a prior role. She has 6 years of experience administering the K-SADS to more than 100 youth and their families. Dr. Seager van Dyk will record the youth and parent responses to the interview questions on a separate PDF copy of the KSADS for each participant, which will be saved after the interview on a secure Yale Box folder. In addition, diagnostic findings of the KSADS will be recorded in a de-identified spreadsheet saved in a secure Yale Box folder.

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 time points in the study. A master link file will connect participant names, phone numbers, email addresses, and physical addresses to their study code number. The link file will be password protected and only accessible to the study team as required for study tasks (e.g., providing participants with intervention-related materials). All data collection materials will be stored on password-protected folders on Yale Secure Box that requires dual-factor authentication to access.

Pre-intervention assessment measures will be sent to youth participants and their parents via Qualtrics within two weeks of the first intervention session.

All intervention sessions will be audio-recorded for supervision purposes, and audio recordings will be saved in a secure Yale Box folder. De-identified transcripts will be created of the interview data (also saved on Box).

Weekly assessments will be sent via Qualtrics to youth immediately following each intervention session. In addition, the study therapist (Dr. Seager van Dyk) will complete a weekly post-intervention Qualtrics survey tracking each participant's attendance and homework compliance for the previous week. Participants will be asked to submit an electronic copy (e.g., PDF, photo) of any completed home practice assignments to the study team via Yale's Secure File Transfer, in order to evaluate the acceptability of these assignments. Study staff will de-identify all home practice materials before saving them in a secure Yale Box folder with the participant's study ID number. In line with the clinical protocol, home practice assignments will be reviewed by the study team within 24 hours or the next business day to assess for any report of harm to self or others.

Post-intervention assessment measures will be sent to youth participants and their parents immediately following the last intervention session, and will be available for three weeks. None of the measures in these surveys require licensure for their administration. All measures can be found in the "Measures Packet" uploaded with the study protocol.

Exit-interviews will be conducted via Zoom following the completion of the last intervention session and the post-intervention assessment. Audio recordings of the exit-interviews will be saved in a secure Yale Box folder, and transcripts will be created of the interview data (also saved on Box). Following the verification of the transcripts, the original audio files of the interviews will be deleted, and the transcripts will be de-identified.

The study participant's contact information will be securely stored for internal use 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 identifiable records for the study will be destroyed.

6.2 Method of Assignment/Randomization (if applicable)

Participants will be assigned to groups based on the timing of their enrollment (i.e., participants who enroll in fall 2021 will be assigned to the first group, participants who enroll in winter/spring 2022 will be assigned to second group). In the event that more participants screen eligible for the study than is needed, priority will be given to participants who represent a diverse cross-section of identity groups (e.g., diverse sexual orientation, gender identity, race, ethnicity).

6.3 Adverse Events Definition and Reporting

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans. 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 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 investigator will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project (e.g., through regular study meetings, via email as they are reviewed by the principal investigator.)

6.4 Reaction Management

Participants will be reminded that they can stop participation at any time, skip any question, or take a break if experiencing mild distress during the assessments or during the intervention sessions. In the unlikely event that a participant experiences considerable distress, the study team will initiate our lab's clinical protocol, attached to this proposal, which provides concrete steps for team members to take if a participant expresses suicidality, homicidality, emotional distress, violent/aggressive or disruptive behavior, intoxication, and/or suspected abuse or maltreatment. Research team members will receive training in this protocol from Dr. John Pachankis, a licensed clinical psychologist. This training will address the appropriate handling of imminent threats/concerns and provision of referrals to free counseling services in less imminent clinical situations. Identified clinically trained study team members (e.g., Drs. Seager van Dyk, Soulliard, Pachankis) will be on call for emergency consultation.

6.5 Withdrawal Procedures

Participants will be able to withdraw from the study at any point. The consent forms 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 intervention sessions, assessments, and online surveys will be completed from the participants' personal electronic devices (e.g., phones, tablets, or computers). All intervention and assessment sessions will be conducted via the PI or postdoctoral researchers' Yale-affiliated HIPAA compliant Zoom video-conferencing accounts and require a passcode to enter. All measures will be conducted utilizing the secure Yale Qualtrics online survey software. The project is housed within the PI's lab, which is physically located at 220 East 23rd Street, New York, NY 10010.

