RESEARCH PROTOCOL

Evaluation of TransLife Center (TLC): A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

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I. PROJECT OVERVIEW

a. Project Title

Evaluation of TransLife Center: A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

b. Protocol Summary

This study is funded as a cooperative agreement (U01) with the Centers for Disease Control and Prevention (CDC) in response to RFA-PSA-16-003, "Evaluating Locally-Developed or Adapted (Homegrown) Combination HIV Prevention Interventions for Transgender Persons who have Sex with Men." Chicago House and Social Service Agency (Chicago House) is the prime awardee and Lurie Children's is sub-awardee. The Multiple Principle Investigators (MPIs) are Judy Perloff, MSW at Chicago House and Lisa Kuhns, PhD, MPH at Lurie Children's.

Combination interventions to reduce disparities in HIV infection for transgender women who have sex with men are sorely needed, as this population is one of the highest risk and most underserved groups in the United States.[1] The goal of this proposed research project is to evaluate a locally developed and potentially effective intervention, Chicago House's TransLife Center (TLC), which provides combination (i.e., biomedical, behavioral, social/structural) HIV prevention and care services to transgender women at high risk for HIV infection, in a culturally specific and accessible environment. Transgender women (TW) are a key population at high risk of HIV infection, with HIV prevalence estimates in the U.S. of 28% (laboratory confirmed)[2] and evidence of very high rates of previously undiagnosed HIV infection.[3] Evidence suggests that socioeconomic marginalization (e.g., unemployment, incarceration, homelessness) is prevalent among TW[4-8] and drives HIV-related risk behaviors.[7,9] Pre-exposure prophylaxis (PrEP) is a new HIV prevention approach in which individuals who are at high risk take anti-retroviral medications to prevent HIV infection. This approach, specifically daily dosing with two medications (tenofovir and emtricitabine) was approved by the US Food and Drug Administration (FDA) in 2012 for the prevention of HIV infection. While PrEP is indicated and potentially effective in preventing HIV infection among TW,[10,11] knowledge about PrEP and uptake among TW, outside of clinical trials, is low,[12,13] indicating a need for comprehensive HIV prevention efforts targeted to their unique circumstances and vulnerabilities.

To date there are no evidence-based HIV prevention interventions (EBIs) for TW listed in the CDC compendium of EBIs. The proposed study will address this gap through collaboration between Chicago House, a long-standing HIV/AIDS service provider in Chicago which is leading the expansion of services to TW in the city, and HIV prevention researchers (Kuhns, Garofalo, Hotton), who have been actively engaged in both basic social and behavioral research[4,5,9,12,14] and development of HIV prevention interventions for TW.[15,16] This collaborative team has been working together for the past three years to develop, refine and evaluate the TLC service model with funding from both philanthropic sources and the Health Resources and Services Administration (HRSA; for HIV-positive TW). The TLC intervention directly addresses the structural barriers to effective health promotion among TW through a coordinated screening and service model, including direct access to transgender-specific services most needed and requested by TW: employment, housing, legal, and health services, following a social determinants of health conceptual model.[17] The intervention has been adapted and refined over the past three years by transgender-identified staff leaders of the TLC with input from the agency's TW-specific community-advisory board (CAB).

c. Roles and Responsibilities:

MPIs:	Lisa M. Kuhns, PhD, MPH, Ann & Robert H. Lurie Children's Hospital of Chicago
	Judy Perloff, MSW, Chicago House & Social Service Agency
Co-I:	Robert Garofalo, MD, MPH, Ann & Robert H. Lurie Children's Hospital of Chicago
Co-I:	Anna Hotton, PhD, MPH, University of Chicago
Project Director:	Josie Paul, MSW, Chicago House & Social Service Agency
Project Manager:	Kevin Pleasant, Chicago House & Social Service Agency
Senior Data Manager:	Abigail Muldoon, MA, Ann & Robert H. Lurie Children's Hospital of Chicago

As MPI, Dr. Kuhns' role will be to lead research and academic activities, including study design and methods, data collection and analyses and supervision of the data manager at Lurie Children's. As MPI, Ms. Perloff's role will be oversee day-to-day research activities and staffing at Chicago House including supervising personnel as well as providing administrative oversight. Both Dr. Kuhns and Ms. Perloff will take responsibility for the scientific and fiscal oversight. Co-Investigator, Dr. Robert Garofalo will advise the study team on all aspects of the study design and implementation for transgender women. Co-Investigator Dr. Hotton will support all aspects of study design and methods and will perform all study analyses. As a licensed clinical social worker (LCSW) trained in research methods, Ms. Paul will oversee the intake process and TLC program operations, supervise front line staff, and serve as the primary contact to the study data management team to ensure data collection and reconciliation. As the TLC Program Manager, Mr. Pleasant will lead recruitment and retention efforts, serve as the primary liaison to community partners for outreach efforts, coordinate the delivery of services to participants within the TLC program, and complete study visits. Both Ms. Paul and Mr. Pleasant will be trained in collection of hair samples by Dr. Kuhns. HIV/STI testing will be performed by clinical providers of Heartland Health Outreach (HHO; the medical provider for the TLC program) or by non-research staff of Chicago House under contract with Chicago Department of Health (CDPH). Abigail Muldoon, Senior Data Manager at Lurie Children's will carry out data-related tasks on this study, including quality assurance monitoring, abstraction and coding of medical records data, cleaning and coding of data files, and preparation of the study codebook.

