**A Cognitive Behavioral Therapy Group Intervention to Increase HIV Testing and PrEP Use Among Latinx Sexual Minority Men**

January 6, 2020

**PROTOCOL SUMMARY**

**1. Background and Rationale**

HIV-related disparities persist among Latinx communities, especially those who are immigrants and sexual minority men (SMM). In 2017, Latinx adults showed HIV rates 3.2 times higher than White adults, and Latinx SMM (LSMM) accounted for 75% of all HIV diagnoses among Latinx adults; 67% of newly diagnosed HIV infections among LSMM were immigrants. Latinx adults, especially those who are immigrants, are diagnosed with HIV (i.e., tested) at a later disease stage, leading to delays in treatment. In addition, only 13.1% of Latinx adults reported pre-exposure prophylaxis (PrEP) use in 2016, compared to 68.7% of White adults. However, of the HIV prevention interventions listed in the CDC's Compendium of Evidence-Based Interventions, only one was developed for LSMM, and none have yet been developed or assessed for PrEP use.

In this study we will integrate HIV prevention strategies into a coping intervention that includes 8-sessions of group cognitive behavioral therapy (CBT) for HIV-negative LSMM that aims to improve adaptive coping responses to discrimination and increase preventive strategies. We hypothesize that the intervention will improve coping responses to discrimination and HIV testing and PrEP use.

**2. Objectives**

This objectives of this study are to: 1) conduct a randomized controlled trial of a coping intervention that is a culturally congruent CBT group intervention for immigrant LSMM, to test intervention effects on regular HIV testing and PrEP use; 2) examine mechanisms of intervention effects on regular HIV testing and PrEP use, including more effective coping; and 3) conduct a cost-effectiveness analysis of the intervention.

**3. Study Design**

We will conduct 10 intervention groups and 10 standard of care control groups of about 15 participants each (n=300). After participants complete the baseline assessment, we will randomize them into the intervention or standard of care control groups. Participants will complete audio computer-assisted interviews at baseline, and 4, 8, and 12-month follow-ups. The intervention will last 8 weeks (7 sessions of content plus a "graduation").

The proposed study is a partnership among academic researchers and stakeholders of Los Angeles County (LAC) Latinx and HIV-affected communities. Bienestar will be a full and equal partner throughout the research. Bienestar, LAC's largest Latinx-serving HIV service organization, provides services (e.g., case management, substance use, mental health) in 7 offices in LAC to people living with HIV and HIV prevention to those at risk.

Participants in the standard of care control group will be provided with information about an ongoing weekly two-hour open wellness-oriented support group available to all clients at Bienestar. The program includes an open support group; psychoeducation on wellness topics (e.g., HIV prevention, sexuality, spirituality, self-esteem, other health promotion topics); and social and cultural activities with food, art, and music.

## 4. Methods

*Screening/Recruitment*

As in our prior pilot test, we will recruit participants via fliers left at the clinic at which the intervention will be conducted (Bienestar) and other community-based organizations and clinic (in waiting areas, on bulletin boards), fliers disseminated by Bienestar staff (e.g., HIV testing counselors, substance use counselors) to clients, and online advertisements. We will hold brief information sessions at client and staff gatherings. We will hire a research assistant from the local community for recruitment and tracking who is well-connected with the local HIV population and familiar with local HIV services for Latinx adults. Members of the Community Advisory Committee will also be asked to assist with recruitment.

Participants will be eligible if they are ≥18 years-old, biologically male at birth; identify as male; identify as a Latino immigrant; report having sex with men in the past 12 months; report HIV-negative or unknown serostatus; anticipate being available for the next 12 months to attend study visits; and able to interact and communicate in spoken Spanish or English. The latter two criteria will be important to ensure that individuals will be able to actively participate in the intervention sessions.

Women, including transgender women, will not be eligible because they face discrimination regarding gender/gender identity that would necessitate a differently tailored intervention with additional content and components that the present intervention lacks.

*Procedures*

The coping intervention will be conducted in groups and situated in a trusted community venue. The intervention was developed with, and will be delivered by, credible community stakeholders knowledgeable about SMM culture—individuals not viewed as authority figures or part of the medical system. The intervention will be led by an expert facilitator (with experience leading groups) and a peer co-facilitator (with experience working with SMM). Both facilitators are matched on client ethnicity to increase credibility and trust.