7 Statistical Design

7.1 Sample Size Considerations

This pilot study is powered to assess the feasibility, acceptability, and need for refinement of LGBTQ-affirmative cognitive behavioral therapy adapted for youth. As was determined in prior studies in our lab (e.g., ESTEEM-conneCT; see IRB #2000022422), two groups is the minimum possible number of groups needed to gain this information. In line with prior studies in the lab, as well as the PI's and postdoctoral associate's clinical experience delivering psychotherapy groups, 10 participants per group is an ideal number of group members to facilitate optimal learning and information exchange.

Our primary analysis plan involves 1) analysis of qualitative interviews with participants to gather feedback necessary for future testing and implementation and 2) quantitative analyses appropriate for estimating effect sizes necessary to power future trials. We are recruiting 20 youth to participate in the pilot study to generate sufficient depth and breadth of qualitative data. Drawing from similar research in the field, we estimate that 20 participants will allow us to gather data until saturation is reached and no new data will be introduced through further interviews. The quantitative data gathered from the 20 participants and their parents/guardians at pre-intervention, after weekly intervention sessions (youth only), and post-intervention will provide preliminary data to guide a future trial with a larger sample population.

7.2 Planned Analyses

For the primary study objective (assessing the feasibility, acceptability, and need for refinement of the intervention), all participants' qualitative and quantitative data will be analyzed. Qualitative exit interview data will be analyzed using an inductive approach to identify factors that might have increased and decreased the feasibility and acceptability of the intervention, as well as identify parts of the intervention that need refinement. Quantitative data (see Visit Schedule for summary of all available data related to feasibility, acceptability, and need for refinement at each timepoint) will be examined descriptively (e.g., means, standard deviations, proportions where appropriate), both within participants (e.g., plots of each participant's feasibility, acceptability, and need for refinement data over the 10 weekly sessions) and across participants. We will also examine whether there are differences in responses by age in average acceptability, feasibility, and need for refinement of each session separately and the intervention as a whole (e.g., descriptives, t-tests).

7.2.1 Secondary Objective Analyses (if applicable)

For the secondary study objective (investigating whether youth's mental health symptoms, minority stress reactions, and emotional regulation and coping difficulties reduce over the course of the intervention), all participants' quantitative responses to questionnaires addressing these topics will be examined for change over time (e.g., paired-sample t-tests

comparing pre-intervention scores to post-intervention scores) in order to provide preliminary data to guide a future trial with a larger sample population. In addition, descriptive analyses will be run (e.g., means, standard deviations).

7.2.2 Analysis of Subject Characteristics (if applicable)

We will collect demographic data about youth participants and their parents, including age, ethnicity, sex assigned at birth, gender identity, sexual orientation, education level, marital/relationship status (for parents), and family income. A complete list of all demographic variables is presented in the attached measures packet. All 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 assess the feasibility, acceptability, and need for refinement of an LGBTQ-affirmative therapy adapted for youth. The data that we will collect in this study is highly relevant to our primary objective. We will measure youth-reported acceptability of each session's content, format, and facilitation; youth-rated feasibility of weekly home practice components and delivery mechanism; youth-reported suggestions for intervention refinement each week; and parent-rated intervention acceptability, feasibility, and suggestions for refinement at the end of the intervention program. In addition to this self- and parent-report data, we will also obtain objective measures of intervention feasibility by tracking session attendance, home practice completion, and technical difficulties. Finally, in alignment with our secondary objective to assess whether youth's mental health symptoms, minority stress reactions, and emotional regulation and coping difficulties reduce over the course of the intervention, youth and their parents will complete quantitative questionnaires related to these topics at both pre-intervention and post-intervention timepoints. All data collected as part of this study is highly relevant to our research questions.

7.4 Data Coding

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

Qualitative data from the exit interviews and feedback forms will be analyzed using an inductive approach.

7.5 Data Analysis Tools

Data will be managed and analyzed utilizing SPSS Statistics.

7.6 Data Monitoring

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

7.7 Handling of Missing Data

Given the small sample size (N = 20), the use of qualitative data, and the primarily descriptive nature of these analyses, no imputation methods will be used to account for missing data. All available data will be analyzed, and no cases will be dropped.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Participant confidentiality 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 IRB may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.

