Building Mobile HIV Prevention and Mental Health Support in Low-resource Settings

NCT06229132

2/15/2025

BACKGROUND

In July 2021, the study team received a supplement to the R01 grant to enroll a small sample (N=45) of transgender and gender-diverse (TGD) Romanians in addition to the original sample of 800 GBM. This decision is based on the following rationale. TGD individuals remain a hidden group in the Central Eastern European (CEE) country of Romania, with few protections, few equal rights, and many unmet needs. Emerging research with TGD persons in the region indicates that TGD Romanians report particularly high rates of depression, HIV, and hazardous alcohol use, primarily driven by the country's high structural stigma. Romania's healthcare system has little expertise for addressing these syndemic health threats. No targeted needs assessments or interventions exist to date in order to remedy these adversities and promote the wellbeing of TGD in Romania, or anywhere in CEE – the region with the fastest-growing HIV epidemic in the world. In response, we proposed to create and pilot-test the first intervention in CEE to address the mental, sexual, and behavioral health of TGD people. Compared to the GBM sample, however, TGD participants in formative work indicated that a mental health focus, rather than a sexual or behavioral health focus (while still addressing these as relevant to each participant) should be adopted. As a result, our EQuIP (Empowering Queer Identities in Psychotherapy) intervention is being delivered in this supplement to the TGD sample of 25 participants.

In Aim 1, we will identify unique needs of TGD Romanians via focus groups. Findings will be used in Aim 2 to modify the intervention manual to address gender minority stress and other TGD-specific determinants of mental health, hazardous alcohol use, and HIV risk. In Aim 3, we will evaluate the adapted intervention's feasibility, acceptability, and efficacy potential in a one-arm trial with 25 TGD Romanians.

Research Aims & Abstracts

The aim of this study is to evaluate the intervention's feasibility, acceptability and efficacy potential in a one-arm trial with 25 TGD Romanians. Participants will receive 16 weekly mHealth sessions hypothesized to reduce depression, anxiety, HIV risk, and hazardous alcohol use; outcome data will be collected at baseline and 5-month follow-up.

Scientific Abstract

Transgender and gender diverse (e.g., gender non-binary) (TGD) individuals remain a hidden group in the Central Eastern European (CEE) country of Romania, with few protections, few equal rights, and many unmet needs. Emerging research with TGD persons in the region indicates that TGD Romanians report particularly high rates of depression, anxiety, HIV, and hazardous alcohol use, primarily driven by the country's high structural stigma. Romania's healthcare system has little expertise for addressing these syndemic health threats. No targeted needs assessments or interventions exist to date in order to remedy these adversities and promote the wellbeing of TGD in Romania, or anywhere in CEE – the region with the fastest-growing HIV epidemic in the world. In response, we propose to create and pilot-test the first intervention in CEE to address the mental, sexual, and behavioral health of TGD people. EQuIP, MPI Pachankis's intervention, was tested with various populations in the US and in China. The first pilot study tested successfully the efficacy of a minority-stress-focused cognitive– behavioral therapy (CBT) intended to improve mental and behavioral health for sexual minority women. This treatment was adapted for the present research based on local Romanian TGD needs uncovered in the first part of this pilot study (which ended in 2021). The adaptation was guided by the gender minority stress framework that acknowledges unique TGD stressors, whose impact the intervention intends to modify. As such, the intervention consists of 16 1-hour sessions delivered by trained therapists on Zoom. The team will evaluate the new intervention's feasibility and acceptability in a one-arm trial with 25 TGD Romanians. Data will be collected at baseline and 5-month follow-up.

STUDY DESIGN

For the transgender sample, the study team completed focus groups with 19 TGD, 6 providers and stakeholders to identify the most suitable intervention targets and approach. This process led the team to identify social gender affirmation, and accompanying mental health issues, as primary intervention targets for TGD Romanians, who face frequent minority stress as a function of difficulties finding providers and hormonal treatment, school and employment discrimination, and lack of affirming providers. Given the role of minority stress in TGD Romanian's lives, the team has adapted the EQuIP LGBTQ-affirmative CBT intervention (Pachankis et al., 2022) for this study. The team will evaluate the intervention's feasibility,

acceptability and efficacy potential in a one-arm trial with Romanian TGD individuals who report depression or anxiety. Participants will receive 16 weekly mHealth sessions delivered on the HIPAA-compliant Zoom platform, and hypothesized to address the outcomes of interest; data will be collected at baseline and 5-month follow-up.

