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Evaluating Locally Developed Interventions to Promote PrEP Among Racially/Ethnically Diverse Transgender Women in the United States: A Unique CDC Initiative

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Abstract

In the United States, transgender women are disproportionately affected by HIV. However, few evidence-based prevention interventions exist for this key population. We describe two promising, locally developed interventions that are currently being implemented and evaluated through the Centers for Disease Control and Prevention Combination HIV Prevention for Transgender Women Project: (1) *ChiCAS*, designed to promote the uptake of pre-exposure prophylaxis (PrEP), condom

*The first two authors listed are the Principal Investigators for the ChiCAS and TLC projects (respectively) and subsequent co-authors are project staff listed in alphabetical order.

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use, and medically supervised hormone therapy among Spanish-speaking transgender Latinas and (2) *TransLife Care*, designed to address the structural drivers of HIV risk through access to housing, employment, legal services, and medical services, including HIV preventive care (e.g., PrEP use) among racially/ethnically diverse urban transgender women. If the evaluation trials determine that these interventions are effective, they will be among the first such interventions for use with transgender women within the context of PrEP, thereby contributing to the evidence-based resources that may be used to reduce HIV risk among this population.

In the United States, transgender women are disproportionately affected by HIV. It is estimated that about 14% of transgender women are living with HIV (Becasen, Denard, Mullins, Higa, & Sipe, 2019). In addition, transgender women have low rates of screening for HIV and, thus, many are unaware of their status (Habarta, Wang, Mulatu, & Larish, 2015; Lippman et al., 2016). In fact, it is estimated that fewer than half of transgender women with HIV know their status (Habarta et al., 2015; Lippman et al., 2016). Some subgroups are particularly affected by HIV, including transgender women of color, such as Black and Latina transgender women (Guilamo-Ramos et al., 2020; Pitasi, Clark, Chavez, DiNunno, & Delaney, 2020; Rhodes, Mann-Jackson, et al., 2020; Smart et al., In press; Sun et al., 2015).

There are many factors that contribute to HIV risk among transgender women, including discrimination and mistreatment in nearly every part of society that affect access to housing, employment, social services, and healthcare (Jennings Mayo-Wilson et al., 2020; Mayer, Grinsztejn, & El-Sadr, 2016; Rhodes, Alonzo, Mann, Sun, et al., 2015; Rhodes, Mann-Jackson, et al., 2020; Smart et al., In press). The adversity faced and the very real struggle for survival can undermine the ability of transgender women to prioritize and practice safer sex or utilize biomedical strategies to prevent HIV (e.g., pre-exposure prophylaxis [PrEP]) (Jennings Mayo-Wilson et al., 2020; Mimiaga et al., 2019; Rhodes, Alonzo, et al., 2020; Sevelius, Keatley, Calma, & Arnold, 2016). Transgender women are disproportionately represented among homeless persons, often as a result of estrangement from their families of origin (Grant et al., 2011; Rhodes, Alonzo, Mann, Sun, et al., 2015; Rhodes, Mann-Jackson, et al., 2020) and housing instability has been found to be associated with condomless sex in transgender women (Fletcher, Kisler, & Reback, 2014; Rhodes, Mann-Jackson, et al., 2020; Sevelius, Reznick, Hart, & Schwarcz, 2009; Smart et al., In press). Moreover, many transgender women report difficulty finding a job (Grant et al., 2011; Rhodes, Mann-Jackson, et al., 2020) and earn money to support themselves through sex work (Rhodes, Alonzo, Mann, Sun, et al., 2015; Rhodes, Mann-Jackson, et al., 2020; Smart et al., In press; Wilson et al., 2009). Transactional sex is related to condomless sex and HIV infection among transgender women; economic pressures can result in compromising safer sex practices for monetary incentives (Harawa & Bingham, 2009; Reisner et al., 2009; Sevelius et al., 2009; Smart et al., In press). Furthermore, the legal problems often experienced by transgender women, including incarceration due to sex work, frequently serve as barriers to HIV-related services and access to care (Remien et al., 2015; Smart et al., In press).

