Siempre Seguiré: A Pilot Intervention to Improve Coping With Discrimination and Adherence Among HIV-Positive Latino MSM

February 1, 2019

1. Background and Rationale

PROTOCOL SUMMARY

HIV-related disparities in diagnosis and disease outcomes persist among Latinos, and Latinos living with HIV show a lower percentage of viral suppression compared to the general HIV-positive population. A growing body of work suggests that stigma and discrimination contribute to health disparities, especially among people living with HIV, who may experience discrimination due to multiple stigmatized identities related to HIV-serostatus, race/ethnicity, and sexual orientation. Internalized stigma and discrimination may lead to health-related disparities by increasing detrimental physiological stress responses, resulting in maladaptive coping and poor health behaviors, including non-adherence to treatment. Moreover, the chronic stress of discrimination may weaken immune function, leading to worse HIV outcomes, including increased HIV viral load.

In the proposed research, we will integrate adherence skills-building strategies into a recently developed intervention, Siempre Seguiré, a 7-session group cognitive behavioral therapy (CBT) intervention for HIV-positive Latino men who have sex with men (LMSM) that aims to improve adaptive coping responses to discrimination. We hypothesize that the intervention will improve coping responses to discrimination and HIV treatment adherence.

2. Objectives

This objectives of this study are: (1) to modify and refine Siempre Seguiré, a newly developed culturally congruent CBT group intervention for HIV-positive LMSM, to include strategies for antiretroviral treatment adherence and retention in HIV care; and (2) to conduct a small randomized pilot of Siempre Seguiré to examine feasibility and acceptability, as well as to explore preliminary effects on: (a) coping responses to discrimination; and (b) antiretroviral treatment adherence, viral load suppression, and HIV care retention, among LMSM living with HIV.

3. Study Design

This randomized controlled trial builds on a pilot trial of the Siempre Seguiré intervention. We will conduct 4 intervention groups and 4 wait-list control groups of 15 participants each (n=120). After participants complete the baseline assessment, we will randomize them into the intervention and wait-list control groups. We will provide the program to any interested control participants shortly after the 6-month follow-up surveys are completed. Our proposed sample size (60/condition) is consistent with those recommended for small intervention tests in staged intervention development.

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 AIDS service organizations (ASOs) (in waiting areas, on bulletin boards), fliers disseminated by Bienestar staff (e.g., case managers) 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 Latinos.

Participants will be eligible if they are ≥18 years-old, are HIV-positive (verified by medication bottles or copies of laboratory results), were biologically male at birth and identify as male, identify as Latino, and report having sex with men in the past 12 months. To maximize chances of showing effects, participants must also either be not on antiretroviral treatment (ART) OR not fully engaged in care (i.e., less than 2 visits in the past 12 months) and/or missed at least 1 ART dose in the past month. Transgender women will not be included because they face discrimination regarding gender identity, which would necessitate a differently tailored intervention.

Procedures

The **Siempre Seguiré 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 LMSM 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 HIV-positive LMSM). Both facilitators are matched on client ethnicity to increase credibility and trust.

The intervention will utilize several unique counseling techniques.

Psychoeducation: All participants will receive basic HIV and adherence education. We will raise awareness about disparities and discrimination (e.g., links between discrimination and nonadherence) and address 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 Latino communities, and how stigma can be a barrier to seeking support, accessing healthcare, and adherence.