Table 1. Study Investigator, Funding Mechanism, FWA and Research Engagement

Name	**Funding Mechanism**	**Federalwide Assurance Number (FWA)**	**Engagement in Research (Yes/No)**
Lisa Kuhns, PhD, MPH Robert Garofalo, MD, MPH	Subcontract Agreement	00001011 (IRB#00000624)	Yes Yes
Judy Perloff, MSW	Cooperative Agreement	00002919 (deferred to Lurie Children's IRB above)	Yes
Anna Hotton, PhD, MPH	Subcontract Agreement	00005565 (IRB#19-0701)	No

CDC Project Officers and Staff

Project Officer HIV/AIDS Prevention.	Damian Denson, Ph.D., M.P.H., Prevention Research Branch, Division of
Co-Project Officer Prevention.	Deborah Gelaude, M.A., Prevention Research Branch, Division of HIV/AIDS
Project Coordinator Prevention	Patricia Bessler, M.P.H., Prevention Research Branch, Division of HIV/AIDS

Dr. Denson and Ms. Gelaude are responsible for providing guidance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. Ms. Bessler assists in preparing submissions for required federal approvals, such as OMB and project determination, and facilitating project meetings and other activities. The CDC staff will neither collect data from nor interact with research participants. Data will be collected by grantee staff. No individually identifiable private information will be shared with or accessible by CDC staff. All datasets will be provided to CDC with individual participant study ID. CDC is responsible for the conduct of the study, and in this role, CDC staff may conduct site visits and review data collection and study procedures as needed.

II. INTRODUCTION

a. Current State of Knowledge

The prevalence of HIV and other STIs is disproportionately high among transgender women who have sex with men, here forward referred to as transgender women (TW), particularly ethnic minority and younger TW. As noted by the CDC, because HIV-related surveillance data are not uniformly collected, data on HIV infection among TW is lacking.[18] However, data from local health departments, large meta-analyses, and multi-city studies using convenience sampling methods suggest high levels of HIV infection among TW.[18] A meta-analysis of the global burden of HIV infection in TW found HIV prevalence was 19.1% (95% CI=17.4-20.7); TW had 49-fold increased odds of HIV infection compared with all adults of reproductive age.[19] A meta-analysis of 29 studies[2] focused on U.S. TW found a prevalence of 27.7% laboratory-confirmed HIV infection (four studies) and 11.8% self-reported (18 studies). Data from local testing of over 500 TW with no known prior positive HIV test results in Miami, San Francisco, and Los Angeles found 12% HIV infection, which suggests a high percentage of unrecognized HIV infection in this population.[20] In an analysis of these new HIV infections by age, the highest number were detected among those ages 20-29 years (i.e., 45% of all cases).[20] Studies among young TW in particular suggest that they have rates of HIV infection comparable to adults. In a study of 51 young racial/ethnic minority TW ages 16-24 years, Garofalo et al. found that 22% self-reported being HIV-infected.[4] While local surveillance of HIV infection among TW in Chicago is largely inaccurate due to the lack of a specific category for reporting transgender identity in morbidity reports, local samples gathered using convenience approaches suggest high prevalence of HIV infection among TW. A study of 151 mostly racial/ethnic minority younger TW ages 15-24 years in Chicago and Los Angeles found that 19% self-reported HIV infection.[21] Findings from a current intervention study of younger TW ages 16-29 years in Chicago and Boston found HIV prevalence of 21.8% among participants at the baseline visit (laboratory-confirmed; see preliminary studies discussed in Section 3.3.d.). In addition, Garofalo and colleagues found that, much like in other high risk populations, while racial/ethnic minority TW have

higher rates of HIV and STIs, sexual risk behavior is lower in this group, particularly among Black TW.[22] While less is known about the epidemiology of STIs among TW, evidence from the U.S. meta-analysis referenced above suggests high rates of STIs: in 10 studies reporting STI data, 21.1% self-reported a prior STI.[2] Rectal STIs and syphilis are indicators of risk for HIV infection in Black men who have sex with men (MSM),[23] however there are no similar studies of the relationship of STI diagnosis to HIV risk in TW specifically.

Condomless sex represents TW's primary risk for HIV acquisition and transmission. In the review of 29 studies referred to above, 31.7% of TW reported multiple sex partners (primarily non-transgender males) and 48.3% reported sex with casual partners (within varying recall periods).[2] Among younger TW in Chicago, Garofalo et al. found 59% reported any condomless anal intercourse in the last year (49% receptive and 37% insertive).[4] Reisner et al. found a similar rate of 52% recent condomless sex among a cohort of younger TW in Boston.[24] Although evidence among TW specifically is not available, recent findings among MSM suggest that inconsistent condom use during anal sex with HIV-infected partners offers little to no protection against HIV infection, and that consistent condom use over time is rare.[25]

The HIV prevention and care continuum (e.g., PrEP/ HIV care initiation, retention, adherence) is not well-characterized in TW, although evidence is emerging of low rates of care initiation and engagement.[26-29] PrEP efficacy and demonstration projects provide evidence of safety, tolerability, and efficacy of PrEP to prevent HIV acquisition,[11,30,31] with some evidence of effectiveness in TW.[10] The limited studies done to date suggest initiation of PrEP among TW is alarmingly low given their HIV risk profiles. Interim analysis of data from an ongoing interventional study of younger TW (see preliminary studies, Section 3.3.d.), indicates that only 5% of the sample had initiated PrEP, although 62% were indicated for PrEP based on CDC criteria.[12] Evidence from a qualitative study of 30 HIV-negative/unknown MSM and TW in three California metro areas suggests that while awareness of PrEP is relatively low, expressed interest once PrEP is described is quite high (76%).[32] This was further supported by a study of TW in San Francisco, which demonstrated that in 2013, after published efficacy of PrEP among men who have sex with men (MSM), fewer than 20% had ever heard of PrEP.[13] In a cohort of younger TW, 31% had heard of PrEP, but 69% expressed interest in PrEP once described.[12]

Limited evidence also suggests that HIV-infected TW are less likely than other groups to be on antiretroviral therapy (ART), and if on ART, are less likely to adhere.[27,33] There is also some evidence suggesting that transgender-specific factors are related to ART adherence, including gender affirmation and adherence to cross-sex hormone therapy.[29] Thus evidence suggests lower engagement in biomedical HIV prevention interventions among TW. To date, there are no culturally-specific interventions in the published literature that link, engage, and retain TW in biomedical HIV prevention efforts.