PrEP Use among Transgender Women in the United States

Although PrEP is a critical biomedical strategy to prevent new HIV infections, overall awareness and knowledge of PrEP are relatively low among transgender women (Kuhns et al., 2016; Rhodes, Alonzo, et al., 2020; Smart et al., In press), as is PrEP use, particularly among transgender women of color (Poteat et al., 2019; Rhodes, Alonzo, et al., 2020). Thus, interventions are needed to support the uptake of biomedical HIV prevention strategies, such as PrEP, to reduce HIV burden among transgender women.

HIV Prevention Interventions

Currently, only two risk reduction interventions focused on transgender women are included within the *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention* compiled by the Centers for Disease Control and Prevention (CDC) (<https://www.cdc.gov/hiv/research/interventionresearch/compendium/>): (1) *Couples HIV Intervention Program (CHIP)*, a couples-based intervention designed for transgender women coupled with a cisgender male partner found effective to reduce condomless anal or vaginal sex with primary partners, reduce sex with any casual partner, and reduce number of casual partners (Operario et al., 2017); and (2) *Project LifeSkills*, a group-based, empowerment-focused intervention to reduce HIV risk among younger transgender women found effective to reduce condomless anal sex and reduce number of sex partners (Garofalo, Kuhns, Reisner, Biello, & Mimiaga, 2018). While these interventions are critical resources, they were developed, implemented, and evaluated prior to the approval of PrEP as a biomedical strategy to prevent HIV. Currently there are no PrEP interventions yet included for transgender women (<https://www.cdc.gov/hiv/research/interventionresearch/compendium/prep/index.html>). Thus, there is an urgent need for culturally congruent, effective HIV prevention interventions for transgender women.

CDC Innovative and Locally Developed Interventions

To make effective locally developed HIV prevention interventions more broadly available, the CDC initiated the Innovative Interventions Project (CDC, 2004; Collins & Tomlinson, 2014). The project identified and supported rigorous evaluations of culturally congruent, community-based HIV prevention interventions developed for and delivered to racial/ethnic minority populations at increased risk for HIV infection in the United States, which had shown promise of being effective but had not been rigorously evaluated. These interventions included the *Many Men, Many Voices (3MV)* intervention for Black men who have sex with men (MSM) (Wilton et al., 2009), the *Healthy Love Workshop* intervention for Black heterosexual women (Diallo et al., 2010), and *Preventing AIDS through Live Movement and Sound (PALMS)* intervention for incarcerated and adjudicated minority adolescent males (Lauby et al., 2010). Since that time, CDC implemented the Homegrown Interventions Project to continue to identify and support rigorous evaluations of community-based HIV prevention interventions (CDC, 2009; Collins & Tomlinson, 2014). Racial/ethnic minority MSM were the population of focus with rigorous evaluations of *MyLife MyStyle* for young Black MSM (Maulsby et al., 2013), *Critical Thinking and Cultural Affirmation* intervention for Black MSM (Williams, Ramamurthi, Manago, & Harawa, 2009), and *HOLA en Grupos*

for Latinx MSM and transgender women (Alonzo et al., 2016; Rhodes, Alonzo, Mann, Freeman, et al., 2015; Rhodes et al., 2017; Rhodes et al., 2014), because of the persistent, disproportionate impacts of HIV on these communities.

Building on these important successes, in 2016, the CDC released RFA-PS-16-003 that was designed to support evaluations of locally developed or adapted and potentially effective but insufficiently evaluated interventions that were designed to deliver a combination of HIV prevention, HIV care and treatment, and other social and support services to transgender persons who have sex with men at high risk of HIV infection or living with HIV. Combination HIV prevention interventions are defined as having mutually reinforcing biomedical, behavioral, and social/structural components that together optimize prevention impact (Kurth, Celum, Baeten, Vermund, & Wasserheit, 2011). Evaluations of two highly innovative and promising interventions were funded; the interventions are (1) *ChiCAS* (*Chicas Creando Acceso a la Salud* [*ChiCAS: Girls Creating Access to Health*]) and (2) *TransLife Care* (*TLC*). Both interventions address biomedical, behavioral, and social/structural factors that facilitate access and utilization of HIV prevention (e.g., PrEP) services among racially/ethnically diverse transgender women.

