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Randomised controlled trial of LGBTQ-affirmative cognitive-behavioural therapy for sexual minority women's minority stress, mental health and hazardous drinking: Project EQuIP protocol

John Pachankis ,[1] Danielle Chiaramonte,[1] Jillian R Scheer,[2] Hadley Ankrum,[1] Benjamin Eisenstadt,[1] Rebekah Hobbs,[1] Hunter Baldwin,[1] Jeremy D Kidd,[3] Katie Witkiewitz,[4] Denise Ann Esserman,[5] Kendra Plourde ,[5] Laurie Drabble,[6] Tonda Hughes[7]

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For numbered affiliations see end of article.

Correspondence to
Dr John Pachankis;
john.pachankis@yale.edu

ABSTRACT

Introduction Sexual minority women represent one of the highest-risk groups for hazardous drinking and comorbid mental health problems (eg, depression, anxiety). Research has identified cognitive (eg, expectations of rejection), affective (eg, emotion dysregulation) and behavioural (eg, avoidant coping) pathways through which minority stress (eg, stigma) places sexual minority women at disproportionate risk of hazardous drinking and comorbid depression/anxiety; yet no evidence-based interventions have been tested to address these pathways in this population. This article describes the design of Project EQuIP (Empowering Queer Identities in Psychotherapy), a randomised controlled trial of a transdiagnostic lesbian, gay, bisexual, transgender, queer (LGBTQ)-affirmative cognitive-behavioural therapy intervention (CBT) designed to improve minority stress coping and reduce sexual minority women's hazardous drinking and mental health comorbidities.

Methods and analysis This two-arm randomised controlled trial, funded by the National Institute on Alcohol Abuse and Alcoholism, has two objectives: (1) test the efficacy of 10 sessions of LGBTQ-affirmative CBT compared with 10 sessions of supportive counselling for sexual minority women in the community (anticipated n=450) who report hazardous alcohol use and meet criteria for a *Diagnostic and Statistical Manual of Mental Disorders - 5* diagnosis of a depression or anxiety disorder and (2) examine psychosocial mechanisms and demographic factors as potential mediators and moderators, respectively, of the treatment-outcome relationship. This study's primary outcome is change in the proportion of heavy drinking days. Secondary outcomes are changes in depressive and anxious symptoms.

Ethics and dissemination The Yale University Human Subjects Committee reviewed and approved the research protocol. Results of this study will be disseminated to researchers and practitioners through peer-review publications and conference presentations, and directly to study participants.

Trial registration number Registered on 17 August 2022 (ClinicalTrials.gov identifier: NCT05509166).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A randomised controlled trial can test the efficacy of this treatment against community treatment-as-usual.
⇒ Identifying treatment mediators over 12 months can encourage treatment efficiency.
⇒ Identifying treatment moderators can inform treatment personalisation and matching.
⇒ Enrolled participants might not be representative of the population of sexual minority women in need of evidence-based treatment.
⇒ The use of a single control condition limits comparisons to treatment approaches not focused on alleviating the psychosocial effects of stigma and minority stress.

BACKGROUND

Sexual minority women (SMW) represent one of the highest-risk groups for hazardous drinking (HD), a risk factor for alcohol use disorder (AUD).[1–4] HD is increasingly recognised as a women's health issue.[5 6] Alcohol consumption and related morbidity and mortality are increasing more steadily among US women than men,[7 8] and women are now recognised as being at a greater risk of certain alcohol-related cancers, cardiovascular disease and liver disease.[9 10] Furthermore, women with AUD are about half as likely as men to perceive a need for, or to seek,

treatment for alcohol-related problems.[11] Among SMW, these disparities are particularly acute. SMW are 6–7 times more likely than heterosexual women to meet the criteria for alcohol dependence and 8 times more likely to report seeking help for alcohol-related problems.[4 12–14] Given SMW's higher rates of AUD and treatment seeking, developing interventions specifically for SMW who experience alcohol-related problems can potentially reduce population prevalence of HD. Among SMW, HD is also more likely to co-occur with depression, anxiety and post-traumatic stress disorder (PTSD), compounding treatment needs.[15–19]

SMW's elevated risk of HD is linked to exposure to unique identity-related stressors, known as minority stressors (eg, family and peer rejection, discrimination and identity-based sexual or physical abuse).[20–29] Minority stressors put SMW at risk of HD for several reasons. For instance, many SMW turn to alcohol as a coping strategy (ie, negative reinforcement).[30] In fact, SMW's high rates of positive alcohol use expectancies, such as worry disengagement, partially explain their greater risk.[31] Additionally, SMW frequently socialise in alcohol-focused venues (eg, queer bars), in part to find support and cope with stress, enhancing their normative perceptions of heavy drinking.[32–36] Finally, the cumulative impact of lifetime trauma exacerbates minority stressors and stress reactions (eg, emotion dysregulation), which also helps explain the sexual orientation disparity in HD.[37–41] For many SMW, sexual minority stressors intersect with race/ethnicity-, class- or gender-based stress to confer even greater vulnerability to behavioural and mental health risks.[42–48]

Evidence suggests that minority stressors give rise to maladaptive identity-based cognitive, emotional and behavioural reactions. For instance, SMW's discrimination predicts internalised stigma, concealment and chronic rejection expectations, which in turn predict HD and comorbid depression/anxiety.[49] Minority stressors also contribute to maladaptive reactions, such as emotion dysregulation, impulsivity and hypervigilance.[21 50–54] Because these reactions confer vulnerability to a broad range of negative outcomes—including HD, depression and anxiety—they are considered transdiagnostic.

An intervention capable of reducing maladaptive cognitive, emotional and behavioural minority stress reactions can simultaneously improve SMW's HD and mental health comorbidities.[55 56] Drawing on advancements in emotion science,[57] psychiatric nosology[58] and cognitive-affective neuroscience,[59] there is strong evidence that SMW's psychosocial health challenges are highly comorbid and represent functionally similar maladaptive reactions to minority stress.[24 55] For example, chronic exposure to the stressors that SMW often experience from an early age disrupts neurobiological stress pathways and yields rejection schemas, emotion dysregulation, unassertiveness and impulsivity,[60 61] which are associated with HD and poor mental health.[62 63] Researchers have developed and tested this model, depicted in figure 1, which shows that minority stressors elicit minority stress reactions that predict depression, anxiety and HD.[38 64–70] Given that these stress reactions underlie SMW's HD, depression and anxiety, a treatment that improves these reactions may improve multiple behavioural and mental health challenges simultaneously.

Despite clear evidence of need,[71–75] few targeted HD interventions have been tested among SMW.[4 76 77] To our knowledge, only two studies have been published, and these were narrowly focused on reducing alcohol risk through gamified normative feedback among SMW[78] or behavioural couples therapy for heavy drinking among both lesbian and gay participants with AUD.[79] Further, despite strong evidence of the role of minority stress, depression and anxiety in SMW's HD, no intervention has addressed these factors to reduce SMW's disproportionate risk of HD. Responding to the near-complete lack of interventions for SMW's mental and behavioural health, the current study is designed to test the efficacy of lesbian, gay, bisexual, transgender, queer (LGBTQ)-affirmative cognitive behavioural therapy (CBT), a transdiagnostic intervention.

LGBTQ-affirmative CBT was created with extensive input from SMW, following our team's history of developing interventions 'by and for' the sexual minority community.[56 80–85] Specifically, LGBTQ-affirmative CBT is based on the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders,[86–90] a flexible protocol that distils CBT into its core components (eg, motivational interviewing for treatment engagement, mindfulness, cognitive restructuring, behavioural exposures). The Unified Protocol shows strong efficacy across several randomised controlled trials (RCTs) for reducing depression, anxiety and HD[89 91 92] in non-SMW samples by targeting the maladaptive cognitive, affective and behavioural processes shared across disorders involving emotion dysregulation. In pilot research, we adapted the Unified Protocol's CBT principles and techniques to distinctly respond to SMW's minority stress,[93] resulting in LGBTQ-affirmative CBT.[94 95] In our pilot waitlist-controlled trial of LGBTQ-affirmative CBT with 60 SMW, we found large reductions in depression (Cohen's d=0.85) and anxiety (d=0.86), and moderate reductions in emotion dysregulation (d=0.44) and HD (d=0.29).[90] In the current trial, we strengthen LGBTQ-affirmative CBT's focus on HD (eg, through personalised feedback and weekly assessment to increase self-awareness and inform case conceptualisation), another transdiagnostic outcome driven by minority stress,[96] that co-occurs with depression and anxiety,[97 98] and is highly suitable to being addressed by this transdiagnostic treatment.[56]

We expect that LGBTQ-affirmative CBT will result in a greater reduction of HD, depression and anxiety compared with treatment-as-usual (TAU). To test this hypothesis, participants from the community will be randomised to receive LGBTQ-affirmative CBT or TAU, and all participants will complete assessments of alcohol use, mental health and minority stress reactions at baseline, 4, 8 and 12 months. We further expect