Despite research documenting high rates of sexual risk behaviors and HIV infection among TW, to our knowledge, only five published, non-randomized interventions, all non-biomedical, have attempted to reduce HIV risk in TW. These include:

- Bockting et al. (1999)[34]: A two-day, 16-hour health seminar developed to address components of the Sexual Health Model for both male-to-female (MTF) and female-to-male (FTM) transgender adults (N=181).
- Nemoto et al. (2005)[35]: An 18-session workshop organized around the topics of (1) sex, relationships, and health; (2) substance use, coping skills; and (3) life needs. A total of 109 participants completed 10 groups.
- DeSantis, et al (2010)[36]: A one-day HIV prevention program based on the Many Men, Many Voices intervention and a community needs assessment. 50 transgender women attended; no evaluation data were collected.

- Taylor et al. (2011)[37]: Four 90-120 minute sessions delivered over a 4-day period to reduce HIV risk with effects evaluated using a pre-post design (N=63).
- Garofalo et al. (2012)[15]: Six group-based sessions delivered over a 3-week period to reduce HIV risk in younger TW (ages 16-24) with effects evaluated using a pre-post design (N=51).

Four of these studies (Nemoto, Bockting, Taylor, Garofalo)[15,34,35,37] documented modest reductions in sexual risk behavior among TW, with some evidence that effects diminished over time (Nemoto, Bockting).[34,35] None of these interventions included biomedical components, such as HIV/STI testing or referral/linkage to PrEP (as they occurred prior to the approval by the Food and Drug Administration of PrEP for HIV prevention), and none directly addressed the structural barriers to health promotion and preventive behavior among TW.

The TLC intervention addresses the specific structural and social drivers of HIV risk among TW, drawing on a social determinants theoretical model of HIV risk. Social determinants of health are the overlapping social structures, conditions, economic systems and circumstances that influence health and drive health inequities,[17] including in HIV-related outcomes.[38,39] There is mounting evidence that social and economic factors are associated with high rates of HIV transmission and adverse HIV-related outcomes.[39] Among TW, social structures and conditions include discrimination, mistreatment, and adversity in the form of rejection from friends, family, and others, which can become a central part of their experience,[4,22,40-43] affecting ability to secure housing, employment, social services, and healthcare.[4,22,44] This basic struggle for survival undermines TW's ability to prioritize and practice safer sex.[45,46] TW are disproportionately represented among homeless people, often as a result of estrangement from families of origin,[47] and housing instability has been found to be associated with inconsistent condom use in TW.[48] In addition, TW experience discrimination in seeking housing.[22,49-51] In studies of younger TW in Chicago and Los Angeles, 46% reported difficulty finding a safe place to sleep[4] and 47% were homeless.[44] With regard to employment, 63% reported having trouble finding a job.[4] Many TW earn money to support themselves through sex work.[8,47,52,53] In two studies, 59% and 67% of younger TW reported sex work, respectively.[4,8] In a Boston study of sexually active TW, 33% reported sex work and 25% unstable housing (mean age 19.4).[24] Transactional sex is significantly related to condomless sex and HIV infection in transgender women; economic pressures often result in compromising safer sex practices for monetary incentives.[48,52,54,55] In addition to economic incentive, sex work may serve to validate feminine gender roles.[56-58] "Passing," often an important component of transgender identity, may facilitate the ability of TW to exchange sex for money.[47,49] Prior studies of TW suggest high rates of prior incarceration (~20%),[6] largely related to arrest and conviction for commercial sex work. Evidence suggests that both history of sex work and incarceration are related to the psychosocial factors which often drive HIV risk.[9] Furthermore, the legal problems encountered by TW may serve as barriers to HIV-related services and access to care.[59]

Access to basic services (housing, employment, legal aid, health services) via the TLC intervention may promote protective processes, including affirmation of gender identity and collective and supportive experiences among TW, reducing HIV-related risk.[60,61] Some evidence suggests trans-specific resiliency is related to HIV outcomes in TW, including, for example, transgender adaptation and integration, adjustment and positive experiences specific to becoming comfortable and self-affirmed in transgender identity,[62] which may be protective for HIV-related outcomes.[29] Prior research suggests that positive identification with one's social group, termed collective self-esteem,[63] is inversely related to psychological distress in transgender women.[64] The relationship between positive social group identification and better psychosocial health outcomes has been found among racial/ ethnic minorities,[65,66] sexual minorities,[67] and women.[68,69] Positive identification with one's social group (collective self-

esteem/ community empowerment) may help buffer the effects of social and economic marginalization for TW and represent a protective mechanism influencing HIV risk reduction behaviors as well as PrEP engagement. Among younger TW enrolled in an ongoing intervention study, collective self-esteem was negatively related to indication for PrEP, reducing risk for those with higher collective self-esteem (see preliminary studies, Section 3.3.d.).[70] Social support is protective for young adults,[71] including TW,[46] and transgender peer social support influences the relationship between discrimination and psychological distress.[72] Transgender community involvement has been shown to influence the association between gender abuse and HIV/STIs.[73] Unique social support structures exist for TW (e.g., "trans mothers"),[55] including in the House/Ball community.[74,75] Similar to the impact of multiple psychosocial conditions on HIV risk, resiliency processes may be additive[60,61] in reducing risk.

b. Justification for Study

In summary, research completed to date suggests that TW are at high risk of HIV infection, which is driven in part by social and structural factors, including discrimination and marginalization from basic services, which are related to HIV risk. Despite these disparities, interventions developed to address TW's specific needs and vulnerabilities are lacking. The TLC intervention, which has demonstrated promise to reduce HIV-related risk and promote engagement in care, directly addresses the social and structural drivers of HIV risk in TW and warrants evaluation in a structured trial.

c. Study Design

This study will take place in Chicago, Illinois at three sites with many years of supporting HIV prevention research: Chicago House and Social Service Agency (Chicago House), Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's) and University of Chicago (U of C). Study visits will take place at Chicago House and Lurie Children's or, due to the COVID-19 pandemic, may occur virtually via teleconference or telephone; intervention delivery will occur at Chicago House or virtually via teleconference or telephone. Primary data analysis of de-identified data will take place at U of C and Lurie Children's.