To ensure confidentiality, participant names and contact information (e.g., email address, phone number, physical address), which will only be recorded during the initial online screener and on consent/assent forms, will be kept separate from all other data. All data will be collected via the secure Qualtrics survey server and via Zoom (for assessments and intervention sessions). Participants will be assigned a unique code number after consenting to the screening phase of the study, as well as a separate unique code after selection to enroll in the intervention phase of the study. The use of these unique codes will permit linkage of the data being collected across all time points in the study. A master link file will connect participants' names and contact details to their study code number. The link file will be password-protected and only accessible to the PI and study team members. The link file will be stored separately from the rest of participants' data in a separate Yale Secure Box folder. Upon collection of the study data, de-identified data 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 and stored on password-protected computers by the study team.

Breaches of confidentiality will occur if a participant reports a clear intention to harm themselves or another person. Health care professionals are required by state law to report suspected cases of abuse or neglect. Breach of confidentiality can also occur if participants in this group-based intervention disclose information about participants to outside parties. Participants will be informed during the consent process that any information shared during group sessions may be discussed outside of the intervention, although study staff will encourage participants to respect each other's confidentiality. During the consent process, we will indicate that youth will be able to pick a username that they will be known by during the Zoom sessions. This can be any name they want, including their affirmed first name (last names will not be allowed, nor will any other names that clearly identify the youth; e.g., phone number or address). The goal of using a username is to protect their privacy, so youth will be informed that using their legal name introduces some risk to their confidentiality. Youth will be kept in the Zoom waiting room until their study username is displayed. Youth will be reminded of their study username by email a few days before the first session, and will be provided instructions about how to change their username. Moreover, participants will be reminded at the beginning of each session that all information shared in the intervention

setting is private and confidential. Participants will also be notified on the consent form and at the start of each session that by participating in the study they acknowledge the risk that other participants will become aware of any information they disclose during the group intervention sessions and might disclose such information to others outside of the study.

The likelihood that any additional breaches of confidentiality would occur is minimal, as steps will be taken to guard against this risk. To protect participants' confidentiality, all study therapists and research assistants (RAs) will undergo rigorous training in maintaining participants' confidentiality and will be in possession of valid Collaborative Institutional Training Initiative (CITI) certificates. All contact with participants will be made by research staff under explicit guidelines to preserve confidentiality when telephoning, emailing, or mailing information to participants.

The study participant's contact information will be securely stored for internal use 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 identifiable 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 in a Yale Secure Box folder only accessible by research study team members. As previously noted, this will not include the participant's contact or 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 in a Yale Secure Box folder.

Taken together, these measures are anticipated to be highly effective in protecting the confidentiality of participants and have proven successful in other studies that the PI and their research team have implemented.

8.2 Data Quality Assurance

All assessment measures for the online screening questionnaires, pre-intervention assessments, weekly surveys, and post-intervention assessment will be administered via the secure Qualtrics survey platform using contact list functions to accurately and consistently administer surveys to participants. Additionally, attention check questions will be placed throughout the surveys at each time point in order to better ensure participant attention when answer the survey questions. Dr. Seager van Dyk (who will be delivering the intervention) will follow intervention session outlines consistently, in order to facilitate comparisons across the two age groups of participants. Study research assistants will be trained to follow up with participants who miss all or part of an assessment to minimize missing data (although RAs will only provide up to two reminders, in order to avoid participants feeling pressured to complete the study tasks).

8.3 Data or Specimen Storage/Security

To ensure confidentiality, participant names and contact information (e.g., email address, phone number, physical address), which will only be recorded during the initial online screener and on consent/assent forms, will be kept separate from all other data. All data will be collected via the secure Qualtrics survey server and via Zoom (for assessments and intervention sessions). Participants will be assigned a unique study ID number after consenting to the screening phase of the study, as well as a separate unique study ID after selection to enroll in the intervention phase of the study. The use of these unique study ID numbers will permit linkage of the data being collected across all time points in the study. A master link file will connect participants' names and contact details to their study code number. The link file will be password-protected and only accessible to the PI and study team members. The link file will be stored separately from the rest of participants' data in a separate Yale Secure Box folder. Upon collection of the study data, de-identified data 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 and stored on password-protected computers by the study team.