Purpose

In this article, we describe these interventions, which are designed to promote PrEP use among transgender women who have sex with men. *ChiCAS* is designed to meet the needs and priorities of Spanish-speaking transgender Latinas, and *TLC* is designed to meet the needs and priorities of racially/ethnically diverse urban transgender women. These interventions are currently being implemented.

ChiCAS

Developed and delivered in Spanish by a long-standing community-based participatory research (CBPR) partnership in the U.S. South (Rhodes, Alonzo, et al., 2020; Rhodes et al., 2014; Rhodes, Tanner, et al., 2018), *ChiCAS* is a small-group intervention that aims to increase uptake of PrEP, condom use, and medically supervised hormone therapy among HIV seronegative transgender Latinas who have sex with men. Overall, transgender Latinas in the U.S. South have very low rates of awareness of PrEP, and among those aware of PrEP, interest in PrEP use and PrEP uptake are low (Rhodes, Alonzo, et al., 2020; Smart et al., In press). Despite low interest in PrEP, transgender Latinas have high reported interest in medically supervised hormone therapy which is associated with positive mental health outcomes and behaviors (e.g., lower rates of suicidal ideation and drug and alcohol use) that also influence sexual risk behaviors. However, transgender Latinas report limited access to and use of medically supervised hormone therapy (Rhodes, Alonzo, Mann, Sun, et al., 2015; Rhodes, Mann-Jackson, et al., 2020; Sun et al., 2015). Transgender women facing barriers to medically supervised hormone therapy often prioritize those services over HIV-related concerns and may engage in sex work or transactional sex to pay for services to affirm their gender identity (Becasen et al., 2019; Rhodes, Alonzo, et al., 2020; Rhodes, Alonzo, Mann, Sun, et al., 2015; Sevelius, Patouhas, Keatley, & Johnson, 2014) or may obtain hormones from non-medical sources (e.g., *tiendas*, the internet, and other transgender women), which

pose potential safety risks (Rhodes, Alonzo, Mann, Sun, et al., 2015; Rhodes et al., 2011; Vissman et al., 2011). Thus, *ChiCAS* outcomes include promoting the use of and navigating transgender Latinas to medically supervised hormone therapy in addition to PrEP.

ChiCAS is informed by social cognitive theory (Bandura, 1986) and the theory of empowerment education (Freire, 1973). The *ChiCAS* curriculum is designed to: (1) increase awareness of the magnitude of HIV and other sexually transmitted infections (STIs) among transgender Latinas; (2) increase knowledge of types of infections, modes of transmission, signs, symptoms, and prevention strategies (including PrEP and condom use); (3) offer guidance on PrEP and medically supervised hormone therapy services, eligibility requirements for accessing these services, and “what to expect” when accessing services and within healthcare encounters; (4) build condom use and negotiation skills; (5) help to overcome barriers to accessing PrEP and medically supervised hormone therapy services; (6) change health-compromising norms and expectations (e.g., decrease internalized transphobia); and (7) build supportive relationships and sense of community. The *ChiCAS* intervention modules and abbreviated content are presented in Table 1.

The *ChiCAS* intervention demystifies the process for obtaining PrEP and medically supervised hormone therapy, and helps transgender Latinas plan for, navigate, and overcome the challenges that they may face when accessing and using healthcare services. *ChiCAS* provides tailored information to each participant regarding where they can obtain PrEP and medically supervised hormone therapy (e.g., precise locations and providers’ contact information within each participant’s community), the terms of accessing those services (e.g., eligibility requirements and costs), the conditions of accessing the services at each location (e.g., availability of interpretation services and hours of operation), how to request services (e.g., making an appointment and what documentation to bring), and what to expect during their medical visit to obtain the services (e.g., HIV testing and other bloodwork required for PrEP eligibility, informed consent process for hormone therapy, and follow-up appointments).

