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Study protocol

Randomization: At baseline we will randomly assign participants through computer-generated allocation sequence. We anticipate minimal risk of contamination but will survey participants about whether they have discussed the intervention with other participants. We considered alternative designs, including a waitlist control condition or an active treatment arm without the *novela* but these were deemed impractical for the pilot intervention.

Baseline and exit assessment and interview visits: At baseline assessment, study staff will evaluate participants using instruments to measure demographics and self-perceived barriers to care for Hispanic immigrant populations. Study interviews to administer the questionnaires will last up to 4 hours and will occur in a private room at the clinic or community-based organization. Participants will receive $40 in gift card and $10 transportation for completing this study visit. Study staff will offer a meal or meal ticket and allow for breaks as needed by the participant. The instruments we have selected are based on published evidence of barriers to HIV care in Latino immigrants, our qualitative research, and framed by our adapted Andersen Model of Health Care Utilization. Consistent with this conceptual model, instruments will measure the environment (e.g. neighborhood characteristics and access to services); predisposing individual-level factors (e.g. acculturation, family cohesion, social position, depression, substance use); individual enabling factors (e.g. self-efficacy, patient activation, cultural norms); and perceived health care need. We have selected scales that as much as possible have been validated in a Spanish-speaking low-literacy population. Most of the measures have been developed and validated by a national epidemiological survey in Latinos led by members of the study team that have strong reliability and validity in Spanish-speaking populations. For scales that have no prior Spanish language translation, the study team composed of multi-national native-Spanish speaking investigators, have performed translations and reviewed the translations for accuracy of content. Study staff will guide the participant through questions administered on REDCAP. If REDCAP is not available at the time of administration, questions will be documented on paper and subsequently uploaded to REDCAP. Latino immigrants have numerous barriers that may inhibit their ability to participate in research (e.g. multiple jobs, lack of access to transportation, family responsibilities). In the event, that the participant cannot come in person for the study visit and requests to participate in the baseline or exit assessment and interview visits by telephone, study staff will arrange to conduct the interview by telephone in a private room with the conversation recorded for accuracy and fidelity. Answers to the questionnaires will be documented in REDCAP by study staff. While we will attempt to obtain all exit assessments and interviews (quantitative measurements and qualitative feedback) at week-24, we will allow a window of approximately 2 weeks prior and 4 weeks after the week-24 date to accommodate participants' availability.

CHW-delivered questionnaires: At each CHW session, the CHW will also administer a 3 item questionnaire covering antiretroviral adherence, perceived need for HIV care, and global effort needed to attend HIV visits.

Intervention evaluation: To ensure fidelity of the intervention, we will obtain client consent to audio record the sessions. The CHW will also provide a brief written survey for the participant to complete on feedback for the session. Responses will be anonymous. Study staff will also conduct an exit assessment and interview with participants. During the interview study staff will use qualitative methods to assess impressions and ideas for improvement on the intervention process including suitability of the instruments to assess risk factors for inconsistent HIV clinic

attendance. The CHW will likewise complete an exit survey to solicit feedback for improvement. Study staff will present de-identified results to a Latino/HIV oriented community advisory board, to discern the need for iterative revisions of the intervention manual and intervention design. Study staff will make revisions to the questionnaire content to account for participant feedback on acceptability of the content and feasibility based on duration to complete the questionnaire. We estimate a need to enroll 100 individuals to randomize 75. Estimated conservative rate of attrition is 30%. This sample size is consistent with recommendations for randomized pilot studies for preliminary estimation of effect sizes and lower bounds. The primary purpose of our pilot is to determine the feasibility of the intervention program and evaluation protocols, including treatment acceptability, data collection procedures, and expected eligibility, recruitment time and effort, and follow-up rates. Given the small sample size, we will not be able to determine intervention efficacy; rather, our analyses will be mainly descriptive and will focus on confidence interval estimation. The primary focus is to assess feasibility and acceptability of the CHW+*telenovela* intervention and its impact on retention in care. Study staff will measure attended HIV primary care visits over weeks 0-16 and 17-32 weeks as well as CD4 and HIV RNA from the electronic medical record at week-24 and week-48, to assess short and long-term effects of the intervention. To obtain further information on feasibility and acceptability of the instruments at baseline and exit assessment and interview visits, study staff will present portions of the questionnaires to a focus group of Latino HIV peer workers with extensive experience working with the population, drawn from local HIV-related community advisory boards or AIDS service organizations. Study staff will present instruments to the group and perform cognitive debriefing to ascertain if the items are conveying the intended meaning. We will also receive additional feedback on acceptability of format and content. We will also ask work with these community colleagues to perform back translation from Spanish to English on items created by the study team to confirm preservation of content. We will reimburse these individuals each for $40 for two hours of service.

Data analysis: We will compare baseline distributions of key demographic and outcome variables for comparability between intervention and control groups using nonparametric tests. The pre-specified primary outcome was retention in care. We defined this outcome as having at least one visit attended in HIV clinic at both time periods (weeks 1-16 and 17-32) post-randomization. These definitions are consistent with consensus guidelines on visit consistency. Two study staff blinded to randomization allocation, extracted HIV primary care appointment history from the medical record with disagreements reconciled by a third reviewer. An HIV primary care appointment was defined as an appointment with an HIV provider, meaning a health care provider (e.g., physician or mid-level provider) who could prescribe antiretroviral treatment. The prespecified secondary outcomes were proportion with viral suppression (HIV RNA<200 copies/ml) and change in CD4 count (cells/microliter) from baseline to weeks-24 and -48 post-randomization, extracted from the medical record. Obtaining a measure of effect size may not be justified given the limited sample size but we will use these data to inform power calculations for a subsequent large-scale trial with attention to matched-arms in an R01. Participant sociodemographic and clinical characteristics were summarized by intervention allocation with Chi-square tests and t-tests. The primary outcome of RIC and secondary outcomes of viral suppression and CD4 count at weeks-24 and -48 were compared by group using Chi-square tests. Statistical significance was defined by two-sided $p \leq 0.05$. Analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).