Eligibility. Potential participants will be eligible if they 1) identify on the transfeminine, transmasculine, or gender non-binary spectrum and declare a gender that is different from their assigned birth sex; 2) be 18 years old; 3) report depression or anxiety symptoms (score past 90-day symptoms of depression or anxiety: 2.5 or higher score on depression or anxiety subscale of the Brief Symptom Inventory); 4) own a phone, tablet, or laptop. Additionally, to be eligible, participants must not be receiving regular mental health services on an ongoing basis (e.g., more than once per month) and cannot have received 8 or more sessions of CBT within the past 12 months.

Intervention Content. MPI Pachankis (Yale University) has created and tested EQuIP with various populations in the US and in China. The first pilot study tested the efficacy of a minority-stress-focused cognitive– behavioral therapy (CBT) intended to improve mental and behavioral health for sexual minority women. The intervention was delivered to young adult sexual minority women in the US (n = 60; M age = 25.58; 41.67% racial/ethnic minority; 43.33% transgender/nonbinary) experiencing depression/anxiety and past 90-day heavy alcohol use. Compared to waitlist (n = 30), participants randomized to immediately receive EQuIP (n = 30) experienced significantly reduced depression and anxiety (d = 0.85, 0.86, respectively). In pre to post-intervention pooled analyses, effect sizes for minority stress processes (mean d =.25) and universal risk factors (mean d =.48) were reduced. This treatment was adapted for the present research based on local Romanian TGD needs uncovered in the first part of this pilot study (which ended in 2021). As such, the intervention will consist of 16 1-hour sessions delivered by our trained therapists on Zoom. These sessions are based on 6 principles of LGBTQ-affirming CBT, as follows: (1) normalizing mood and anxiety as a common response to LGBTQ related stress; (2) challenging persistent, inflexible LGBQ-related stress-induced cognitions; (3) encouraging assertive behavior and open self-expression to effectively cope with the consequences of LGBTQ-related stress; (4) validating LGBTQ clients' unique strengths; (5) building authentic relationships as an essential resource for LGBTQ people's mental health; and (6) recognizing intersectional identities as a source of stress and resilience.

STATISTICAL ANALYSIS

Feasibility and acceptability measures and analyses. Feasibility will be assessed by: 1) examining screener data for eligibility ratio and reasons for enrollment refusal; and 2) participants' rating of participation ease, including in using the mobile platform, and counselors' rating of intervention delivery ease (mean score of ³4 on a scale of 1-5 indicates high feasibility). Acceptability will be assessed by: 1) tracking # of sessions completed, with a minimum session completion dose by ³80% of participants (which is ³10 sessions, completed by 86% of participants); and 2) post-intervention ratings (mean score of ³4 on a scale of 1-5 indicates high acceptability) of the: a) usefulness of intervention content and perception of personal progress, b) intervention structure, c) delivery modality, d) counselor expertise, and e) therapeutic alliance including trust and comfort. Finally, exit interviews with all participants and counselors will qualitatively assess intervention accessibility and participation comfort, content relevance and TGD-sensitivity, perceived impact on health and wellbeing, duration, and if participants would recommend it to friends (compensated with the Romanian equivalent of $30).

Intervention outcomes. This pilot will establish effect sizes necessary to power a future larger trial for our main outcomes: depression, anxiety, HIV risk, and hazardous alcohol use.

Analyses for intervention evaluation. Findings will allow us to assess the intervention's potential impact on mental health, HIV risk, hazardous drinking, and psychosocial mechanisms theorized to underlie the adverse impact of gender minority stressors on participants' health. Outcome distributional properties will be examined using standard summary statistics (means, SDs, medians, skew, kurtosis) and graphical summaries (boxplots, density plots). For continuous or discrete variables with skewed distributions (e.g., hazardous drinking frequency), we will investigate transformation to symmetry (e.g., log and square root). Given the small sample size (n = 25), we will not have sufficient power to use traditional statistical significance testing. However, in order to gather preliminary data on the magnitude of the intervention's possible impact on each outcome, we will conduct paired-sample t-tests to assess pre-post intervention change (from baseline to immediately post-intervention 5 months later).

Power. Utilizing the t-tests results, we will calculate Cohen's d as a measure of effect size and interpret effects as small (d = 0.2), medium (d = 0.5), and large (d = 0.8) following published guidelines.