The specific aims of the study are as follows:

1. To determine the pre-post efficacy of the TLC intervention in a single arm trial on the primary outcome: number of condomless anal sex acts without protection by PrEP in the last month among 150 sexually active, HIV-uninfected TW (ages 17 and older), with assessments at baseline, 4 and 8 months.

    a. To assess the dose response relationship by intervention exposure (i.e., the proportion of intervention components received/expressed need) as well as exposure to specific components (i.e., employment, housing, legal, and health) on reductions in the primary outcome.

    b. To assess mediation of intervention effects on protective processes (gender affirmation, collective self-esteem, social support) theorized to increase with intervention exposure;

2. To examine the implementation experiences of TLC intervention participants and staff through semi-structured interviews with 20 TLC participants and 10 TLC and Chicago House staff members involved in delivery of services through the TLC intervention.

3. Exploratory Aims:

a. To describe the trajectory of PrEP indication, uptake, retention and adherence in the community-based sample over an 8-month follow-up period and evaluate the impact of the TLC intervention on the PrEP continuum of care.

b. To explore whether reductions in HIV risk are associated with epidemiologically-linked moderators including age and race/ethnicity.

Primary Hypotheses**:** We hypothesize that participants in the TLC intervention will demonstrate a reduction in number of condomless anal sex acts not protected by PrEP pre-post intervention.

Primary Outcome: The primary outcome of interest is the number of condomless anal sex acts without protection by pre-exposure prophylaxis (PrEP) reported in the previous month.

III. PROCEDURES/METHODS

a. Design

This study will use a pre-post design to compare pre-intervention levels of HIV risk to those at 4 and 8-months post baseline. Participants will be recruited from community-based locations, including venues and public places where TW socialize and congregate. 150 participants will be recruited over an 18-month enrollment period (5-6 per month) and then followed for a total of 8 months with follow-up data collected at 4 and 8-month visits. Additionally, semi-structured interviews will be conducted with TLC intervention participants and staff to describe implementation experiences and to identify areas for improvement of the intervention.

All of the study procedures are being done for research purposes.

Study Timeline: Participants will be enrolled over an 18-month rolling enrollment period and then followed for 8 months. The entire study will be conducted over a 4-year period. In Year 1, we will develop and submit the IRB protocol for approval to both the local Lurie Children's IRB and the CDC Project Determination, and will seek other reviews and approvals as needed and as requested by the CDC. We will also refine assessment instruments in consultation with the CDC. In Year 2, we will begin enrollment, implement the TLC intervention, and begin to conduct the qualitative interviews (i.e., timed to coincide with 8-month study visits). Enrollment for the trial will end in Year 3; follow-up visits and interviews will be completed in Years 2-4. In Year 4, we will complete remaining follow-up assessments, conduct final data analyses and complete translation planning and undertake dissemination efforts.

b. Study Population

The target population of interest is HIV-negative transgender women (ages 17 and older) who have sex with men and are at risk of HIV infection. In this study, we anticipate enrollment of a diverse sample of transgender women comprised mainly of racial/ethnic minority participants under 35 years of age, consistent with the current TLC program and the epidemiology of HIV infection among TW.

The anticipated cohort will meet the standard for the inclusion of minorities; [137] based on our prior research we anticipate > 80% of participants to be racial/ethnic minorities. We will not recruit cisgender women into this study. Although women assigned female sex at birth are at risk for HIV, we are examining cultural-specific patterns of HIV risk among transgender women. It is not plausible that

cisgender women would experience the same stressors (e.g., transgender minority stress) as transgender women.

Children/adolescents age 17 will be included in the proposed study.

i. Inclusion/Exclusion Criteria:

TLC Participants: For participation in the TLC intervention, interested individuals will be screened for eligibility, based on the following criteria: (1) aged 17 and older; (2) self-identify as transgender, transsexual, woman, and/or female who was assigned male sex at birth; (3) self-reported history of sex with men in the past 4 months (4) HIV-negative via self-report, verified by HIV testing at baseline; (5) able to speak/understand English; (6) willing and able to provide informed consent/assent; (7) intention to reside in the local area throughout the 8 month follow-up period; (8) no exposure to the TLC intervention in the prior 4 months (i.e., any component).

Participants will be excluded based on the following criteria: (1) they are unable to provide informed consent due to severe mental or physical illness, or substance intoxication at the time of interview; or (2) active suicidal ideation (spontaneous report; referred immediately for treatment, and may re-screen when this is resolved). NB: Participants who report taking PrEP (regardless of level of adherence) will not be excluded given evidence of low medication adherence over time[10] and therefore potential risk of HIV infection during the study period.

Semi-structured interviews: All staff who interface with TLC participants or program components and all TLC participants themselves will be eligible to participate in semi-structured interviews.

ii. Sampling:

For the intervention trial, because TW are a unique and hidden population, with no sampling frame, multiple convenience and referral-based sampling techniques will be used to identify and recruit participants for a total sample size of 150. Sample sizes have been estimated to yield ≥80% power for paired differences (proportions or mean differences) measured at baseline and 1 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). Thus our study should be well powered to detect effects of relatively small magnitude even with attrition.

For the 30 qualitative interviews, we will choose TLC participants randomly. 20 TLC participants will be selected using a random number generator linked to their ID number within strata by race (Black, Latino, White, Other) and age category (17-29, 30-39, 40-49, 50+). 10 staff will be selected randomly within strata by job type/rank (front line, middle management, executive) to insure representation of each level.

iii. Recruitment/Enrollment:

Active recruitment will be carried out by study front-line staff, who will be members or allies of the target population. Participants will be recruited actively at the TLC drop-in center, "TransSafe" (or virtual TLC drop-in center or via virtual TLC services, during COVID-19 restrictions) by study staff and staff will visit local gathering places of TW, such as night clubs,

pageants/balls and public places, such as local parks, to identify and recruit potential participants. Participants will also be asked to refer friends or others who that may be eligible. Passive approaches include posting of study flyers (see Recruitment materials, Appendix a).