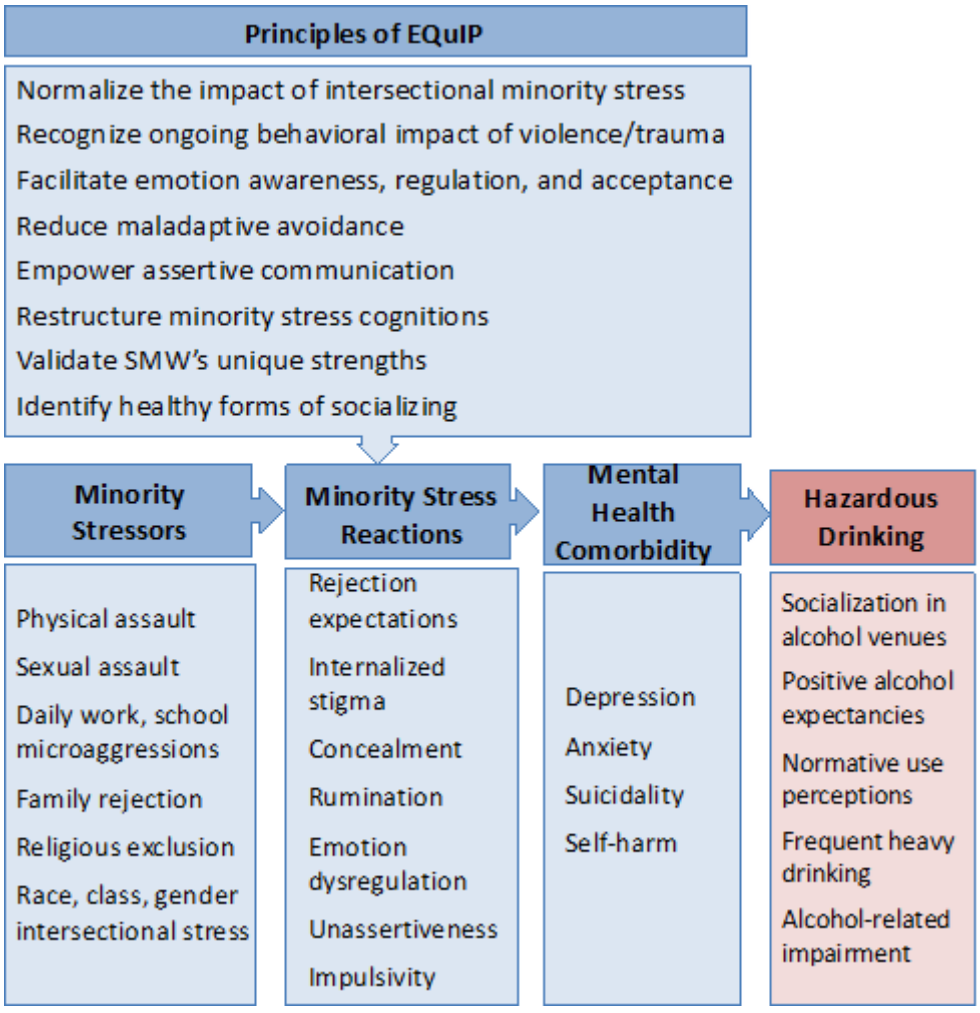

Figure 1 Conceptual model. CBT, cognitive-behavioural therapy; LGBTQ, lesbian, gay, bisexual, transgender, queer; SMW, sexual minority women

that LGBTQ-affirmative CBT will be more efficacious than TAU in reducing stress reactions, including those specific to sexual minority identity (eg, rejection expectations, internalised stigma, identity concealment) and those elevated among sexual minority people because of minority stress (eg, emotion dysregulation, impulsivity). Longitudinal assessments at baseline, 4, 8 and 12 months will be used to determine if reductions in the intended psychosocial mechanisms of LGBTQ-affirmative CBT (eg, internalised stigma, rejection sensitivity, emotion dysregulation) mediate reductions in heavy drinking. To advance personalised medicine (ie, person-to-treatment matching), we will also examine whether LGBTQ-affirmative CBT is differentially efficacious across key demographic factors, including race and ethnicity, sexual identity (eg, lesbian, bisexual), gender identity and expression, and stigma exposure at three socio-ecological levels: individual (eg, internalised stigma), interpersonal (eg, discrimination) and structural (eg, local laws and policies in the cities/counties in which participants live).

METHODS

Design

In this two-arm RCT starting on 1 February 2023 and anticipated to end 1 June 2027, LGBTQ-affirmative CBT will be compared with TAU (ie, LGBTQ-affirmative supportive counselling) to test the benefit of LGBTQ-affirmative CBT regarding (1) the primary outcome: the change in proportion of heavy drinking days in the past 30 days; and (2) the secondary outcomes: reduction in WHO risk drinking level, the absence of a major depression and anxiety disorder diagnosis, and reduction in depression and anxiety symptoms. Both LGBTQ-affirmative CBT and TAU groups receive 10 sessions of therapy—both delivered remotely via telehealth—and complete weekly surveys to track symptoms and alcohol use. Baseline and follow-up assessments at 4, 8 and 12 months will allow us to determine whether LGBTQ-affirmative CBT successfully improves minority stress reactions (see figure 2 for study flow).

Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Yale University.[99 100] REDCap is a

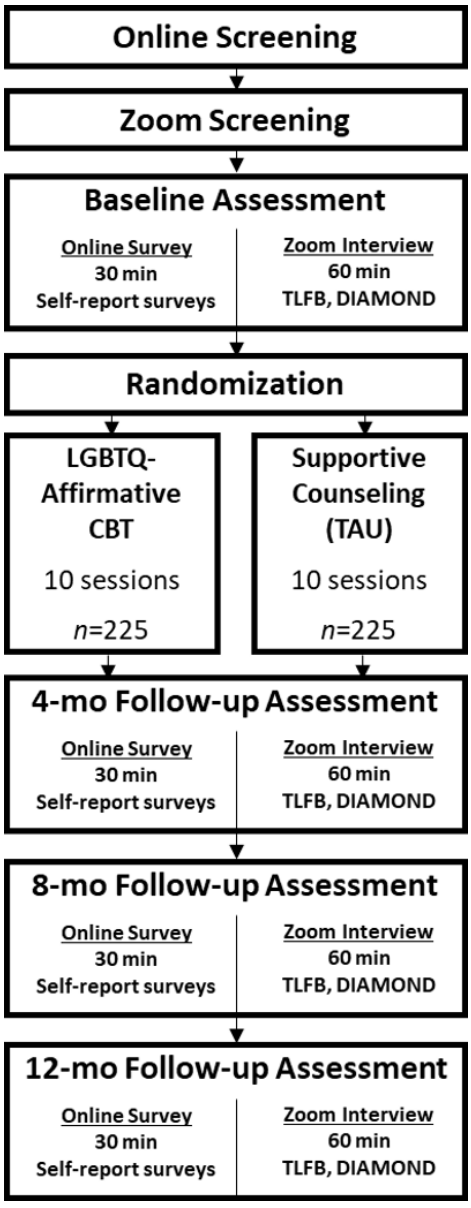

Figure 2 Study flow. CBT, cognitive-behavioural therapy; DIAMOND, Diagnostic Interview for Anxiety, Mood, OCD and Related Neuropsychiatric Disorders; LGBTQ, lesbian, gay, bisexual, transgender, queer; TAU, treatment-as-usual; TLFB, timeline follow-back.

secure, web-based software platform designed to support data capture for research studies, providing (1) an interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages and (4) procedures for data integration and interoperability with external sources.

Recruitment

Participants are recruited in the states of New York, New Jersey and Pennsylvania.[101] Recruitment staff post ads on online platforms (eg, Instagram, Lex, Facebook), on streets in various neighbourhoods and in venues frequently visited by SMW (eg, bars, bookstores, restaurants/cafes). Staff speak directly with prospective participants at SMW-oriented venues, community events and through social media platforms. Additional recruitment methods rely on community-based organisations (eg, health centres, community organisations), school/university groups and local LGBTQ sports teams to spread information about the study.

Eligibility

Inclusion criteria

SMW are eligible if they report (1) being 18 years of age or older; (2) being fluent in English; (3) self-identifying as lesbian, bisexual, queer, pansexual or other non-heterosexual identity; (4) drinking ≥8 standard drinks/week, on average, in the past 30 days, or report at least two heavy drinking days (≥ 4 drinks in 1 day) in the past 30 days; (5) current *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-5*) depression or anxiety disorder (screened initially using a cut-off of ≥2 on the Brief Symptom Inventory-4 and further confirmed by diagnostic interview via the Diagnostic Interview for Anxiety, Mood, OCD and Related Neuropsychiatric Disorders (DIAMOND)); (6) at least minimum motivation to reduce drinking (measured by the Readiness Ruler) and (7) living in New York, New Jersey or Pennsylvania and planning to stay for at least the next 4 months.

Exclusion criteria

SMW are ineligible under the following conditions: (1) reporting current mental health treatment ≥1 day/month; (2) having received any CBT in the past 3 months, although participants are not ineligible on enrolling in the study if they seek concomitant care and interventions after enrolment; (3) reporting current alcohol or drug use disorder treatment, except mutual self-help (eg, Alcoholics Anonymous); (4) exhibiting a need for alcohol detoxification, based on an adapted Clinical Institute Withdrawal Assessment for Alcohol-Revised[102]; (5) exhibiting active psychosis or active mania, as initially assessed by a trained research assistant (RA) and confirmed by a study clinician; (6) exhibiting active suicidality or active homicidality, as assessed by the Suicidal Ideation Attributes Scale (SIDAS)[103] and confirmed by a study clinician; (7) reporting being currently legally mandated to attend treatment or (8) demonstrating gross cognitive impairment, as assessed with the St. Louis University Mental Status Cognitive Assessment,[104] and confirmed by a study clinician.

Screening and consent

Prospective participants complete an eligibility screener via Qualtrics. After the preliminary assessment for eligibility, participants attend a Zoom screening interview with an RA, and study clinician if indicated, to determine if participants are ineligible due to (1) geographical location, (2) need for alcohol detoxification, (3) active psychosis or active mania, (4) active suicidality or (5) gross cognitive impairment. Once individuals are

deemed eligible to continue in the study, a research staff member reviews the full study consent form and clarifies any points of confusion. Individuals still interested in participating give consent electronically via Qualtrics.