Cognitive Behavioral Therapy (CBT): CBT, one of the most widely used and well-supported treatment approaches for improving mental health and health behaviors, including ART adherence, is well-suited as a change strategy for MSM and people of color. 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; nonadherence) 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 take all of my medications"). 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 use similar **participant surveys** to those in the pilot, which we found to be feasible (and not overly burdensome) for participants to complete in about 90 minutes as well as psychometrically sound (as evidenced by the internal consistency reliabilities presented below). We will administer 3 survey waves [baseline, 1-week post-intervention (~4-months post-baseline), 6-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 for appointment attendance in the last year from **medical records**, from which we will examine whether the participant had at least one HIV medical care visit in each 6-month period over the last 12 months, with a minimum of 60 days between visits. Participants will list all prescribed ART medications using medication bottles (brought to the interview). Adherence will be measured continuously and electronically from baseline to 6-month follow-up with the **Medication Event Monitoring System** (MEMS). At baseline (~2 months prior to the first intervention session, to allow time for any reactance to the MEMS assessment to decrease prior to the intervention), interviewers will assist clients with dispensing the medication with the most complex dosing schedule or the base medication of the regimen if all medications have the same schedule (e.g., non-nucleoside reverse transcriptase inhibitor, protease inhibitor, integrase inhibitor), into a MEMS bottle. Monthly from 2-6-months post-baseline, interviewers will download adherence data and participants will report instances in which the cap was not used as intended in the past 2 weeks (how often the bottle was opened without removing a dose, a dose was taken from a source other than the bottle, such as a pillbox, and whether multiple doses were removed at a time and “pocketed” for later ingestion). Data for the past two weeks at each time-point will be adjusted using these responses for a more valid assessment. MEMS software calculates the percentage of total scheduled doses actually taken, which will be dichotomized at ≥85% of doses taken at each time-point, following research suggesting that moderate adherence has clinically significant effects. We will assess self-reported adherence using items validated against viral load and pill counts: number of doses missed last week; percentage of prescribed medications taken last month (on a visual analogue scale), and ability to take all medications as prescribed in the past 4 weeks. We will obtain HIPAA consent to extract the last two viral load values from medical records. Viral load suppression will be defined as <200 copies of virus per milliliter of blood plasma.

For **process evaluation** purposes, we will record number of intervention sessions attended per participant, and participants will complete a brief survey after each session on facilitator clarity, preparedness, and likeability, and utility of session content. Facilitators and a research team observer will complete post-session evaluation forms to assess session flow, areas for improvement, and whether key elements and activities were covered adequately; this will allow us to assess whether some activities need to be shortened or eliminated. After the last session, we will conduct 60-minute qualitative debriefing exit interviews with intervention participants, which will be transcribed and translated. Topics will include general reactions to the program (content, format, logistics), and reasons for any intervention non-participation or discontinuation. We will elicit suggestions for improvement (e.g., what topics to add). We will develop a codebook listing key themes related to program feedback and suggestions for improvement. Using *Dedoose* (a qualitative data management program), two coders will mark text areas with each code. We will measure coder consistency in 20% of participants’ responses,

aiming for κ≥.70. Following coding, study PIs will examine all coded passages and compile a list of key intervention feedback.

5. Statistical Analysis

Consistent with R34 guidelines, our primary purposes are to develop the intervention and collect preliminary data regarding feasibility and acceptability; conducting formal statistical tests of outcomes or attempting to obtain a measure of effect size is not justified with a limited sample size. Thus, the proposed analyses are meant to be exploratory, to aid in planning for a full RCT. We do not expect to have sufficient statistical power to adequately examine program effects in multivariate models. However, we will explore bivariate effects in the proposed analyses, and will also examine use of a small set of covariates.

We will explore whether the program improves coping responses to discrimination; reduces medical mistrust, distress, and internalized stigma; improves adherence and retention in care; and increases rates of viral suppression in the intervention vs. control group. We will use generalized linear mixed models, i.e., a repeated-measures linear regression approach to predict coping with data collected at baseline and 4- and 6-month follow-up that compares differences between intervention and control means over time. We will employ a parallel repeated-measures logistic regression approach to predict optimal adherence (i.e., dichotomous adherence, ≥85% of doses taken) with electronic monitoring data collected at baseline and 2, 4, and 6-month follow-up. We will conduct logistic regressions predicting viral load (dichotomized as suppressed vs. not suppressed) at 6-months post-baseline with dichotomized baseline viral load. We will use similar repeated-measures linear models to examine intervention effects on the other secondary outcomes, as well as on linear adherence (percentage of prescribed doses taken) and log viral load change from baseline. We will select covariates from variables that are hypothesized on the basis of theory and previous research to predict outcome variables (see Fig. 1), and for which we find support for hypotheses in bivariate baseline analyses. We will use intention-to-treat analysis, i.e., we will analyze participants according to the condition to which they were randomized, regardless of their subsequent session attendance. We will account for all participants who responded to the baseline survey, regardless of follow-up survey or item completion, using nonresponse weighting or multiple imputation, as appropriate. Because each participant will complete the baseline survey prior to randomization, we will compare follow-up survey respondents with nonrespondents on demographics and medical variables. If we have high survey participation and find significant differences between respondents and nonrespondents, we will use inverse predicted probability nonresponse weights (and use linearization to correct estimated standard errors if there are modest deviations from standard statistical inference assumptions). We will address item nonresponse through multiple imputation.