In summary, we will keep four separate electronic and password-protected files.

1. The first will be a database that contains participant names, all the contact information that they provide for scheduling the study appointments (including telephone number, email address, mailing address, and date of birth), and study ID number
2. The second will contain all survey information.
3. The third will track study payments.
4. The fourth will contain study ID numbers from the screening survey and study ID numbers from the intervention study, so that we can link data from the different surveys. ("master link file")

Only the first database will contain participant names, while the others will only contain study ID numbers.

8.4 Study Records

Study records will consist of responses from self- and parent-report surveys, study therapist(s) reports of participant attendance and homework completion, as well as audio-recordings of intervention sessions. 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 documents will consist of surveys and other study measures that will all be administered online via Qualtrics or Zoom. All source data will be electronic (i.e., no surveys with handwritten responses). Research data will only be accessible in a Yale Secure Box folder by members of the research team (all of whom will be appropriately trained in data management). Although there are currently no plans to transfer data to collaborators, such a

transfer would only include de-identifiable data/documents, and the transfer would occur using Yale's secure file transfer service.

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 identifiable 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 safety reviews weekly during collection periods of pre-intervention data, weekly intervention data, and post-intervention 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 (PI, clinical psychologist) and Seager van Dyk (postdoctoral associate with a PhD in clinical psychology) will be primarily responsible for ensuring the scientific, clinical, and technical robustness of the intervention, including its adaptation for adolescents, translation to the remote format (i.e., Zoom), and its ongoing delivery. Dr. Seager van Dyk, with the aid of undergraduate research assistants, will be responsible for overseeing recruitment and selection of potential participants into the study. Dr. Seager van Dyk will provide undergraduate research assistants with live training on selection procedures, including how to obtain consent/assent from participants, and how to conduct phone screens with youth and their families. Dr. Seager van Dyk (who has extensive training in and years of experience using the KSADS diagnostic interview with adolescents and their families) will be responsible for completing the diagnostic interview portion of the screening process. Dr. Seager van Dyk, in consultation with Drs. Pachankis and Soulliard (postdoctoral associate with a PhD in clinical psychology), will be responsible for the preparation of session materials. Dr. Seager van Dyk, with the support of the study team, will deliver the intervention. Dr. Seager van Dyk, with the aid of undergraduate research assistants, will be responsible for online administration of the study measures, as well as the cleaning and organizing of the study data. Drs. Seager van Dyk and Layland (postdoctoral associate) will be primarily responsible for data analysis. Dr. Pachankis will be responsible as the PI for oversight of the previously mentioned responsibilities.

All study team members (including undergraduate research assistants) will undergo rigorous training in responsible research conduct with human subjects (including maintaining participants' confidentiality) and will be in possession of valid Collaborative Institutional Training Initiative (CITI) certificates. All clinical team members (e.g., Drs. Seager van Dyk, Soulliard) will undergo a comprehensive training in the lab's clinical protocol by Dr. Pachankis, which outlines procedures for managing participants in distress, including those expressing symptoms of suicidality, homicidality, active distress, violence, and other possible clinical presentations. This clinical protocol has previously been approved by the Yale IRB, and is attached to this application.

9.3 Study Monitoring

The study will be monitored internally for accuracy and adherence to study protocols by 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 IRB per their policies.

Unanticipated problems (UP) 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 days 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 experience unanticipated adverse events (e.g., increased active suicidality) over the course of study completion. The IRB will be involved in such a discussion.

9.6 Study Completion

Data collection for the study will end in late June 2022. Data analysis is expected to continue through August 2022. The study is anticipated to be completed upon the writing of a manuscript for publication by December 2022. At this time, the study team will notify the IRB that the study is complete.

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 funded by Yale-administered gifts, including the David R. Kessler M.D. ’55 Resource Fund for LGBTQ Mental Health Research at YSPH and the Yale Fund for LGBTQ Studies (FLAGS).

9.9 Publication Plan

Upon the completion of data analysis by August 2022, the research team anticipates submitting a manuscript for publication (led by the study’s lead postdoctoral associate, Dr. Seager van Dyk) by December 2022. It will be the PI’s primary responsibility for publishing the study results.

10 Appendices

Appendix #	Title	Section	Topic

11 List of Tables