Participants receive compensation as follows: $45 for completing the baseline assessment, $50 for completing the 4-month follow-up assessment, $55 for completing the 8-month follow-up assessment, $60 for completing the 12-month follow-up assessment and $5 for completing the survey after each of 10 intervention sessions.

Randomisation

The research staff conducting baseline and follow-up assessments are masked to study condition assignment. Participant conditions are hidden from masked staff in REDCap to prevent them from becoming unmasked. At the end of the Zoom portion of the baseline assessment, the unmasked project coordinator randomises the participant into the LGBTQ-affirmative CBT or TAU condition in a 1:1 ratio using the REDCap randomiser and orients the participants to their condition.

LGBTQ-affirmative CBT condition

LGBTQ-affirmative CBT is a 10-session, individually delivered intervention based on the Unified Protocol. Sessions will be delivered remotely from the offices of an academic research centre. The intervention has demonstrated efficacy in reducing stress-sensitive mental health disorders (eg, depression, anxiety) and enhancing emotion regulation skills, reducing avoidance patterns and improving motivation and self-efficacy for behaviour change. LGBTQ-affirmative CBT was created with input from LGBTQ community members and expert treatment providers over a multistage intervention development process.[82 93] Figure 1 summarises LGBTQ-affirmative CBT's principles and box 1 outlines its techniques. These principles and techniques infuse the Unified Protocol to normalise the adverse impact of minority stress, reduce internalised stigma and rejection schemas, reduce avoidant coping patterns and validate SMW's unique strengths. The Unified Protocol employs modules for motivation enhancement, interoceptive and situational exposure, cognitive restructuring, mindfulness and self-monitoring techniques. Modules were adapted to help SMW identify minority stress experiences; track unhealthy reactions to minority stress, focusing on avoidance reactions (eg, substance use); attribute distress to minority stress rather than to personal failure; and assert themselves against minority stress in safe situations. In this trial, participants complete ten 50 min sessions via videoconferencing software within a 4-month period and are encouraged to complete one session per week.

TAU condition

Participants in the TAU condition receive 10 sessions of individually delivered LGBTQ-affirmative supportive counselling, the current standard of care for LGBTQ individuals, from a community clinic in New York City. Sessions will be delivered remotely. LGBTQ-affirmative supportive counselling is defined, for example, as a diverse set of supportive practices informed by general guidelines of the American Psychological Association (APA) that broadly direct clinicians to be aware of the distinct influences on sexual minority individuals' mental health and address them in a manner that respects the

Box 1 Techniques of LGBTQ-affirmative CBT

Module 1: motivation enhancement for LGBTQ-affirmative CBT engagement
- ⇒ Discuss alcohol use and its health impact.
- ⇒ Review normative HD feedback report against SMW norms.
- ⇒ Clarify primary and behavioural health goals.
- ⇒ Build motivation to address mental and behavioural health.
- ⇒ Review SMW's unique strengths.

Module 2: the nature and emotional impact of minority stress
- ⇒ Review minority stress's impact on mental and behavioural health.
- ⇒ Identify early and ongoing forms of intersectional minority stress.
- ⇒ Discuss current coping strategies, including alcohol use.

Module 3: tracking emotional experiences
- ⇒ Raise awareness of the emotional impact of early and ongoing minority stress and trauma.

Module 4: awareness of minority stress reactions
- ⇒ Raise awareness of behavioural impact of minority stress and trauma.
- ⇒ Teach mindful, present-focused reactions to minority stress.
- ⇒ Teach distress tolerance skills for managing the emotional impact of trauma.

Module 5: cognitive appraisal and reappraisal
- ⇒ Connect minority stress and trauma to maladaptive thinking patterns.
- ⇒ Identify thoughts driven by minority stress and learn to update them.

Module 6: emotion avoidance
- ⇒ Learn how avoiding strong emotions can lead to HD.
- ⇒ Discuss how minority stress and trauma might lead to avoidance of certain people, places or experiences.

Module 7: emotion-driven behaviours
- ⇒ Focus on how minority stress and trauma can lead to avoidant coping.
- ⇒ Discuss intimacy, relationships and alcohol use.
- ⇒ Create an emotional and behavioural avoidance hierarchy.

Module 8: behavioural experiments
- ⇒ Engage SMW in behavioural experiments in which previously avoided experiences are gradually confronted.
- ⇒ Increase tolerance of strong emotions in uncomfortable situations.

Module 9: behavioural skills training
- ⇒ Continue graduated behavioural experiments.
- ⇒ Focus on assertiveness training for coping with minority stress.

Module 10: relapse prevention
- ⇒ Review new cognitive, affective and behavioural coping strategies and their application to future minority stress experiences.

CBT, cognitive-behavioural therapy; HD, hazardous drinking; LGBTQ, lesbian, gay, bisexual, transgender, queer; SMW, sexual minority women.

individual's autonomy to choose their treatment goals while validating their identities.[105] We selected LGBTQ-affirmative supportive counselling as our control because it is recommended by the APA and is likely to be safe and acceptable for SMW participants. Otherwise, by design, LGBTQ-affirmative supportive counselling was selected as the TAU because it does not follow a standard protocol prescribed by the study. In previous research on LGBTQ-affirmative supportive counselling, we have found a relatively low degree of both CBT content and psychodynamic-interpersonal content in recorded sessions of this counselling.[106] Therapists provide TAU online to match the videoconferencing delivery modality of LGBTQ-affirmative CBT. TAU participants complete the ten 50 min sessions within a 4-month period and are encouraged to complete one session per week.

Therapist training and fidelity monitoring

Therapists across both conditions are master's- or PhD-level therapists or trainees (eg, advanced graduate students or postdoctoral fellows in clinical psychology); different therapists deliver each condition. Each therapist is assigned to deliver either the intervention or TAU. Before delivering LGBTQ-affirmative CBT, study therapists who deliver that condition receive approximately 16 hours of training involving didactics on the minority stress model and experiential exercises applying the model through CBT techniques. Sessions are audio-recorded with participants' consent. Clinical supervisors review approximately 20% of all study sessions using fidelity checklists created for this treatment.[90] Fidelity is also reviewed in weekly supervision and shortfalls are remediated. All LGBTQ-affirmative CBT therapists receive weekly individual supervision from a clinical supervisor. A a licensed clinical psychologist and study principal investigator, leads biweekly group supervision with all study therapists and supervisors. A clinical protocol guides the handling of participant suicidality and distress. All staff receive training in the clinical protocol at the beginning of their study involvement and in the event of a protocol deviation. TAU therapists receive clinical supervision from a licensed psychologist at the community clinic. Study staff will also review audio-recordings from TAU sessions using standard CBT rating schemes to assess for CBT contamination on enrolment of 50 participants into the TAU condition. If we find that the coded sessions include substantial CBT content, we will discuss results with directors at the TAU community site so that future TAU participants only meet with therapists who do not practise CBT.[107]

Study assessments

Participants complete assessments at four timepoints: baseline, and 4-, 8- and 12-month follow-ups (figure 2). Each assessment consists of a self-report online assessment of alcohol use, mental health, minority stress and universal mechanisms of mental health risk, as well as an interviewer-administered assessment of alcohol use and mental health via Zoom. We facilitate retention of participants across 12 months by (1) providing evening and weekend availability for sessions and assessments, (2) verifying contact information at all appointments and 3) collecting multiple forms of contact information.

Primary outcome

Alcohol use

The primary outcome of the study is change in past-30-day proportion of HD days, as measured through the 30-day timeline follow-back (TLFB), a semi-structured interview.[108–110] The TLFB collects participants' report of daily number of drinks over the past 30 days. These estimates are then used to calculate average past 30-day drinks per week and HD days (defined as four or more drinks within 1 day) at all timepoints. The TLFB is administered by a trained RA over Zoom and recorded for quality assurance purposes.

Secondary outcomes

Mental health

The DIAMOND[111] is a semistructured diagnostic interview based on the DSM-5 that enables non-clinician RAs to determine the presence and severity of mood, anxiety and stress-/trauma-related disorders. The DIAMOND is administered at each of the four timepoints over Zoom by a trained RA. Participants complete the Brief Symptom Inventory,[112] the Beck Anxiety Inventory,[113] the Center for Epidemiology Studies Depression Scale,[114] the Overall Anxiety and Depression Severity and Impairment Scale,[115 116] the SIDAS[103] and the PSTD Checklist for DSM-5[117] via an online survey at each timepoints.