Interested participants will be screened for eligibility either in person, over the telephone, or via teleconference prior to enrollment (see Study Screener, Appendix b). The screening script includes a brief description of the research study and procedures and related risk and indicates that participation is voluntary and confidential. No identifying information or contact information will be collected from participants who are ineligible for the study. The screening form briefly describes the study and procedures, indicates participation is voluntary and confidential, and briefly describes risks and benefits of participation. Screening failures and reasons for ineligibility will be carefully tracked.

Immediately following screening (or as soon as possible thereafter if screening occurs by telephone; re-screened if more than 30 days elapses after initial screening), participants who are eligible and interested in participation will be consented for participation and enrolled (see Locator and Consent forms, Appendices c-d).

c. Data Collection

Study visits will be completed at Chicago House, or Lurie Children's facilities/locations except in cases in which travel to study sites is not possible due to scheduling difficulties, moving from the local area, or due to COVID-19 restrictions, in which case a remote version of computerized questionnaires may be completed. During the COVID-19 pandemic, visits may be conducted in-person, using precautions, or remotely via telephone or web-based telemedicine conference. Chicago House has adopted HIPAA compliant Doxy.me telehealth software for use during the pandemic, which will also be used to conduct remote research visits. TLC intervention participants will complete computerized assessments through interviewer and self-administration modes at three separate assessment visits (baseline, 4, and 8 months; see Data Collection Instruments, Appendix e.). Study assessments will include report of demographic characteristics and psychosocial factors (substance use, mental health symptoms), sexual risk behavior- the primary outcome, PrEP care engagement- secondary outcome, intervention mediators (gender affirmation, collective self-esteem, social support) and intervention satisfaction (4 and 8-months only). All variables will be measured at all time points unless otherwise specified (see Table 2). Medical records abstraction will be completed by the study data manager with training for the abstraction process conducted by Dr. Kuhns.

Table 2. Study Trial Outcomes by Type, Construct, Measure & Time Point (see Citations in III.c.i)

Outcome Type	Construct	Measure	Baseline	4 month	8 month
Primary Outcome:	Sexual Risk	ARBA	•	•	•
Secondary Outcomes:	PrEP care engagement	Self-report care linkage, initiation, retention Medical records abstraction	•	•	• •
Mediators:	Gender affirmation Collective self-esteem Social support	GEN AFFIRM, CSES SS items	• • •	• • •	• • •
Demographic & Psychosocial Factors:	Demographics Substance use Depressive symptoms Anxiety symptoms Victimization	Demographic items ASSIST CES-D GAD-7 Victimization scale	• • • • •	• • • •	• • • •

Satisfaction/Acceptability:	Acceptability Satisfaction Intervention dosage	Acceptability items CSQ Intervention exposure		• • •	• • •
Biological Markers	PrEP protection HIV Infection STI Infection	PrEP Hair analysis/DBS* 4th generation HIV algor* Chlam/GC AMP Probe* Syphilis Health Check/RPR*	• • • •	• • • •	• • • •

Participants who withdraw from the study voluntarily or who are administratively withdrawn will be carefully tracked via a tracking log with reasons recorded for withdrawal.

*During the COVID-19 pandemic, PrEP hair analysis/DBS, Chlam/GC, and Syphilis Health Check will not be collected at any time point. HIV testing will be completed at the baseline visit only.

i. Variables

Primary outcome: The primary outcome, condomless anal sex acts not protected by PrEP adherence (defined as anal sex acts without a condom in the prior month without use of PrEP at protective levels) will be analyzed as a composite variable of condomless anal sex acts that confer risk in the prior month, adjusting condomless acts to "0" for those participants with protective levels of PrEP adherence verified by biomarker (i.e., hair analysis, see below). We will use the AIDS-Risk Behavior Assessment (ARBA; revised for transgender women) for measurement of sexual risk. The ARBA is a computerized self-interview designed to assess self-reported sexual behaviors.[99] Self-reported PrEP adherence will be measured using time-line follow-back (TLFB) for the 1-month recall period.[101,102] Objective verification via hair samples will only be completed for those individuals who report levels of adherence consistent with protection over the entire recall period (i.e., 4 doses/week for PrEP[100]). We will collect hair samples (100 strands) for analysis of uptake/adherence to PrEP (tenofovir disoproxil fumarate. Hair analysis will be completed at the University of California (UCSF) Hair Analysis Lab. Among participants from whom a hair sample is not feasible, either due to short hair or hair extensions, for example, a blood sample will be collected via a dry blood spot (DBS), for analysis of PrEP level. The DBS will be collected by venipuncture (4mL of blood or approximately one teaspoon). DBS processing and analysis will be performed by University of Colorado. During the COVID-19 pandemic, no hair or DBS samples will be collected at any time point.

Secondary outcomes: PrEP continuum outcomes, including PrEP linkage to care, PrEP initiation and retention in PrEP care will be measured using self-report with confirmation via medical records abstraction with a release of information (NB: release of information to be updated at each visit; abstraction timed to occur immediately after the 8-month visit, see Release of Information, Appendix f.; Case Report Forms, Appendix g.): 1) Linkage to PrEP care is defined as attending at least one PrEP-related care visit to assess medical eligibility for PrEP initiation; 2) PrEP initiation questions will measure the date of initiation of medication, current use and most recent date the medication was taken; 3) Retained in PrEP care will be measured over the 8-month follow-up interval as at least 1 primary care visit over the 8-month follow-up period.