ChiCAS Implementation

ChiCAS is being implemented in North Carolina, a state that consistently ranks in the top 10 U.S. states with the highest rates of new HIV diagnoses (CDC, 2019b). The U.S. South is experiencing disproportionate HIV rates compared to other regions of the country and has been referred to as the “latest” U.S. HIV epicenter (CDC, 2018; Wiltz, 2014). Eight of the 10 states with the highest rates of new HIV diagnoses, and nine of the 10 metropolitan statistical areas with the highest rates, are in the South (CDC, 2019a). Southern states account for an estimated 51% of new HIV diagnoses in the United States each year, despite having only 38% of the overall population. At the same time southern states have experienced large increases in Latinx populations since the 1990s, increasing by nearly 700% between 1990 and 2015 (U.S. Census Bureau, 2019). These states have become recent Latinx settlement destinations, resulting from rapid growth of the Latinx population within the past three decades, while states such as Arizona, California, New Mexico, and Texas have had well-established Latinx populations for multiple generations.

ChiCAS is delivered as a small-group intervention (of about 10 participants, but no fewer than 4) and is held in safe and convenient locations within the community, such as a hotel meeting room. We have found hotels close to main highways to be easy for participants to find and locations that do not carry the stigma or connotations that an HIV service, an immigrant-serving, or an LGBT-serving organization might. *ChiCAS* consists of two 4-hour sessions led by three well-trained interventionists: a native Spanish-speaking transgender Latina, a native Spanish-speaking Latino cisgender gay man, and a White cisgender heterosexual woman, fluent in Spanish. The interventionists have decades of experience in implementing sexual health-promoting interventions. The interventionists organize the session materials, review session objectives and ground rules at the beginning of every session, and implement the intervention in accordance with the detailed Spanish-language *ChiCAS* intervention curriculum manual. They lead interactive activities as instructed by the manual, model skill development, and coordinate group exercises.

ChiCAS Evaluation

The evaluation of *ChiCAS* uses a randomized intervention/delayed-intervention comparison group (waitlist) design to test the efficacy of the intervention. The primary outcome variables to evaluate the *ChiCAS* intervention are PrEP use, medically supervised hormone therapy use, and consistent condom use. Measurement also includes intervention-targeted variables such as knowledge of HIV and STIs (e.g., types of infections, modes of transmission, signs, symptoms, and prevention strategies); knowledge of PrEP and medically supervised hormone therapy services, eligibility requirements for accessing these services, and what to expect when accessing services/in healthcare encounters; perceived access to available health care and related services; intentions and readiness to obtain PrEP and medically supervised hormone therapy; healthcare barriers and self-efficacy to overcome barriers; healthcare provider trust; condom use skills, self-efficacy, and intention; skills and self-efficacy to communicate with providers and sexual partners; internalized transphobia; ethnic group pride; and social support.

Eligibility to participate in the study is limited to individuals who: (a) self-identify as male-to-female transgender or report having been assigned male at birth and identifying as female; (b) self-identify as Hispanic or Latina; (c) are 18 years of age; (d) report sex with at least 1 man in the past 6 months; (e) are HIV negative (based on self-report and verification by HIV testing); (f) are fluent in Spanish; and (g) provide informed consent. The exclusion criterion is having participated in any HIV prevention intervention within the past 12 months.

Up to a total of 140 transgender Latinas, who meet inclusion criteria, will be randomized into the *ChiCAS* intervention (n=70) or a delayed-intervention comparison group (waitlist) (n=70). Participants enter the study in waves of about 20 to avoid long delays between recruitment, randomization, and participation that may be caused by recruiting, randomizing, and delivering the intervention to the entire participant cohort. As participants for each wave are recruited following completion of screening, HIV testing, and completing the study informed consent process and the baseline assessment, they are randomized

using a block randomization scheme (block size=4) generated with SAS version 9.3 (SAS Institute, Cary, NC).

Data are collected at baseline and at 6-month follow-up using an interviewer-administered quantitative assessment. Findings from our earlier formative research indicate that participants are more likely to engage with a well-trained interviewer who is a member of their own community (e.g., transgender and immigrant), and who can establish rapport and trust (Rhodes, Alonzo, et al., 2018; Rhodes, Duck, Alonzo, Downs, & Aronson, 2013). Our interviewer-administered approach is considered to be culturally congruent by Latinx communities given that some Latinx persons value *personalismo*, which is a cultural feature that stresses the importance of interpersonal relationships (Gilbert & Rhodes, 2014). Utilizing interviewer-administered assessments, in-person or by phone, also overcomes obstacles that are associated with participants' potential low literacy levels and poor vision (resulting from lack of access to vision services) (Grzywacz et al., 2009).