Alcohol and substance use

In addition to the TLFB, participants complete the following assessments of alcohol and substance use and associated impairment via online survey at each timepoint: the Patient-Reported Outcomes Measurement Information System Alcohol Use Short Form,[118] the Brief Comprehensive Effects of Alcohol Scale,[119] the Daily Drinking Questionnaire,[120] the Alcohol Abstinence Self-Efficacy Scale,[121] the Drug Use Disorders Identification Test,[122] and the Cannabis Use Disorder Identification Test.[123]

Mediators and moderators

Minority stress mediators

All participants complete the Lesbian, Gay, Bisexual Identity Scale (LGBIS),[124] the LGBTQ-Hypervigilance Scale[125] and the LGBTQ-Specific Parental Disclosure & Support Scale[126] at all timepoints through an online survey to measure LGBTQ-specific identity concealment motivations, internalised stigma, acceptance concerns, hypervigilance and parental acceptance, respectively. Identity-specific minority stressors are assessed at all timepoints through an online survey and include the following: the Bisexual-Specific Stress Scale,[127] the Gender Minority Stress and Resilience Measure[128] and the LGBT People of Color Microaggressions Scale.[129]

Universal mechanism mediators

Universal mechanism mediators are hypothesised to be operating for all individuals in CBT and are assessed through online surveys at all four timepoints. Measures include the Perceived Stress Scale,[130] the UCLA Loneliness Scale,[131] the Difficulties in Emotion Regulation Scale—Short Form,[132] the Response Style Questionnaire Rumination Scale,[133] the Rathus Assertiveness Scale—Short Form,[134] the Interpersonal Support Evaluation List[135] and the Social Safety Scale.[136]

Treatment moderators

Several participant demographics and stigma-related variables are assessed via the same online survey as potential moderators of treatment efficacy. Demographics are collected at baseline and include age, race, ethnicity, gender identity, sexual orientation, relationship status, level of education, employment status, income and general health, as assessed by items from the Behavioral Risk Factor Surveillance Survey.[137] Stigma-related variables that might serve as potential treatment efficacy moderators, assessed at all four time points, include individual-level stigma (ie, internalised stigma measured using the LGBIS), interpersonal-level stigma (measured by the Heterosexist, Rejection, and Discrimination Scale[138]), and structural-level stigma (measured by the Perceived Structural Stigma Scale[139]). We also assess endorsement of traditional gender roles (measured by the Traditional Masculinity-Femininity Scale[140]) as a potential treatment efficacy moderator, consistent with research and theory suggesting that greater adherence to masculine gender norms is associated with greater risk of HD among SMW.[47]

Data collection, management and analysis

Participants complete the baseline and follow-up online surveys via Qualtrics. The DIAMOND and TLFB assessments are administered by RAs over Zoom. Data are entered into a Qualtrics survey or stored on Yale's secure Box server in a password-protected file, respectively. Participant contact, tracking and scheduling information is recorded in REDCap. Therapy sessions and Zoom assessments are audio-recorded for supervision and quality assurance. These files are stored on Yale's secure Box server. Therapy recordings are reviewed on a weekly basis by a licensed clinical psychologist. Zoom-administered assessments undergo quality assurance checks performed by the study therapists and other members of the research team.

General statistical considerations

All primary analyses will be performed as intent-to-treat with an overall type I error rate of 5% (two-sided). Parametric distributional assumptions will be checked, and diagnostic and sensitivity analyses will be performed. We will assess the missing mechanism and impact of missing data. Sensitivity analyses under missing at random or missing not at random will be considered, as appropriate. R and Mplus[141] will be used to conduct analyses. Baseline descriptives (including demographics and clinical variables) will be presented separately by treatment group. Comparability of continuous variables will be examined graphically and using summary statistics (eg, means, SD). Categorical variables will be examined by calculating frequency distributions.

Sample size justification

Our primary goal is to demonstrate a greater reduction at 12 months in the proportion of heavy drinking days, defined as four or more standard drinks/day, in LGBTQ-affirmative CBT versus TAU supportive counselling. Our sample size is based on a waitlist controlled pilot study of SMW,[90] in which we saw a 40.2% reduction in HD at 6-month follow-up in the LGBTQ-affirmative CBT arm restricting analyses to participants who reported HD, and on existing meta-analyses of CBT for HD, including remote CBT and CBT for HD and comorbid mental health problems, showing a standardised effect size of d=0.39 compared with other active treatments.[142–144] Because our supportive counselling TAU has been previously shown to involve low CBT content,[106] we expect that LGBTQ-affirmative CBT will yield a comparable effect size as in these previous trials. To address the possibility that the effect size may not be as strong as in previous trials, we have designed the trial to find an effect size of d=0.29. With at least 80% power at a 5% type I error rate (two-sided), we need 191 participants per arm to detect this difference between the LGBTQ-affirmative CBT and TAU arms.[145] Based on the retention rate in our pilot study and our other intervention studies with sexual minority individuals, we estimate the retention at 12 months to be 85%. Therefore, we plan to randomise 225 SMW to LGBTQ-affirmative CBT and 225 to TAU. Sample size calculations were carried out using PASS 19 (Kaysville, Utah, USA).

Efficacy analyses

We will employ a linear mixed-effects model to assess change in proportion of heavy drinking days. The model will include fixed effects for time, treatment arm and the interaction between time and treatment. An unstructured covariance pattern will allow for correlation between repeated observations. We will use a contrast statement for the primary comparison of interest: reduction in the proportion of heavy drinking days at the 12-month follow-up. Secondary outcomes of interest include one-level reduction in WHO risk level, the absence of a major depression or anxiety disorder diagnosis and reduction in depression and anxiety symptoms. We will use generalised linear mixed models with a log link for dichotomous outcomes and identity link (linear) for continuous outcomes. If the proportion of heavy drinking days outcome is non-normally distributed, then transformations and other distributions will be considered, including a negative binomial distribution. Sensitivity analyses will adjust for any covariates that are not balanced across arms by the randomisation. To control the false discovery

rate and maintain an overall type I error rate of 0.05 for the secondary outcomes, we will use the Benjamini and Hochberg method.[146]

Mediation analyses

To examine whether changes in mediators (eg, rejection sensitivity, internalised homophobia, emotion dysregulation, social support) precede and mediate intervention effects consistent with our minority stress conceptual model (figure 1), we will use path analysis/structural equation modelling to model and assess the size of the indirect effect from intervention condition to 12-month outcomes through mediators assessed at 8-month follow-up controlling for baseline effects of these mediators. Using Mplus[141] to perform a Monte Carlo simulation power analysis,[147] we estimated that sample sizes of 191 (LGBTQ-affirmative CBT) and 191 (TAU) would provide at least 80% power to detect a small effect size (d=0.2) in the indirect treatment effect with a level of significance of 5%, consistent with effect sizes in our pilot.

Moderation analyses

We will conduct moderation analyses to examine whether the efficacy of LGBTQ-affirmative CBT is moderated by demographic factors (eg, race and ethnicity, sexual identity, gender identity and expression) as well as stigma assessed at the individual (eg, identity concealment), interpersonal (eg, discrimination) and structural (eg, participant perception of their local laws and policies concerning the LGBTQ community) levels. Starting with the linear mixed-effects model (or generalised mixed-effect model) used for the primary efficacy analyses, we will add fixed effects for each of the demographic moderators and stigma moderators and their interaction with time, treatment arm and the interaction between time and treatment arm. Similar to Aim 1, we will control for false discovery using the Benjamini and Hochberg method.[146] Demographic factors[148–150] and stigma exposures[90 151–155] are increasingly shown by our team and others to moderate intervention efficacy, which, if also identified in this study, will lead us to direct clinicians to address the relevance of these factors in treatment, consistent with personalised medicine approaches.[156–158] This will also help identify further adaptations to fine-tune the relevance and fit of this intervention across various groups of SMW.[159]

Ethics and dissemination

This study poses no greater than minimal risk to participants. Breach of participant's confidentiality and experiences of emotional discomfort when completing assessments represent two possible risks. The study team has taken every possible step to minimise such risks and the consent documentation clearly delineates these risks to participants.

Our research protocol informs participants that they may refuse to answer questions, pause and take breaks during interview assessments or psychotherapy sessions, and may discontinue participation at any time. Participants are also welcomed to reach out to the PI or to Yale University's Human Subjects Committee (HSC) throughout the course of the study. All research staff are thoroughly trained by licensed clinical psychologists to handle situations in which participants become distressed or pose a risk to self or others. Our clinical protocol prioritises participant safety and an immediate referral process.

To minimise the risk of breach of confidentiality, all research team members undergo rigorous training in maintaining participants' privacy and confidentiality. All team members also undergo Health Insurance Portability and Accountability Act compliance training to protect participants' protected health information. Further, each participant is assigned a unique study identification number and all study data are kept separately from identifying data. Participants are informed that confidentiality may be compromised in order to provide immediate help if we determine that they are at risk of hurting themselves or another person. We inform participants that they may benefit from participating in this study by learning more about themselves, their mental health and ways of managing stress and negative emotions. Participants may also benefit from 10 weeks of LGBTQ-affirmative therapy that many in our prior studies have found valuable. Benefits to the SMW community are anticipated through the dissemination of RCT findings to inform future trainings and implementation.

To further protect participants, a data and safety monitoring board (DSMB) convenes annually, and as needed, to determine safe and effective study conduct and recommend conclusion of the study if significant risks develop or if the trial is unlikely to be concluded successfully. Members of the DSMB are faculty from the two sponsoring institutions with no competing interests. Every adverse event is evaluated by PI JP within 24 hours and classified as serious (mild, moderate, severe) or non-serious and graded by the Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. This study follows HSC requirements for reporting adverse events. All serious or unexpected adverse events that are definitely, probably or possibly related to study participation are reported to the HSC within 48 hours of Yale researchers becoming aware of the event. The NIH project officer will be provided copies of these reports and informed of any actions taken by the HSC as a result of such events. PIs JP and TH will promptly inform the NIH and HSC of any changes in recruitment or in the protocol relevant to safety as the study is being performed. They will additionally notify NIH of any actions taken by the HSC during continuing study review and of any major changes in the protocol, which would occur with the HSC's approval.

Research resources generated by this research will be freely distributed, as available, to qualified academic investigators for non-commercial research. The study investigators as well as their institutions—Yale University, Columbia University, San José State University, Syracuse

University and University of New Mexico—will adhere to the NIH Grants Policy on Sharing of Unique Research Resources, including the 'Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts' issued in December 1999.[160] The data, codes and study protocols are available by request to qualified researchers on completion of this study. To access the data, codes and study protocols, a proposal should be submitted by an applicant with a PhD or an equivalent degree. Proposals will be reviewed and granted according to principles of ethical and scientific soundness.