Psychosocial Mediators Gender Affirmation is a 10-item measure that assess adjustment and experiences that are specific to gender identity and gender affirmation.[126] The Collective Self-Esteem Scale (CSES)/Empowerment is a 16-item measure with 4 subscales of social group and empowerment: membership, private, public, and identity.[127] The scale was modified to capture "social group" as being "other transgender people" for TW in our ongoing RCT. Social support will be measured with peer social support measures used in prior studies of transgender women.[72,73]

Demographic and Psychosocial Factors: We will measure age, race/ethnicity, and other demographics (i.e., income, education, school status) using standard questions used in prior research with TW. Within this assessment of demographics, we will measure housing, employment, legal and medical care status more specifically to track changes over time. We will also measure psychosocial factors, given the prevalence of these conditions in TW, and assess their distribution in the sample at baseline and over time. Among the psychosocial factors measured include substance use, depression and anxiety symptoms, and experiences of victimization. To measure substance use we will use the World Health Organization Alcohol, Smoking, and Substance Involving Screening Test (ASSIST), which includes assessment of 10 substances and related problems. To measure depression and anxiety symptoms we will use widely used screening tools: the Center for Epidemiologic Studies Depression Scale (CESD-10) and the Global Assessment Generalized Anxiety Disorder Scale (GAD-7), respectively. To measure victimization we will use the 10-item Victimization Scale, which includes questions related to both verbal and physical abuse.

*Intervention Satisfaction and Acceptability***:** To measure acceptability, we will ask participants to report the degree to which they find the intervention appropriate and useful using Likert-type scales. To measure satisfaction, we will use the Client Satisfaction Questionnaire[129] to assess participant satisfaction, including the procedures, quality and quantity of service, outcome, and general satisfaction. The CSQ-8 has high internal consistency across a large number of studies (alpha >0.80) and has been used in prior studies of TW. Intervention dosage. Delivery of the intervention will be measured via tracking of intervention participation in attendance logs maintained within each component of the TLC program (see Case Report Forms, Appendix g).

Biological specimens/Biomarkers. STI/HIV screening will include a rapid HIV test via oral fluid or finger stick, self-collected urine and anal swab specimens for chlamydia and gonorrhea testing, and finger stick (rapid test) or blood draw for syphilis testing. Participants with a reactive rapid HIV or syphilis test (or those who report prior syphilis infection) will also have blood drawn for confirmatory testing (10 mL or 2 teaspoons total; 8 mL for HIV testing and 2 mL for syphilis testing). Participants with active STI infections or HIV will be referred to affiliated clinics for evaluation and treatment. Participants who test positive at baseline for HIV infection will be withdrawn, however those who test positive for HIV at subsequent waves or who test positive for any STI infection at any visit will remain on study (see Case Report Forms, Appendix g). During the COVID-19 pandemic, no STI samples will be collected at any time point. HIV testing will be completed at the baseline visit only, for screening purposes, and will include the HIV In-home Oraquick test for visits initiated remotely. The HIV In-home test will be delivered to potential participants by courier prior to the baseline visit.

Completion of study assessments at each visit is expected to take 60 minutes.

Semi-structured Interviews. We will also examine the implementation experiences of TLC intervention participants and staff through semi-structured interviews with 20 TLC participants and 10 TLC and Chicago House staff members involved in delivery of services through the TLC intervention. The qualitative interviews will be conducted by study consultants beginning in year 2 of the study (after enrollment has begun), either in-person (when COVID-19 stay-at-home orders are lifted) or by telephone (due to COVID-19 stay-at-home requirements), and audio-recorded, transcribed, with data analyzed to describe: 1) the TLC intervention implementation process; 2) the process through which the TLC intervention impacts HIV risk behavior; and 3) the role of the intervention in addressing social determinants of health (housing, employment, legal issues, health care access). TLC participants and staff will be asked a similar set of questions to identify salient

themes pertaining to each of the three areas identified above (see Data Collection Instruments, Appendix e.).

Interviews are expected to take 60 minutes.

ii. Intervention

In order to reduce HIV risk in this study, all study participants will be screened for Chlamydia, gonorrhea (urogenital/anal CT, GC), syphilis and HIV infection and referred to PrEP care (if indicated) at all time points (see above).

The TLC Intervention follows a patient-centered case management and service delivery model and is delivered through a one day per week drop-in "one-stop-shop" milieu ("TransSafe") and through on-going interactions with TLC staff, i.e., to provide referral and linkage to housing, employment, legal and medical services. Participants enter the TLC program through direct referral or through drop-in to TransSafe. Basic services 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 linkage to services (housing, employment, legal, medical) as needed, which are delivered over the entire 8-month enrollment period. TransSafe provides a social and service milieu in which participants may access services in a barrier-free and affirming environment. Participation in the TLC intervention may include referrals to services known as "TransWorks," "TransHousing," "TransLegal," and "TransHealth"

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 employment and housing discrimination, representation in seeking public benefits, and misdemeanor defense. If the 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 Health Outreach (HHO) to provide Medical Services on-site at the TransSafe drop-in program. For participants with a medical complaint, an HHO nurse practitioner meets with each individual and focuses on the presenting complaint; the medical provider also conducts a general health assessment, including sexual health risk assessment and need for cross-sex hormones and HIV prevention and treatment services. The provider makes referrals for any necessary continuing care, including PrEP initiation and care or HIV treatment services.

During COVID-19 restrictions, TLC services, including TransSafe, "TransWorks," "TransHousing," "TransLegal," and "TransHealth" are offered in virtual mode, via telephone, web-based telehealth and teleconference, as well as email communication.

All study staff will receive training on human subjects' protection, interviewing and data collection, and data handling prior to beginning engaged research activities. Study staff will be trained to remain neutral and professional in their interactions with participants and to encourage honest responses to the study questionnaire.

d. Data handling and Analysis

Paper files include: 1) locator information, 2) informed consent, 3) intervention attendance records). The first two types of paper files have identifying information and are not considered study data. Consents are stored in a locked cabinet away from workstations and are only accessed in the event of a study visit, consent amendment, or an audit. Locator files are kept in a locked cabinet in the research area, separate

from data files, and are updated monthly and at each research visit. Case report forms are coded using a participant identification number (PID); intervention attendance records contain identifying information to increase data quality (de-identified attendance records would be difficult to accurately maintain) and stored in locked hard copy file cabinets or in password protected electronic files on a secure server. Only study staff will have access to paper file.