Power calculations for analyses of these data are based on a sample size of 100 (50 per group). However, to ensure sufficient power to detect effect sizes that may be smaller than our hypothesized effect size, we will re-estimate the sample size in light of interim results as the *ChiCAS* trial is ongoing. In order to avoid increasing the Type I error rate at the time of the final analysis, we will use sample size reassessment (Mehta & Pocock, 2011). After we have recruited and completed follow-up assessments for 80 participants, we will calculate the conditional power based on data accumulated from these participants. The use of 80 participants will enable us to maximize the precision of our interim estimate. If power based on our accumulated knowledge is "promising" (defined as greater than 50% but less than 80% based on bounds calculated using formulas from Mehta and Pocock [2011]), we will increase the sample size to a maximum of 140 (70 per group). If the power is "favorable" (defined as 80% or greater), we will continue recruitment to our original sample size of 100. If the power is "unfavorable" (defined as less than 50%) we will also continue to our original sample size (N=100). This approach does not discontinue a study due to futility. At a minimum it continues to the original sample size.

Primary data analyses to evaluate the effects of the *ChiCAS* intervention include comparing rates of PrEP use, medically supervised hormone therapy use, and consistent condom use by intervention and delayed-intervention comparison (waitlist) participants (before the delayed-intervention participants have been exposed to the intervention) at the six-month post-intervention follow-up assessment, adjusting for baseline rates. Adjusting for baseline rates at the follow-up has the advantage of being unaffected by baseline differences. If baseline rates, by chance, were different in the intervention group the intervention effect would be overestimated by looking at change scores and underestimated by a follow-up score analysis. The ANCOVA approach gives the same answer whether or not there is baseline imbalance. Additionally, this approach generally has greater statistical power to detect an intervention effect than the other methods (Vickers & Altman, 2001). Statistical analysis will be performed using generalized linear mixed modeling (Wolfinger & O'Connell, 1993) for binary outcomes, sometimes termed random effects logistic regression. These models can assume a logit link for binary data (i.e., presence or absence of behavior) and allow for the

modeling of within-group correlation of risk behaviors. The generalized linear mixed model is an extension of general linear models that allows for non-independence of observations.

TLC Program

In contrast with the U.S. South, the U.S. Midwest has been stable in terms of new cases of HIV infection over recent years, from 2014–2018 (CDC, 2020). Over this same period, the number of new cases in Chicago has declined by approximately 20%; however, racial/ethnic minorities and transgender women, in particular, carry disproportionate HIV burden. Overall, new diagnoses and late diagnoses (concurrent with AIDS) were more than twice as likely among non-Hispanic/Latinx Blacks (Chicago Department of Public Health, 2019). Among persons newly diagnosed with HIV infection in Chicago in 2018, transgender women were disproportionately represented at approximately 3% of new cases. Recent reductions in new infections signal an opportunity to advance the city’s goal of “functional zero” infections by 2030 by focusing on key populations with disproportionate incidence (Illinois Department of Public Health, 2019). Addressing the current disparities in new infections among transgender women is an important strategy to reach this goal.

The *TLC* program, developed and being implemented by Chicago House and Social Service Agency (Chicago House), is focused on addressing disparities in HIV infection among transgender women. Founded in 1985, Chicago House supports individuals impacted by HIV and the larger LGBTQ community with housing, health, and employment support. Chicago House’s *TLC* provides combination (i.e., biomedical, behavioral, and social/structural) HIV prevention and care services to transgender women at elevated risk for HIV infection, in a culturally specific and accessible urban environment. The *TLC* program addresses structural and social drivers of risk, applying the social determinants of HIV risk conceptual model (Beltran, Harrison, Hall, & Dean, 2011; Sharpe, Harrison, & Dean, 2010).