Authorship for manuscripts will be determined using the four criteria established by the International Committee of Medical Journal Editors[161]: significant contribution to the study conceptualisation, study design, or data collection, analysis or interpretation; drafting or critically reviewing the manuscript; approval of the final version of the manuscript; and the agreement to be held responsible for all aspects of the study and to assist in investigating any concerns about the study's accuracy or integrity. An individual must meet each of these criteria to be considered as an author. We do not intend to use professional writers for manuscripts.

Results of this study will be disseminated to researchers and practitioners through peer-review publications and conference presentations, and directly to study participants. The study sponsor will have no role in the interpretation of data, writing of the resulting reports or the decision to submit the report for publication or presentation.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

DISCUSSION

This article describes the protocol for Project EQuIP, a two-arm RCT testing the efficacy of LGBTQ-affirmative CBT, a transdiagnostic psychotherapy intervention targeting the pathways through which minority stress compromises LGBTQ individuals' mental and behavioural health. SMW represent one of the highest-risk groups for HD, which frequently co-occurs with depression and anxiety.[1 4 16 17] Responding to the near-complete lack of interventions for SMW's mental and behavioural health, our team developed and pilot tested LGBTQ-affirmative CBT with 60 SMW in a waitlist-controlled trial.[90] Findings demonstrated preliminary efficacy of LGBTQ-affirmative CBT to improve minority stress coping and reduce SMW's HD and mental health comorbidities. Further, SMW indicated that LGBTQ-affirmative CBT was acceptable when delivered in-person and when delivered remotely in a second small open trial. The present study now tests the efficacy of LGBTQ-affirmative CBT delivered remotely to SMW across New York, New Jersey and Pennsylvania compared with TAU (ie, supportive counselling) also delivered remotely.

This study represents the first RCT of a psychotherapy intervention specifically developed to address mental and behavioural health among SMW. The intervention being tested here is grounded in minority stress theory and focuses on raising awareness of the harms of minority stress, reducing internalised stigma and rejection schemas, reducing avoidant coping behaviours and validating SMW's strengths. The intervention is informed by the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders,[86–89] a flexible protocol that distils CBT into its core components (eg, motivational interviewing for treatment engagement, mindfulness, cognitive restructuring, behavioural exposures). The Unified Protocol shows strong efficacy across several RCTs for reducing depression, anxiety and HD[89 91 92] in non-SMW samples and is transdiagnostic by targeting the maladaptive cognitive, affective and behavioural processes (eg, emotion dysregulation, impulsivity) shared across disorders involving emotion dysregulation (eg, depression, anxiety and HD). Given that SMW's HD often co-occurs with depression and anxiety and given the association of these conditions with minority stress, a transdiagnostic treatment targeting the underlying role of minority stress can synergistically reduce SMW's HD and comorbid depression and anxiety. Results from this RCT can support implementation in frontline settings in need of evidence-based interventions and ways to expand access for SMW.

Author affiliations
[1]Department of Social and Behavioral Sciences, Yale University School of Public Health, New Haven, Connecticut, USA
[2]Syracuse University, Syracuse, New York, USA
[3]Columbia University Irving Medical Center, New York, New York, USA
[4]Univ New Mexico, Albuquerque, New Mexico, USA
[5]Department of Biostatistics, Yale University School of Public Health, New Haven, Connecticut, USA
[6]San Jose State University, San Jose, California, USA
[7]Columbia University School of Nursing, New York, New York, USA

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Contributors JP and TH led the development of the protocol and prepared the initial draft. DC contributed to protocol design, oversaw data collection and contributed to manuscript writing. DAE contributed to the protocol design and contributed to manuscript writing. HA, BE, RH and HB supported data collection and manuscript writing. JRS, KW, LD, KP and JDK provided ongoing consultation regarding the protocol and supported manuscript writing. JP is the guarantor.

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ORCID iDs
John Pachankis http://orcid.org/0000-0002-2015-9225
Kendra Plourde http://orcid.org/0000-0001-6654-0710

REFERENCES

1 Hughes TL, Wilsnack SC, Kantor LW. The Influence of Gender and Sexual Orientation on Alcohol Use and Alcohol-Related Problems: Toward a Global Perspective. *Alcohol Res* 2016;38:121–32.
2 Saunders JB, Degenhardt L, Reed GM, *et al*. Alcohol Use Disorders in ICD-11: Past, Present, and Future. *Alcoholism Clin Exp Res* 2019;43:1617–31.
3 Saunders JB, Peacock A, Degenhardt L. Alcohol Use Disorders in the Draft ICD-11, and How They Compare with DSM-5. *Curr Addict Rep* 2018;5:257–64.
4 Hughes TL, Veldhuis CB, Drabble LA, *et al*. Research on alcohol and other drug (AOD) use among sexual minority women: A global scoping review. *PLoS One* 2020;15:e0229869.
5 Alcoholism NIoAAa. Alcohol-related deaths increasing in the United States 2020. 2020. Available: https://www.niaaa.nih.gov/news-events/news-releases/alcohol-related-deaths-increasing-united-states
6 White A, Castle IP, Chen CM, *et al*. Converging Patterns of Alcohol Use and Related Outcomes Among Females and Males in the United States, 2002 to 2012. *Alcoholism Clin Exp Res* 2015;39:1712–26.
7 Grant BF, Chou SP, Saha TD, *et al*. Prevalence of 12-Month Alcohol Use, High-Risk Drinking, and DSM-IV Alcohol Use Disorder in the United States, 2001-2002 to 2012-2013: Results From the National Epidemiologic Survey on Alcohol and Related Conditions. *JAMA Psychiatry* 2017;74:911–23.
8 White AM, Castle IP, Hingson RW, *et al*. Using Death Certificates to Explore Changes in Alcohol-Related Mortality in the United States, 1999 to 2017. *Alcoholism Clin Exp Res* 2020;44:178–87.
9 Erol A, Karpyak VM. Sex and gender-related differences in alcohol use and its consequences: Contemporary knowledge and future research considerations. *Drug Alcohol Depend* 2015;156:1–13.
10 Hommer DW. Male and female sensitivity to alcohol-induced brain damage. *Alcohol Res Health* 2003;27:181–5.
11 Oleski J, Mota N, Cox BJ, *et al*. Perceived need for care, help seeking, and perceived barriers to care for alcohol use disorders in a national sample. *Psychiatr Serv* 2010;61:1223–31.
12 Drabble L, Midanik LT, Trocki K. Reports of alcohol consumption and alcohol-related problems among homosexual, bisexual and heterosexual respondents: results from the 2000 National Alcohol Survey. *J Stud Alcohol* 2005;66:111–20.
13 Talley AE, Hughes TL, Aranda F, *et al*. Exploring alcohol-use behaviors among heterosexual and sexual minority adolescents: intersections with sex, age, and race/ethnicity. *Am J Public Health* 2014;104:295–303.
14 McCabe SE, Hughes TL, Bostwick WB, *et al*. Sexual orientation, substance use behaviors and substance dependence in the United States. *Addiction* 2009;104:1333–45.
15 Johnson TP, Hughes TL, Cho YI, *et al*. Hazardous drinking, depression, and anxiety among sexual-minority women: self-medication or impaired functioning? *J Stud Alcohol Drugs* 2013;74:565–75.
16 Condit M, Kitaji K, Drabble L, *et al*. Sexual Minority Women and Alcohol: Intersections between drinking, relational contexts, stress and coping. *J Gay Lesbian Soc Serv* 2011;23:351–75.
17 Bostwick WB, Hughes TL, Johnson T. The co-occurrence of depression and alcohol dependence symptoms in a community sample of lesbians. *J Lesbian Stud* 2005;9:7–18.
18 Mereish EH, Lee JH, Gamarel KE, *et al*. Sexual orientation disparities in psychiatric and drug use disorders among a nationally representative sample of women with alcohol use disorders. *Addict Behav* 2015;47:80–5.
19 Scheer JR, Helminen EC, Cascalheira CJ, *et al*. Probable PTSD, PTSD symptom severity, and comorbid PTSD and hazardous drinking among sexual minority women compared to heterosexual women: A meta-analysis. *Clin Psychol Rev* 2023;102:102283.
20 Hughes TL, Johnson TP, Steffen AD, *et al*. Lifetime Victimization, Hazardous Drinking, and Depression Among Heterosexual and Sexual Minority Women. *LGBT Health* 2014;1:192–203.
21 Roberts AL, Rosario M, Corliss HL, *et al*. Elevated risk of posttraumatic stress in sexual minority youths: mediation by childhood abuse and gender nonconformity. *Am J Public Health* 2012;102:1587–93.
22 Roberts AL, Austin SB, Corliss HL, *et al*. Pervasive trauma exposure among US sexual orientation minority adults and risk of posttraumatic stress disorder. *Am J Public Health* 2010;100:2433–41.
23 Hughes TL, Szalacha LA, Johnson TP, *et al*. Sexual victimization and hazardous drinking among heterosexual and sexual minority women. *Addict Behav* 2010;35:1152–6.
24 Scheer JR, McConocha E, Behari K, *et al*. Sexual violence as a mediator of sexual orientation disparities in alcohol use, suicidality, and sexual-risk behaviour among female youth. *Psychol Sex* 2021;12:37–51.
25 Balsam KF, Rothblum ED, Beauchaine TP. Victimization over the life span: a comparison of lesbian, gay, bisexual, and heterosexual siblings. *J Consult Clin Psychol* 2005;73:477–87.
26 Austin SB, Jun H-J, Jackson B, *et al*. Disparities in Child Abuse Victimization in Lesbian, Bisexual, and Heterosexual Women in the Nurses' Health Study II. *J Womens Health (Larchmt)* 2008;17:597–606.
27 Friedman MS, Marshal MP, Guadamuz TE, *et al*. A Meta-Analysis of Disparities in Childhood Sexual Abuse, Parental Physical Abuse, and Peer Victimization Among Sexual Minority and Sexual Nonminority Individuals. *Am J Public Health* 2011;101:1481–94.
28 Bos H, de Haas S, Kuyper L. Lesbian, Gay, and Bisexual Adults: Childhood Gender Nonconformity, Childhood Trauma, and Sexual Victimization. *J Interpers Violence* 2019;34:496–515.
29 Zou C, Andersen JP. Comparing the Rates of Early Childhood Victimization across Sexual Orientations: Heterosexual, Lesbian, Gay, Bisexual, and Mostly Heterosexual. *PLoS ONE* 2015;10:e0139198.
30 Dyar C, Lee CM, Rhew IC, *et al*. Sexual minority stress and substance use: An investigation of when and under what circumstances minority stress predicts alcohol and cannabis use at the event-level. *J Psychopathol Clin Sci* 2023;132:475–89.
31 Fish JN, Hughes TL. Alcohol Expectancies, Heavy Drinking, and Indicators of Alcohol Use Disorders in a Community-Based Sample of Lesbian and Bisexual Women. *LGBT Health* 2018;5:105–11.
32 Gruskin E, Byrne K, Kools S, *et al*. Consequences of Frequenting the Lesbian Bar. *Women & Health* 2007;44:103–20.
33 Trocki K, Drabble L. Bar patronage and motivational predictors of drinking in the San Francisco Bay Area: gender and sexual identity differences. *J Psychoactive Drugs* 2008;Suppl 5:345–56.
34 Ehlke SJ, Stamates AL, Kelley ML, *et al*. Bisexual Women's Reports of Descriptive Drinking Norms for Heterosexual, Bisexual, and Lesbian Women. *Psychol Sex Orientat Gend Divers* 2019;6:256–63.
35 Lee CM, Blayney J, Rhew IC, *et al*. College Status, Perceived Drinking Norms, and Alcohol Use among Sexual Minority Women. *Psychol Sex Orientat Gend Divers* 2016;3:104–12.
36 Cochran SD, Grella CE, Mays VM. Do substance use norms and perceived drug availability mediate sexual orientation differences in patterns of substance use? Results from the California Quality of Life Survey II. *J Stud Alcohol Drugs* 2012;73:675–85.
37 Valentine SE, Elsesser S, Grasso C, *et al*. The Predictive Syndemic Effect of Multiple Psychosocial Problems on Health Care Costs and Utilization among Sexual Minority Women. *J Urban Health* 2015;92:1092–104.
38 Lewis RJ, Mason TB, Winstead BA, *et al*. Pathways to Hazardous Drinking Among Racially and Socioeconomically Diverse Lesbian