The intervention will utilize several counseling techniques:

*Psychoeducation*: All participants will receive basic HIV and prevention education. We will raise awareness about disparities and discrimination (e.g., links between discrimination and lack of engagement in medical care) and address medical mistrust. Facilitators will acknowledge historical and current challenges, including discrimination, which lead to mistrust, and mental health, substance use, and poverty (and, if necessary, provide referrals for services). The intervention will also address HIV and sexual orientation stigma in Latinx communities, and how stigma can be a barrier to seeking support, accessing healthcare, and adherence to prevention strategies such as PrEP.

*Cognitive Behavioral Therapy*: CBT aims to empower clients to be their own agents of change, building on existing strengths and skills. CBT involves educating clients about the relations among their thoughts, behaviors, and emotions. Counselors help clients to understand a given problem behavior (e.g., rumination after discrimination) in terms of the chain of events that led to the behavior (a functional analysis/chain analysis) as well as the behavior's consequences. Clients can be guided through a step-by-step, micro-level recounting of thoughts, feelings, and emotions related to a specific event/behavior chain (distal vulnerability factors, proximal prompting events, immediate and longer-term consequences of coping strategies), and they work with the counselor collaboratively to identify problematic 'links' in the chain. Counselors teach clients cognitive and behavioral skills (mindfulness, cognitive restructuring, relaxation) for better coping. Skills are practiced in session, and behavioral self-monitoring and further practice are assigned between sessions to facilitate skills generalization. The counselor teaches clients the utility of having a 'toolbox' of potential strategies to use for different situations, and how to

strategically select a skill that best matches a given problem. Skills are understood and evaluated in the context of clients' values ("It's important to stay healthy") and goals ("I want to get tested regularly for HIV"). CBT is useful in groups because antecedents or consequences of many problem behaviors are interpersonal (e.g., disrupted relationships) and because clients can 'test out' new skills vicariously through the experiences of other group members.

We will administer 4 survey waves: baseline, 4-months post-baseline (shortly after intervention completion), 8-months post-baseline, and 12-months post-baseline. Surveys will be administered at Bienestar using audio computer-assisted self-interviews. Participants will complete the baseline survey before randomization. Participants who drop out of the program will be encouraged to complete all surveys.

To validate self-reports, we will obtain HIPAA consent to obtain medical and administrative records, which we will use to verify HIV status, HIV testing practices, service use, and PrEP use.

For **process evaluation** purposes, we will assess feasibility and acceptability to inform future dissemination efforts. Following implementation science recommendations, we will assess feasibility in terms of: recruitment rate (number recruited per month, of number expected); refusal rates, and intervention session retention. We will assess feasibility of eligibility criteria (sufficient vs. too restrictive) by examining proportion of potential participants screened as ineligible and reasons why. Feasibility will also be assessed with post-session evaluation forms completed by facilitators and the site Co-Investigator (who will listen to all recorded sessions), to assess session flow, areas for improvement (whether some activities need to be changed, shortened, or eliminated), and whether key elements were covered adequately (which will also be used for fidelity). Acceptability, the extent to which people delivering or receiving an intervention consider it to be appropriate, based on anticipated or experienced responses, will be assessed via facilitator and participant post-session evaluation forms, which will ask how much the facilitator and participant liked or did not like the session on Likert scales, and why, in open-ended responses.

**5. Statistical Analysis**

**Main Analyses**. We hypothesize that the coping intervention will result in higher likelihoods of regular HIV testing and PrEP use, and improved coping with stigma (e.g., reduced internalized stigma). We will perform descriptive statistics and transform outcomes with skewed distributions (log or other as appropriate) to stabilize error variances and reduce outlier influence in regressions. We will select covariates from variables hypothesized on the basis of theory and previous research to predict outcomes, and for which we find support in bivariate baseline analyses (at $p<.10$). We will use intention-to-treat analysis, i.e., analyze participants according to the group to which they were randomized, regardless of session attendance. Aim 1. We will use repeated-measures logistic regression for our primary HIV testing and PrEP dichotomous outcomes. Aim 2. For secondary outcomes (e.g., coping, internalize stigma) on which the coping intervention shows significant effects, to test mediation we will compare: (a) Aim 1 models, adding baseline measures of hypothesized mediators; and (b) the same models as in (a), adding post-intervention measures of hypothesized mediators. We will examine whether including post-intervention mediators in (b) decreases the coefficient for intervention effects on the outcome relative to the corresponding coefficient from (a). We will test interactions between each moderator and intervention group in the models for Aim 1.