The *TLC* program facilitates direct access to basic services (e.g., housing, employment, legal aid, and health services), and may promote other protective processes through its drop-in social milieu, including affirmation of gender identity and collective and supportive experiences to reduce HIV-related risk (Hendricks & Testa, 2012; Testa, Habarth, Peta, Balsam, & Bockting, 2015). Transgender adaptation and integration (Sjoberg, Walch, & Stanny, 2006) may be protective for HIV-related outcomes (Sevelius, Saberi, & Johnson, 2014). Prior research suggests that positive identification with one’s social group, termed collective self-esteem (Crocker & Luhtanen, 1990), is inversely related to psychological distress in transgender women (Sánchez & Vilain, 2009) and may help buffer the effects of social and economic marginalization. Similar to the impact of multiple psychosocial conditions on HIV risk, resiliency processes may be additive in reducing risk (Hendricks & Testa, 2012; Testa et al., 2015).

TLC Implementation

The *TLC* program follows a patient-centered case management and service delivery model and is delivered through a one day per week drop-in “one-stop-shop,” known as TransSafe, hosted at two locations (north and west sides of Chicago) (See Table 2). TransSafe provides a barrier-free and affirming environment in which participants access a variety of services.

Basic service needs are assessed upon entry into the *TLC* program through a brief intake with a staff member (to identify areas of service need/interest) and linkages are made to services TransWorks (employment), TransHousing (housing), TransLegal (legal), and TransHealth (medical). *TLC* services are delivered continuously for as long as a participant may need them.

The TransWorks Employment Program offers job readiness workshops, resume assistance, computer access, job search skill development, career counseling, and mentorship. In the TransHousing program, participants are referred to a housing specialist to identify tailored housing services and help to obtain documentation needed for supportive housing programs. The TransLegal program includes assistance with name change and gender marker change on identifying documents, record expungement and sealing, representation in challenging employment and housing discrimination, support in seeking public benefits, and misdemeanor defense. If a participant's legal concerns fall outside of the scope of the TransLegal program, they are referred to alternative legal counsel. In the TransHealth program, *TLC* contracts with Heartland Alliance Health to provide medical services on-site at the TransSafe drop-in program. For participants with a medical complaint, a Heartland Alliance nurse practitioner meets with that participant and focuses on the presenting complaint; the medical provider also conducts a general health assessment, including assessing sexual health risks and needs for transgender care (including hormone therapy) and HIV prevention and treatment services. The provider makes referrals for any necessary continuing care, including PrEP initiation and care or HIV treatment services.

TLC Evaluation

Evaluation of *TLC* uses a single-arm pre-post design to compare baseline HIV risk to 4- and 8-month post baseline HIV risk. The primary outcome is condomless sex not protected by use of PrEP. *TLC* participants complete HIV/STI testing and computerized quantitative assessments through interviewer and self-administration modes. Study assessments include report of demographic characteristics and psychosocial factors (e.g., substance use and mental health symptoms), sexual risk behaviors, PrEP care engagement (secondary outcome), intervention mediators (e.g., gender affirmation, collective self-esteem, and social support), and intervention satisfaction.

Participants are recruited at TransSafe by a Chicago House research assistant to reach a sample of 150 participants. Interested individuals are screened for eligibility based on the following criteria: (a) self-identify as transgender, transsexual, woman, and/or female who was assigned male sex at birth; (b) 17 years of age; (c) self-reported history of sex with men in the past 4 months; (d) HIV-negative via self-report, verified by HIV testing at baseline; (e) able to speak/understand English; (f) willing and able to provide informed consent; (g) intention to reside in the local area throughout the 8-month follow-up period; and (h) no exposure to any component of the *TLC* program in the prior 4 months. Individuals are excluded if they are unable to provide informed consent due to severe mental or physical illness or substance intoxication at the time of interview. Note that access to *TLC* services is not limited by these inclusion and exclusion criteria (e.g., program access

is HIV status neutral); however, only individuals who meet these criteria are eligible for the evaluation described herein.

The sample size has been estimated to yield 80% power for paired differences (proportions or mean differences) measured at baseline and one follow-up point (pre and post-intervention) based on McNemar's test for paired proportions and paired t-tests for continuous outcomes. With anticipated attrition of 20% and thus a final sample of 120 at 8 months, we will have over 80% power to detect differences of 15% or greater in the marginal proportions pre- and post-intervention when the baseline outcome prevalence is 40% (relative risk of 0.62 or smaller). In terms of mean differences, we will have over 80% power to detect small effect sizes (Cohen's D of 0.32).