Women: Sexual Minority Stress, Rumination, Social Isolation, and Drinking to Cope. *Psychol Women Q* 2016;40:564–81.
39 Mason TB, Lewis RJ, Gargurevich M, *et al*. Minority stress and intimate partner violence perpetration among lesbians: Negative affect, hazardous drinking, and intrusiveness as mediators. *Psychol Sex Orientat Gend Divers* 2016;3:236–46.
40 Lewis RJ, Padilla MA, Milletich RJ, *et al*. Emotional Distress, Alcohol Use, and Bidirectional Partner Violence Among Lesbian Women. *Violence Against Women* 2015;21:917–38.
41 Scheer JR, Wall MM, Veldhuis CB, *et al*. Associations Between Latent Classes of Trauma Exposure and Minority Stressors and Substance Use Among Cisgender Sexual Minority Women. *J Interpers Violence* 2023;38:8286–315.
42 Moore MR. Intersectionality and the Study of Black, Sexual Minority Women. *Gender & Society* 2012;26:33–9.
43 Mereish EH, Bradford JB. Intersecting identities and substance use problems: sexual orientation, gender, race, and lifetime substance use problems. *J Stud Alcohol Drugs* 2014;75:179–88.
44 Bostwick WB, Meyer I, Aranda F, *et al*. Mental health and suicidality among racially/ethnically diverse sexual minority youths. *Am J Public Health* 2014;104:1129–36.
45 Warner LR, Shields SA. The Intersections of Sexuality, Gender, and Race: Identity Research at the Crossroads. *Sex Roles* 2013;68:803–10.
46 Calabrese SK, Meyer IH, Overstreet NM, *et al*. Exploring Discrimination and Mental Health Disparities Faced By Black Sexual Minority Women Using a Minority Stress Framework. *Psychol Women Q* 2015;39:287–304.
47 Kidd JD, Everett BG, Corbeil T, *et al*. Gender self-concept and hazardous drinking among sexual minority women: Results from the Chicago health and life experiences of women (CHLEW) study. *Addict Behav* 2022;132:107366.
48 Batchelder AW, Foley JD, Stanton AM, *et al*. Facets of Gender Expression and Discrimination in Relation to Alcohol and Other Drug Use Severity Among Sexual Minority Women and Gender Diverse Individuals Assigned Female at Birth. *LGBT Health* 2023;10:191–201.
49 Lehavot K, Simoni JM. The impact of minority stress on mental health and substance use among sexual minority women. *J Consult Clin Psychol* 2011;79:159–70.
50 Lehavot K, Simpson TL. Trauma, posttraumatic stress disorder, and depression among sexual minority and heterosexual women veterans. *J Couns Psychol* 2014;61:392–403.
51 Weiss BJ, Garvert DW, Cloitre M. PTSD and Trauma-Related Difficulties in Sexual Minority Women: The Impact of Perceived Social Support. *J Trauma Stress* 2015;28:563–71.
52 Niles AN, Valenstein-Mah H, Bedard-Gilligan M, *et al*. Effects of trauma and PTSD on self-reported physical functioning in sexual minority women. *Health Psychol* 2017;36:947–54.
53 Gold SD, Feinstein BA, Skidmore WC, *et al*. Childhood physical abuse, internalized homophobia, and experiential avoidance among lesbians and gay men. *Psychological Trauma: Theory, Research, Practice, and Policy* 2011;3:50–60.
54 Matthews AK, Cho YI, Hughes TL, *et al*. The Influence of Childhood Physical Abuse on Adult Health Status in Sexual Minority Women: The Mediating Role of Smoking. *Womens Health Issues* 2013;23:e95–102.
55 Scheer JR, Pachankis JE. Psychosocial Syndemic Risks Surrounding Physical Health Conditions Among Sexual and Gender Minority Individuals. *LGBT Health* 2019;6:377–85.
56 Pachankis JE. A transdiagnostic minority stress treatment approach for gay and bisexual men's syndemic health conditions. *Arch Sex Behav* 2015;44:1843–60.
57 Kendler KS, Heath AC, Neale MC, *et al*. Alcoholism and major depression in women. A twin study of the causes of comorbidity. *Arch Gen Psychiatry* 1993;50:690–8.
58 Dawson DA, Goldstein RB, Moss HB, *et al*. Gender differences in the relationship of internalizing and externalizing psychopathology to alcohol dependence: Likelihood, expression and course☆. *Drug Alcohol Depend* 2010;112:9–17.
59 Davidson RJ, Jackson DC, Kalin NH. Emotion, plasticity, context, and regulation: perspectives from affective neuroscience. *Psychol Bull* 2000;126:890–909.
60 Sinha R. Chronic stress, drug use, and vulnerability to addiction. *Ann N Y Acad Sci* 2008;1141:105–30.
61 Casement MD, Shaw DS, Sitnick SL, *et al*. Life stress in adolescence predicts early adult reward-related brain function and alcohol dependence. *Soc Cogn Affect Neurosci* 2015;10:416–23.
62 Helen C. F, Keri L. B, Peihua G, *et al*. Interactive Effects of Cumulative Stress and Impulsivity on Alcohol Consumption. *Alcoholism Clin & Exp Res* 2010;34:1376–85.
63 Dawe S, Gullo MJ, Loxton NJ. Reward drive and rash impulsiveness as dimensions of impulsivity: Implications for substance misuse. *Addict Behav* 2004;29:1389–405.
64 Keyes KM, Hatzenbuehler ML, Hasin DS. Stressful life experiences, alcohol consumption, and alcohol use disorders: the epidemiologic evidence for four main types of stressors. *Psychopharmacology (Berl)* 2011;218:1–17.
65 Fitzpatrick S, Dworkin ER, Zimmerman L, *et al*. Stressors and Drinking in Sexual Minority Women: The Mediating Role of Emotion Dysregulation. *Psychol Sex Orientat Gend Divers* 2020;7:46–54.
66 Hatzenbuehler ML. How does sexual minority stigma 'get under the skin'? A psychological mediation framework. *Psychol Bull* 2009;135:707–30.
67 Lewis RJ, Winstead BA, Lau-Barraco C, *et al*. Social Factors Linking Stigma-Related Stress with Alcohol Use among Lesbians. *Journal of Social Issues* 2017;73:545–62.
68 Lewis RJ, Milletich RJ, Mason TB, *et al*. Pathways Connecting Sexual Minority Stressors and Psychological Distress Among Lesbian Women. *Journal of Gay & Lesbian Social Services* 2014;26:147–67.
69 Szymanski DM, Dunn TL, Ikizler AS. Multiple minority stressors and psychological distress among sexual minority women: The roles of rumination and maladaptive coping. *Psychol Sex Orientat Gend Divers* 2014;1:412–21.
70 Scheer JR, Harney P, Esposito J, *et al*. Self-reported mental and physical health symptoms and potentially traumatic events among lesbian, gay, bisexual, transgender, and queer individuals: The role of shame. *Psychol Violence* 2020;10:131–42.
71 Corliss HL, Grella CE, Mays VM, *et al*. Drug Use, Drug Severity, and Help-Seeking Behaviors of Lesbian and Bisexual Women. *J Womens Health (Larchmt)* 2006;15:556–68.
72 Jeong YM, Veldhuis CB, Aranda F, *et al*. Racial/ethnic differences in unmet needs for mental health and substance use treatment in a community-based sample of sexual minority women. *J Clin Nurs* 2016;25:3557–69.
73 Hughes TL. Lesbians' drinking patterns: beyond the data. *Subst Use Misuse* 2003;38:1739–58.
74 Allen JL, Mowbray O. Sexual orientation, treatment utilization, and barriers for alcohol related problems: Findings from a nationally representative sample. *Drug Alcohol Depend* 2016;161:323–30.
75 McCabe SE, West BT, Hughes TL, *et al*. Sexual orientation and substance abuse treatment utilization in the United States: results from a national survey. *J Subst Abuse Treat* 2013;44:4–12.
76 Chaudoir SR, Wang K, Pachankis JE. What reduces sexual minority stress? A review of the intervention 'toolkit'. *J Soc Issues* 2017;73:586–617.
77 McGeough B. A systematic review of substance use treatments for sexual minority women. *Journal of Gay & Lesbian Social Services* 2021;33:180–210.
78 Boyle SC, LaBrie JW, Trager BM, *et al*. A Gamified Personalized Normative Feedback App to Reduce Drinking Among Sexual Minority Women: Randomized Controlled Trial and Feasibility Study. *J Med Internet Res* 2022;24:e34853.
79 Fals-Stewart W, O'Farrell TJ, Lam WKK. Behavioral couple therapy for gay and lesbian couples with alcohol use disorders. *J Subst Abuse Treat* 2009;37:379–87.
80 Lelutiu-Weinberger C, Pachankis JE, Gamarel KE, *et al*. Feasibility, Acceptability, and Preliminary Efficacy of a Live-Chat Social Media Intervention to Reduce HIV Risk Among Young Men Who Have Sex With Men. *AIDS Behav* 2015;19:1214–27.
81 Pachankis JE, Lelutiu-Weinberger C, Golub SA, *et al*. Developing an Online Health Intervention for Young Gay and Bisexual Men. *AIDS Behav* 2013;17:2986–98.
82 Pachankis JE. Uncovering Clinical Principles and Techniques to Address Minority Stress, Mental Health, and Related Health Risks Among Gay and Bisexual Men. *Clin Psychol (New York)* 2014;21:313–30.
83 Golub SA, Peña S, Hilley A, eds. Brief behavioral intervention increases prep drug levels in a real-world setting. In: Conference on Retroviruses and Opportunistic Infections (CROI); 2017
84 Leluțiu-Weinberger C, Manu M, Ionescu F, *et al*. An mHealth Intervention to Improve Young Gay and Bisexual Men's Sexual, Behavioral, and Mental Health in a Structurally Stigmatizing National Context. *JMIR Mhealth Uhealth* 2018;6:e183.
85 Burton CL, Wang K, Pachankis JE. Psychotherapy for the Spectrum of Sexual Minority Stress: Application and Technique of the ESTEEM Treatment Model. *Cogn Behav Pract* 2019;26:285–99.
86 Ellard KK, Fairholme CP, Boisseau CL, *et al*. Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders: Protocol Development and Initial Outcome Data. *Cogn Behav Pract* 2010;17:88–101.