Computer files consist of the visit tracking data base, survey data files, case report forms (CRFs, i.e. for HIV/STI testing results and PrEP care) and audio recordings and transcriptions. In addition, during the COVID-19 pandemic, e-consent forms will be deployed and stored in REDCap, if a participant chooses to enroll remotely. Audio recordings are captured either on password protected audio recorders or through the audio recording feature of web conferencing platforms at Northwestern University (Zoom, Webex). Audio files contain no identifiers and are removed and deleted from audio recorders or web conferencing platforms and transferred immediately to secure study folders. Computer access is password protected. Data files are maintained in de-identified format and stored in password-protected files on secure servers. Tracking files (i.e., linking database) are maintained in a highly secure scheduling and monitoring database, REDCap, at Northwestern University. This database is used to schedule and track study visits and accessible only to study staff; it is completely password protected.

Survey data are captured in web-based format via Qualtrics software (in-person visits and for remote survey questionnaire), which uses Transport Layer Security (TLS) Encryption for all transmitted data; all data collected via Qualtrics is done only by ID number and not by name. Data files are exported from Qualtrics and imported into SPSS database for storage and analysis on a secure server at Lurie Children's. Only the study investigators and data manager have access to these data.

All biological specimens will be labeled with coded identifiers for processing to maintain confidentiality. Biological specimens (urine, anal swabs, blood) for HIV/STI testing will be coded and transferred by local courier for processing in external laboratories used commonly in the testing programs at Lurie Children's, Chicago House, and HHO. Hair samples for assessment of tenofovir disoproxil fumarate level (aka PrEP) will be coded and transferred to the Hair Analysis Lab at University of California San Francisco (UCSF) via mail courier service. All research staff will be trained for collection of hair samples by Dr. Kuhns with guidance from the Hair Analysis Lab at UCSF. DBS samples will be shipped via mail courier service to University of Colorado for analysis. Staff at HHO and/or Lurie Children's will be trained for collection and storage of DBS by Dr. Kuhns. HIV/STI testing will be completed by clinical staff of HHO or staff of Chicago House. Biological specimens collected under this protocol will be used for the purposes outlined herein and not for future research.

Coded and encrypted electronic data files collected at Chicago House, including program attendance records, HIV/STI screening results, and PrEP medical visit information will be transferred from Chicago House to Lurie Children's and from Lurie Children's (in a comprehensive database: survey, biomarker results, attendance records) to University of Chicago via REDCap ("send it" feature) for data analysis.

All identifying information will be destroyed as soon as possible at the end of study and no longer than three years from the closure of the study protocol with the Lurie Children's IRB.

Semi-structured interview data will be collected in a de-identified format, i.e., data will not be linked to individual names or identifiers. The audio-recorder and audio-recordings will be password-protected to protect against breach of confidentiality. Audio-recordings will be transcribed verbatim, with the exception that any inadvertent disclosure of names or other identifying information will be coded or excluded. Transcripts are entered into Dedoose qualitative analysis software for storage and analysis. Computer data files are maintained by ID number only, and are password protected and encrypted for transfer between study sites. Audio files will be destroyed as soon as possible after transcripts are

verified and no later than three years from the closure of the study protocol with the Lurie Children's IRB.

Data quality will be monitored regularly by the Lurie Children's PI and data manager. This will include review of study files and data for accuracy (Quality Assurance), reconciliation of any file and data problems as soon as possible, and cleaning of study data and creation of a codebook prior to analysis.

Only study investigators and the study data manager will have access to survey and interview data. Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (see Data Use Agreement, Appendix h).

Analyses will be conducted with SAS software (SAS Institute, Cary, NC). To determine the pre-post efficacy of the TLC intervention, 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 (GLMs) will be used to assess the combined effect of the intervention on condomless anal sex at 4 and 8-month follow-up. GLMs can accommodate dependent variables with normal, binary, Poisson, and negative binomial distributions and can be adapted to incorporate random and fixed effects (generalized linear mixed models; GLMMs) to account for within-subject correlation among repeated measures over time. Multivariable GLMMs will be used to assess 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) that will be selected based on a priori hypotheses and empirical or theoretical importance. In the original analytic plan we proposed to treat time as discrete, assuming all visits occurred at 4 and 8 months within a margin of error. To account for differences in time between baseline and follow-up visits due to COVID-19 related changes in the recruitment protocol (i.e., extension of 4 and/or 8 month windows), we will conduct additional supplemental analyses to account for variability in person-time contribution among participants. We will calculate the exact time in days between baseline and subsequent visits as a continuous variable, and pre-post analyses will control for the time between measurements. For evaluation of the effect of intervention dose on rates of condomless anal sex over time, we will estimate relative rate ratios by specifying log-time as an offset variable in generalized linear models to account for varying person-time contributions. We will also include an indicator for whether stay at home orders were in place at the time of the assessment to control for behavioral changes that may have resulted from COVID-19 related policies. The analytic approach and interpretation of intervention effect estimates will otherwise be analogous to those described in the original proposal. Potential confounding and effect modification by sociodemographic characteristics and other factors will be examined in exploratory analysis and will be included in multivariable models as appropriate. All models will account for correlation among repeated measures on individuals over time. Inclusion of random effects for intercept and trend over time will be explored to assess subject-specific variability at baseline and in terms of trajectories over time.

e. Handling of Adverse Events

Possible adverse events (AEs) that are anticipated in this study include the need to violate the confidentiality of the participants in the case of spontaneously reported suicidality. All study personnel will be trained regarding the limits of confidentiality. The training will include reviewing possible scenarios and knowledge of key questions to assess risk. We will train staff to err on the side of caution

and to contact the clinical supervisor as needed. Supervisors and Investigators will be available on site or via phone after hours should staff need consult regarding an emergency. In this situation, we will train all staff to immediately contact clinical supervisors before participants leave the interview room. Under the guidance and direction of clinical supervisors, study staff will be trained when to either contact police to ensure the safety of participants, or if appropriate, to escort participants to the nearest Emergency Room, which is located close (less than 1 mile) to the primary recruitment sites.