To determine the efficacy of the *TLC* program, we will assess the change in number of condomless anal sex acts from baseline to 4 and 8 months using paired t-tests or Wilcoxon signed rank tests for continuous outcomes, and McNemar's test for paired proportions for categorical outcomes. To maximize power, extensions of generalized linear models will be used to assess the effect of the intervention on condomless anal sex at 4 and 8-month follow-up. We will use negative binomial regression for count outcomes and logistic regression for binary outcomes, and models will incorporate participant-level random effects to account for within-participant correlation among repeated measures over time. Multivariable models will be used to assess the presence and frequency of condomless anal sex not protected by PrEP at 4- and 8-months post baseline, with an indicator for time as the primary explanatory variable. Models will also include the baseline value of the outcome and covariates (e.g., age, race) as appropriate. Inclusion of random effects for intercept and trend over time will be explored to assess participant-specific variability at baseline and in terms of trajectories over time.

Discussion

We are well into the fourth decade since the identification of HIV, and while an efficacious vaccine and effective cure remain elusive, PrEP, among other biomedical strategies, has emerged as a highly effective HIV prevention strategy. Furthermore, increasing PrEP use is a central component for meeting the U.S. Ending the HIV Epidemic initiative goals to reduce new HIV infections (www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview). However, many populations disproportionately affected by HIV, including transgender women, lack awareness of and/or access to PrEP, and many of those at increased risk are not using, and thus not benefiting from, PrEP. The *ChiCAS* intervention and *TLC* program promote risk reduction and PrEP use among Spanish-speaking transgender Latinas in the U.S. South and racially/ethnically diverse urban transgender women in the Midwest. Each intervention uses content and approaches that come from the community itself; *ChiCAS* convenes small groups of transgender Latinas, focusing on PrEP and medically supervised hormone therapy uptake, and aims to build critical supportive relationships among these transgender women. This may be particularly impactful given that many transgender Latinas live in isolated rural communities and lack social support (Painter et al., 2019; Rhodes, Alonzo, et al., 2020; Sherman et al., 2020; Smart et al., In press). The *TLC* program addresses specific structural drivers of HIV risk

for racially/ethnically diverse urban transgender women (i.e., homelessness and housing insecurity, unemployment and underemployment, legal barriers, and access to medical care). These interventions represent important efforts by members of transgender communities and organization, university, and federal partners to reduce disparities and promote transgender health and well-being. Partnering with academic investigators allows these locally based efforts to be rigorously evaluated. Findings from these evaluations will contribute to the body of evidence-based resources crucial for reducing HIV disparities through PrEP uptake among transgender women of different races/ethnicities in the United States.

Potential Limitations

These studies rely at least in part on self-reported data (e.g., condom use and intervention-targeted variables); however, self-reported data can be highly reliable if collected carefully, including acknowledgments that some questions may cause discomfort and explanations concerning the importance of providing honest responses to ensure the usefulness of the research (Pequegnat et al., 2000; Rhodes et al., 2017; Rhodes et al., 2013). Furthermore, use of PrEP is being abstracted from medical charts at clinical sites to validate self-report. These studies also are being implemented within catchment areas that may not reflect all subsamples of transgender women in other settings; however, they are being conducted in communities carrying disproportionate burdens of HIV and STIs.

COVID-19 Pandemic

It is important to note that the COVID-19 pandemic has profoundly changed the way HIV prevention research is conducted (Rhodes & Sy, 2020). Thus, the research teams implementing and evaluating *ChiCAS* and *TLC* have adapted participant recruitment, screening, and retention; *ChiCAS* and *TLC* implementation; and baseline and follow-up data collection to meet the challenges associated with the pandemic (e.g., physical distancing and wearing of face coverings). However, the components of *ChiCAS* and *TLC* have not changed, and this evaluation research continues.