87 Boisseau CL, Farchione TJ, Fairholme CP, *et al*. The Development of the Unified Protocol for the Transdiagnostic Treatment of Emotional Disorders: A Case Study. *Cogn Behav Pract* 2010;17:102–13.
88 Wilamowska ZA, Thompson-Hollands J, Fairholme CP, *et al*. Conceptual background, development, and preliminary data from the unified protocol for transdiagnostic treatment of emotional disorders. *Depress Anxiety* 2010;27:882–90.
89 Farchione TJ, Fairholme CP, Ellard KK, *et al*. Unified protocol for transdiagnostic treatment of emotional disorders: a randomized controlled trial. *Behav Ther* 2012;43:666–78.
90 Pachankis JE, McConocha EM, Clark KA, *et al*. A transdiagnostic minority stress intervention for gender diverse sexual minority women's depression, anxiety, and unhealthy alcohol use: A randomized controlled trial. *J Consult Clin Psychol* 2020;88:613–30.
91 Barlow DH, Farchione TJ, Bullis JR, *et al*. The Unified Protocol for Transdiagnostic Treatment of Emotional Disorders Compared With Diagnosis-Specific Protocols for Anxiety Disorders: A Randomized Clinical Trial. *JAMA Psychiatry* 2017;74:875–84.
92 Ciraulo DA, Barlow DH, Gulliver SB, *et al*. The effects of venlafaxine and cognitive behavioral therapy alone and combined in the treatment of co-morbid alcohol use-anxiety disorders. *Behav Res Ther* 2013;51:729–35.
93 Scheer JR, Clark KA, McConocha E, *et al*. Toward Cognitive-Behavioral Therapy for Sexual Minority Women: Voices From Stakeholders and Community Members. *Cogn Behav Pract* 2023;30:471–94.
94 Pachankis JE, Soulliard ZA, Morris F, *et al*. A Model for Adapting Evidence-Based Interventions to Be LGBQ-Affirmative: Putting Minority Stress Principles and Case Conceptualization Into Clinical Research and Practice. *Cogn Behav Pract* 2023;30:1–17.
95 Pachankis JE, Harkness A, Jackson S, *et al*. *Transdiagnostic LGBTQ-affirmative cognitive-behavioral therapy: therapist guide*. Oxford University Press, 2022.
96 Rodriguez-Seijas C, Eaton NR, Pachankis JE. Prevalence of psychiatric disorders at the intersection of race and sexual orientation: Results from the National Epidemiologic Survey of Alcohol and Related Conditions-III. *J Consult Clin Psychol* 2019;87:321:321–31:.
97 Bränström R, Pachankis JE. Sexual orientation disparities in the co-occurrence of substance use and psychological distress: a national population-based study (2008-2015). *Soc Psychiatry Psychiatr Epidemiol* 2018;53:403–12.
98 Brière FN, Rohde P, Seeley JR, *et al*. Comorbidity between major depression and alcohol use disorder from adolescence to adulthood. *Compr Psychiatry* 2014;55:526–33.
99 Harris PA, Taylor R, Minor BL, *et al*. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.
100 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
101 The Williams Institute, UCLA School of Law. LGBT demographic data interactive. 2019. Available: https://williamsinstitute.law.ucla.edu/visualization/lgbt-stats/?topic=LGBT#about-the-data
102 Sullivan JT, Sykora K, Schneiderman J, *et al*. Assessment of alcohol withdrawal: the revised clinical institute withdrawal assessment for alcohol scale (CIWA-Ar). *Br J Addict* 1989;84:1353–7.
103 van Spijker BAJ, Batterham PJ, Calear AL, *et al*. The Suicidal Ideation Attributes Scale (SIDAS): Community-Based Validation Study of a New Scale for the Measurement of Suicidal Ideation. *Suicide & Life Threat Behav* 2014;44:408–19.
104 Tariq SH, Tumosa N, Chibnall JT, *et al*. Comparison of the Saint Louis University mental status examination and the mini-mental state examination for detecting dementia and mild neurocognitive disorder--a pilot study. *Am J Geriatr Psychiatry* 2006;14:900–10.
105 American Psychological Association. Guidelines for psychological practice with lesbian, gay, and bisexual clients. 2012.
106 Pachankis JE, Harkness A, Maciejewski KR, *et al*. LGBQ-affirmative cognitive-behavioral therapy for young gay and bisexual men's mental and sexual health: A three-arm randomized controlled trial. *J Consult Clin Psychol* 2022;90:459–77.
107 Hilsenroth MJ, Blagys MD, Ackerman SJ, *et al*. Measuring Psychodynamic-Interpersonal and Cognitive-Behavioral Techniques: Development of the Comparative Psychotherapy Process Scale. *Psychotherapy: Theory, Research, Practice, Training* 2005;42:340–56.
108 Sobell LC, Brown J, Leo GI, *et al*. The reliability of the Alcohol Timeline Followback when administered by telephone and by computer. *Drug Alcohol Depend* 1996;42:49–54.
109 Maisto SA, Conigliaro JC, Gordon AJ, *et al*. An experimental study of the agreement of self-administration and telephone administration of the Timeline Followback interview. *J Stud Alcohol Drugs* 2008;69:468–71.
110 Cohen BB, Vinson DC. Retrospective Self-Report of Alcohol Consumption: Test-Retest Reliability by Telephone. *Alcoholism Clin & Exp Res* 1995;19:1156–61.
111 Tolin DF, Gilliam C, Wootton BM, *et al*. Psychometric Properties of a Structured Diagnostic Interview for *DSM-5* Anxiety, Mood, and Obsessive-Compulsive and Related Disorders . *Assessment* 2018;25:3–13.
112 Derogatis LR, Melisaratos N. The Brief Symptom Inventory: an introductory report. *Psychol Med* 1983;13:595–605.
113 Beck AT, Epstein N, Brown G, *et al*. An inventory for measuring clinical anxiety: psychometric properties. *J Consult Clin Psychol* 1988;56:893–7.
114 Radloff LS. The CES-D Scale. *Appl Psychol Meas* 1977;1:385–401.
115 Norman SB, Cissell SH, Means-Christensen AJ, *et al*. Development and validation of an Overall Anxiety Severity And Impairment Scale (OASIS). *Depress Anxiety* 2006;23:245–9.
116 Bentley KH, Gallagher MW, Carl JR, *et al*. Development and validation of the Overall Depression Severity and Impairment Scale. *Psychol Assess* 2014;26:815–30.
117 Bovin MJ, Marx BP, Weathers FW, *et al*. Psychometric properties of the PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders–Fifth Edition (PCL-5) in veterans. *Psychol Assess* 2016;28:1379–91.
118 Pilkonis PA, Yu L, Colditz J, *et al*. Item banks for alcohol use from the Patient-Reported Outcomes Measurement Information System (PROMIS®): Use, consequences, and expectancies. *Drug Alcohol Depend* 2013;130:167–77.
119 Ham LS, Stewart SH, Norton PJ, *et al*. Psychometric Assessment of the Comprehensive Effects of Alcohol Questionnaire: Comparing a Brief Version to the Original Full Scale. *J Psychopathol Behav Assess* 2005;27:141–58.
120 Collins RL, Parks GA, Marlatt GA. Social determinants of alcohol consumption: the effects of social interaction and model status on the self-administration of alcohol. *J Consult Clin Psychol* 1985;53:189–200.
121 DiClemente CC, Carbonari JP, Montgomery RP, *et al*. The Alcohol Abstinence Self-Efficacy scale. *J Stud Alcohol* 1994;55:141–8.
122 APA PsycTests. Drug use disorders identification test (dudit). APA PsycTests; 2002.
123 Adamson SJ, Sellman JD. A prototype screening instrument for cannabis use disorder: the Cannabis Use Disorders Identification Test (CUDIT) in an alcohol-dependent clinical sample. *Drug Alcohol Rev* 2003;22:309–15.
124 Mohr JJ, Kendra MS. Revision and extension of a multidimensional measure of sexual minority identity: the Lesbian, Gay, and Bisexual Identity Scale. *J Couns Psychol* 2011;58:234–45.
125 Riggle EDB, Folberg AM, Richardson MT, *et al*. A measure of hypervigilance in LGBTQ-identified individuals. *Stigma Health* 2021.
126 Pachankis JE, Goldfried MR, Ramrattan ME. Extension of the rejection sensitivity construct to the interpersonal functioning of gay men. *J Consult Clin Psychol* 2008;76:306–17.
127 Dyar C, Feinstein BA, Davila J. Development and Validation of a Brief Version of the Anti-Bisexual Experiences Scale. *Arch Sex Behav* 2019;48:175–89.
128 Testa RJ, Habarth J, Peta J, *et al*. Development of the Gender Minority Stress and Resilience Measure. *Psychol Sex Orientat Gend Divers* 2015;2:65–77.
129 Balsam KF, Molina Y, Beadnell B, *et al*. Measuring multiple minority stress: the LGBT People of Color Microaggressions Scale. *Cultur Divers Ethnic Minor Psychol* 2011;17:163–74.
130 Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav* 1983;24:385–96.
131 Russell DW. UCLA Loneliness Scale (Version 3): reliability, validity, and factor structure. *J Pers Assess* 1996;66:20–40.
132 Gratz KL, Roemer L. Multidimensional Assessment of Emotion Regulation and Dysregulation: Development, Factor Structure, and Initial Validation of the Difficulties in Emotion Regulation Scale. *J Psychopathol Behav Assess* 2004;26:41–54.
133 Kasch KL, Klein DN, Lara ME. A construct validation study of the Response Styles Questionnaire Rumination Scale in participants with a recent-onset major depressive episode. *Psychol Assess* 2001;13:375–83.
134 Rathus SA. A 30-item schedule for assessing assertive behavior. *Behav Ther* 1973;4:398–406.
135 Cohen S, Mermelstein R, Kamarck T, *et al*. Measuring the functional components of social support. In: Sarason IG, Sarason BR, eds.