Possible adverse events (AEs) that are unanticipated will be brought to the attention of the study PIs and reported immediately to the IRB and to the CDC. The study PIs will report the AEs and serious AEs (SAEs) to the IRB in writing as soon as possible, but within 7 calendar days for death or life-threatening events and within 15 calendar days for all other AEs or SAEs. The IRB will determine whether it is appropriate to stop the study protocol temporarily or will provide suggestions/modifications to the study procedures as necessary. Possible modifications include adding these possible adverse events to the consent form and re-consenting all study participants. The PIs will be responsible for monitoring participant safety on a monthly basis at regularly scheduled research meetings. They will keep a written log of all events and ensure that the IRB and the CDC are contacted immediately. They will also keep a log of the outcome of IRB decisions regarding adverse events and apprise the research team of any changes that need to occur as a result of IRB decisions.

f. Sharing Study Results

Study findings will be disseminated through community forums, academic and community conference presentations, and peer-reviewed publications.

IV. HUMAN SUBJECTS PROTECTIONS

a. Informed Consent

For the TLC intervention trial, written consent will be conducted in a private room, by trained TLC Program Director Josie Paul and Program Manager Kevin Pleasant. Consent will occur after eligibility is determined (i.e., immediately after screening or as soon as possible thereafter) and before any research activities begin. During the COVID-19 pandemic, consent will be conducted in-person with restrictions or remotely via the e-consent module in REDCap. Both Ms. Paul and Mr. Pleasant have completed the web-based course, “Protecting Human Research Participants” provided by the NIH Office of Extramural Research as well as a 4-hour training session on conducting consent, protecting confidentiality and privacy, data collection, and secure storage provided by Dr. Kuhns. If staff feel there is a question about the need for a more formal assessment of the decisional capacity of a potential participant, they will contact the project coordinator, or study investigators, who may refer the participant to medical or psychosocial services for evaluation.

For semi-structured interviews of TLC participants and staff, we are requesting a waiver of documentation of informed consent under 45 CFR 46.117 (c). The request for waiver of documentation of consent is based on the fact that the interview data will be collected in a one-time visit, de-identified (not

linked to an individual participant name or other identifiers), and is minimal risk. This waiver is not expected to adversely impact the rights of participants because the risks of study participation are minimal and the potential for breach of confidentiality is minimal. Participants in the semi-structured interviews will receive a copy of the consent form.

Consent will be conducted immediately prior to baseline data collection (i.e., before completion of any research activities) for potential TLC intervention participants and immediately prior to the semi-structured interview for TLC participants and staff. Potential participants will be encouraged to take as much time as needed to decide whether or not to participate.

In order to avoid coercion, staff will encourage potential participants to ask questions during the consent process, assure them that their participation will not impact their relationship with staff or with the involved institutions.

Individuals who are unable to speak and understand English are excluded from this study. The primary reason for this exclusion is that the study assessments are not translated or validated for non-English speakers.

The study consent forms have been developed using the lowest reading level possible given the templated language required by the IRB of Record at Lurie Children's. The language included in the section, "What is involved in the study and how long will I be in the study?" is at the 8th grade level.

b. Risks and Benefits

Potential risks consist of being uncomfortable or emotionally upset as a result of the questions asked in the TLC intervention assessment (i.e., questions about sexual risk, substance use, mental health) or the semi-structured interviews; potential for breaches of confidentiality; risks usually associated with the collection of blood from a finger stick or from a vein in the arm, such as pain or discomfort at the site of collection, temporary bruising at that site and very rarely, the site of blood collection may become infected or need medical treatment.

In the TLC intervention study visits, it is possible that certain assessment questions regarding sexual behavior, substance use and/or mental health may make participants feel uncomfortable. However, the risk to the participant is no greater than that encountered in standard counseling relationships. Participants are free to refuse to answer any question and may terminate participation in the study at any time. All information disclosed to the research team will remain confidential if the participant chooses not to complete the study. Moreover, the participant can ask study staff to provide referrals to counselors or other means of support if they become emotionally upset. As in any study, there is always risk of inadvertent breach of confidentiality. Both Chicago House and Lurie Children's have been involved in prior studies of TW and each have considerable experience implementing measures to protect confidentiality. These measures include signed confidentiality agreements, in-service trainings on confidentiality, the assignment of study ID numbers, and the protection of study data by collecting and storing data by these ID numbers. Staff who conduct participant recruitment, screening, enrollment, and HIV/STI testing will have been trained in ethical human subject research and screening and interviewing techniques, to minimize participant risk as much as possible.

The potential risk of breach of confidentiality for semi-structured interviews will be minimized by collecting data in a de-identified format, password-protecting the audio-recording device and audio-

recordings, and destroying the audio files immediately after the audio-recordings have been transcribed and verified.

The risks associated with blood draw have been minimized by using a less invasive procedure, finger stick, when possible and by collecting a minimal amount of blood when necessary.

Individual participants may benefit by having an opportunity to receive basic services, including housing, employment, legal and medical services. Possible risks (i.e. discomfort answering questions, potential confidentiality breaches) are outweighed by the new knowledge gained from testing this intervention among the study population, a population at very high risk of HIV transmission and acquisition.

An alternative to participation in this study is referral to standard HIV/STI testing and risk reduction counseling and referral to PrEP providers.

c. Privacy and Confidentiality

We will protect participant confidentiality by collecting all data by study ID numbers rather than by name or other contact information. We will store all data on secure servers and transfer data between sites using coded and encrypted transfer protocols. We will protect participant privacy by conducting study consent and data collection procedures in a private room. Study staff will be trained in all aspects of data collection and handling, informed consent procedures and human subjects' protection, including the importance of protecting the privacy and confidentiality of participants.

We will request a Certificate of Confidentiality from the CDC to further protect the confidentiality of study participants.

d. Token of Appreciation

Participants in the TLC Intervention will be provided with a token of appreciation of $50 (cash or gift card) for each study visit for a total of $150 for all three visits. Individuals who complete semi-structured interviews will receive $50 (cash or gift card) for this one-time interview (including intervention participants and staff).

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