Conclusion

HIV prevention for transgender women requires innovative and comprehensive approaches, including addressing social and structural determinants of health (Institute of Medicine, 2011; Rhodes, Daniel-Ulloa, et al., 2020; Rhodes et al., 2014). *ChiCAS* and *TLC* are potentially well situated to fill this gap by testing two combination strategies that address complementary health priorities (e.g., medically supervised hormone therapy) and social and structural needs (e.g., employment, housing, and legal aid). Communities have an established history in meeting their own HIV prevention needs and priorities (Bloom, Whittier, & Rhodes, 2014), and locally developed interventions are often strong but lack sufficient evaluation (Collins & Tomlinson, 2014). Ensuring that interventions are not only designed but also evaluated using participatory methods (e.g., community-engaged research and CBPR) to meet the unique needs and social realities of transgender women is critical to increase health equity, improve social justice, and reduce health disparities (Rhodes, Daniel-Ulloa, et al., 2020; Rhodes, Malow, & Jolly, 2010; Rhodes et al., 2014). This includes addressing social and structural barriers such as stigma, transphobia, discrimination, lack of access to healthcare, and medical mistrust experienced by transgender women and testing

their effectiveness. Identifying, promoting, and facilitating access to organizations providing culturally appropriate and gender-affirming care and/or services is an important start towards creating inclusivity and working towards achieving health equity. These efforts are key to affecting change as we work towards ending the HIV epidemic.

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Table 1.The *ChiCAS* intervention modules and abbreviated content

Module Title (4 hours each)	Abbreviated Content
(1) General information about the intervention and an introduction to sexual health and transition-related healthcare services	<p>Topics: Purpose of the intervention; what it means to be a transgender Latina; magnitude of HIV and STIs among transgender Latinas; information about HIV, STIs, and their prevention; use of medically supervised hormone therapy; preventing HIV; use of PrEP and condoms; and use of healthcare services</p> <p>Activities:</p> <ol style="list-style-type: none"> 1. Icebreaker, introduction to <i>ChiCAS</i>, participant introductions 2. Group discussion to establish ground rules 3. "Find someone who" game to encourage participants to get to know one another 4. Group discussion of what it means to be a transgender Latina; 5. DVD Segment #1: Presentation and group discussion on magnitude of HIV and STIs among transgender Latinas; 6. HIV/STIs PowerPoint and group discussion 7. Preventing HIV: <ul style="list-style-type: none"> ○ Use of PrEP, including locally available providers, eligibility, and requirements; and how to access them (includes repeat testing) ○ Condom use <ul style="list-style-type: none"> - Demonstrating and practicing how to correctly use a condom using penis models - Identifying the correct steps to use a condom - Female condom use discussion 8. Hormone therapy: Physical effects, benefits, and risks 9. Locally available providers of hormone therapy, eligibility, and requirements; and how to access them for hormone therapy
(2) Reframing beliefs that compromise our health and overcoming challenges to access healthcare services	<p>Topics: How to overcome socio-cultural barriers to health</p> <p>Activities:</p> <ol style="list-style-type: none"> 1. Group discussion reviewing previous Module 2. Condom negotiation role plays with sexual partners 3. Interactive activity to practice confronting health-compromising attitudes and beliefs 4. Further discussion on overcoming socio-cultural obstacles to accessing medical services discussion (focusing on PrEP and hormone therapy) 5. DVD Segment #2: Presentation and discussion: seeking healthcare services (PrEP and hormones) as a transgender Latina 6. Accessing and talking to and communicating with providers role plays 7. Conclusions

Table 2.Abbreviated *TLC* program components and activities

TLC Program Components	Activities
TransSafe	<ul style="list-style-type: none"> • Drop-in service provision and social support milieu
TransWorks	<ul style="list-style-type: none"> • Employment assessment • Employment readiness training (5 sessions) • Employment counseling and coaching services
TransHousing	<ul style="list-style-type: none"> • Housing assessment (e.g., homelessness, housing instability) • Housing referral (e.g., shelter, coordinated entry assessment by skilled assessor) • Housing placement support (e.g., supportive housing) • Housing advocacy (e.g., rent assistance, landlord-tenant issues)
TransLegal	<ul style="list-style-type: none"> • Legal needs assessment and consultation • Legal advice and representation (e.g., discrimination, public benefits, record expungement and sealing, non-felony) • Facilitate name, gender marker change • Legal rights workshops
TransHealth	<ul style="list-style-type: none"> • General health assessment and referral • HIV/STI testing • PrEP navigation • Health education • Linkage to gender affirmative care