Social support: theory, research, and applications. The hague. Netherlands: Martinus Nijihoff, 1985.
136 Diamond LM, Alley J. Rethinking minority stress: A social safety perspective on the health effects of stigma in sexually-diverse and gender-diverse populations. *Neuroscience & Biobehavioral Reviews* 2022;138:104720.
137 CfDCa P. *Behavioral risk factor surveillance system survey questionnaire*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2021.
138 Szymanski DM. Does Internalized Heterosexism Moderate the Link Between Heterosexist Events and Lesbians' Psychological Distress? *Sex Roles* 2006;54:227–34.
139 Hatzenbuehler ML, Lattanner MR. Perceived Structural Stigma Scale. 2021.
140 Kachel S, Steffens MC, Niedlich C. Traditional Masculinity and Femininity: Validation of a New Scale Assessing Gender Roles. *Front Psychol* 2016;7.
141 Múthen LK, Múthen BO. *Mplus user's guide*7th. Los Angeles, CA: Múthen & Múthen, 2012.
142 Magill M, Ray LA. Cognitive-Behavioral Treatment With Adult Alcohol and Illicit Drug Users: A Meta-Analysis of Randomized Controlled Trials. *J Stud Alcohol Drugs* 2009;70:516–27.
143 Riper H, Blankers M, Hadiwijaya H, *et al*. Effectiveness of Guided and Unguided Low-Intensity Internet Interventions for Adult Alcohol Misuse: A Meta-Analysis. *PLoS ONE* 2014;9:e99912.
144 Riper H, Andersson G, Hunter SB, *et al*. Treatment of comorbid alcohol use disorders and depression with cognitive-behavioural therapy and motivational interviewing: a meta-analysis. *Addiction* 2014;109:394–406.
145 Magill M, Ray L, Kiluk B, *et al*. A meta-analysis of cognitive-behavioral therapy for alcohol or other drug use disorders: Treatment efficacy by contrast condition. *J Consult Clin Psychol* 2019;87:1093–105.
146 Benjamini Y, Hochberg Y. Controlling the False Discovery Rate: A Practical and Powerful Approach to Multiple Testing. *Journal of the Royal Statistical Society Series B* 1995;57:289–300.
147 Thoemmes F, Mackinnon DP, Reiser MR. POWER ANALYSIS FOR COMPLEX MEDIATIONAL DESIGNS USING MONTE CARLO METHODS. *Struct Equ Modeling* 2010;17:510–34.
148 Hollinsaid NL, Weisz JR, Chorpita BF, *et al*. The effectiveness and acceptability of empirically supported treatments in gender minority youth across four randomized controlled trials. *J Consult Clin Psychol* 2020;88:1053–64.
149 Rimes KA, Ion D, Wingrove J, *et al*. Sexual orientation differences in psychological treatment outcomes for depression and anxiety: National cohort study. *J Consult Clin Psychol* 2019;87:577–89.
150 Beard C, Kirakosian N, Silverman AL, *et al*. Comparing treatment response between LGBQ and heterosexual individuals attending a CBT- and DBT-skills-based partial hospital. *J Consult Clin Psychol* 2017;85:1171–81.
151 Millar BM, Wang K, Pachankis JE. The moderating role of internalized homonegativity on the efficacy of LGB-affirmative psychotherapy: Results from a randomized controlled trial with young adult gay and bisexual men. *J Consult Clin Psychol* 2016;84:565–70.
152 Lee CS, Colby SM, Rohsenow DJ, *et al*. A randomized controlled trial of motivational interviewing tailored for heavy drinking latinxs. *J Consult Clin Psychol* 2019;87:815–30.
153 Price MA, McKetta S, Weisz JR, *et al*. n.d. Cultural sexism moderates efficacy of psychotherapy: Results from a spatial meta-analysis. *Clinical Psychology: Science and Practice*28:299–312.
154 Price MA, Weisz JR, McKetta S, *et al*. Meta-analysis: Are Psychotherapies Less Effective for Black Youth in Communities With Higher Levels of Anti-Black Racism? *Journal of the American Academy of Child & Adolescent Psychiatry* 2022;61:754–63.
155 Pachankis JE, Soulliard ZA, Layland EK, *et al*. Guided LGBTQ-affirmative internet cognitive-behavioral therapy for sexual minority youth's mental health: A randomized controlled trial of a minority stress treatment approach. *Behav Res Ther* 2023;169:104403.
156 Ng MY, Weisz JR. Annual Research Review: Building a science of personalized intervention for youth mental health. *J Child Psychol Psychiatry* 2016;57:216–36.
157 Gunlicks-Stoessel M, Eckshtain D, Lee S, *et al*. Latent Profiles of Cognitive and Interpersonal Risk Factors for Adolescent Depression and Implications for Personalized Treatment. *J Abnorm Child Psychol* 2019;47:1957–67.
158 Hankin BL. Screening for and Personalizing Prevention of Adolescent Depression. *Curr Dir Psychol Sci* 2020;29:327–32.
159 Hatzenbuehler ML, Pachankis JE. Does Stigma Moderate the Efficacy of Mental- and Behavioral-Health Interventions? Examining Individual and Contextual Sources of Treatment-Effect Heterogeneity. *Curr Dir Psychol Sci* 2021;30:476–84.
160 Health NIo. Sharing research resources: national insititutes of health. 2024. Available: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm
161 Editors ICoMJ. Defining the roles of authors and contributors: international committee of medical journal editors. 2025. Available: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two