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

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Section B: Supporting Statement

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1. Respondent Universe and Sampling Methods

City Selection

The goal of this study is to evaluate TransLife Center (TLC), a locally developed combination HIV prevention intervention for transgender women, located in Chicago, IL. Chicago has high rates of HIV infection. The prevalence of HIV and other STIs is disproportionately high among transgender women who have sex with men, particularly ethnic minority and younger transgender women. As noted by the CDC, because HIV-related surveillance data are not uniformly collected, data on HIV infection among transgender women is lacking.[1] However, data from local health departments, large meta-analyses, and multi-city studies using convenience sampling methods suggest high levels of HIV infection among transgender women.[1] While local surveillance of HIV infection among transgender women 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 transgender women. A study of 151 mostly racial/ethnic minority younger transgender women ages 15-24 years in Chicago and Los Angeles found that 19% self-reported HIV infection.[2] Findings from a current intervention study of younger transgender women ages 16-29 years in Chicago and Boston found HIV prevalence of 21.8% among participants at the baseline visit.[3] In addition, Garofalo and colleagues found that, much like in other high risk populations, while racial/ethnic minority transgender women have higher rates of HIV and STIs, sexual risk behavior is lower in this group, particularly among Black transgender women.[3]

Target population:
This study plans to sample a total of 160 persons. For the quantitative assessment portion of this study, we plan to sample 150 transgender women living in the Chicago, IL metropolitan statistical area. The target population of interest is HIV-negative transgender women at least 18 years of age who have sex with men and are at risk of HIV infection. 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 transgender women.

Inclusion criteria:

* Aged 18 or over
* Assigned male at birth
* Self-identify as transgender, transsexual, women, and/or female who was assigned male sex at birth
* Self-reported history of sex with men in the past 4 months
* HIV-negative via self-report, verified by HIV testing at baseline
* Self-reported ability to read and understand English-language
* Willing and able to provide informed consent/assent
* Intention to reside in the local area (Chicago, IL) throughout the 8-month follow-up period
* No exposure to the TLC intervention in the prior 4 months

Exclusion criterion:

* Unable to provide informed consent due to severe mental or physical illness, or substance intoxication at the time of interview
* Active suicidal ideation (spontaneous report, referred immediately for treatment, and may re-screen when resolved)

For the qualitative interview portion of this study we plan to interview 20 of the 150 TLC participants and 10 TLC staff (30 total interviews).

Exhibit 1.1: Summary of Recruitment Targets

Participant Type	Total
Transgender women • All participants will take part in the quantitative assessment • A subset of 20 participants will take part in the qualitative interview	150
TLC staff • Qualitative interview only	10
Total study enrollment	**160**

We will recruit transgender women into the study through a combination of approaches, including active recruitment 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 as permitted. Participants will also be asked to refer friends or others who may be eligible. Passive approaches include posting of study flyers (**Attachment 3**).

This is an intervention trial which is primarily designed to make comparisons between the pre- and post-intervention group, not to make generalizations to the larger population. In addition, transgender women are a unique and hidden population, with no sampling frame; therefore, multiple convenience and referral-based sampling techniques will be used to identify and recruit participants to the study.

Rationale for proposed number of subjects
150 participants are required to detect a change between the pre- and post-intervention groups. Based on McNemar's test for paired proportions and paired t-tests for continuous outcomes, sample sizes were estimated to yield ≥80% power for paired differences (proportions or mean differences) measured at baseline and 1 follow-up point (pre and post-intervention)/ 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.

The qualitative interview portion of the study (N=30) is not designed to make comparisons between groups or to make generalizations. Standard qualitative sampling methodology aims to ensure a wide range of experiences are captured. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest.

2. Procedures for the Collection of Information

We will collect four types of information for this study: screening information, contact information, quantitative assessment, and qualitative interview information.

Interested participants will be screened for eligibility either in person, over the telephone, or via teleconference prior to enrollment. The screening script (**Attachment 4a**) 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), participants who are eligible and interested in participation will be consented for participation (**Attachment 5a**) and locator (contact) information will be collected (**Attachment 4b**). During the COVID-19 pandemic, consent will be conducted in-person with restrictions or remotely via the e-consent module in REDCap. Participants will also be asked to sign an authorization to release medical information (**Attachment 5c**).

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 quantitative assessments (**Attachments 4c and 4d**) through self-administered modes at three separate assessment visits (baseline, 4, and 8 months). 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).

We will also examine the implementation experiences of TLC intervention participants and staff through semi-structured (qualitative) interviews (**Attachment 4e**) 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 beginning in year 2 of the study (after enrollment has begun) 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. All participants taking part in the interviews will be selected randomly. The 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 (18-29, 30-39, 40-49, 50+). 10 TLC staff will be selected randomly within strata by job type/rank (front line, middle management, executive) to insure representation of each level. Eligible participants will be consented for participation prior to the interview (**Attachment 5b**).

Locator and consent information will be stored on paper forms only, and kept in locked cabinets, away from workstations and separate from other study data. Data files will be stored in password protected files on secure servers. Semi-structured interview data will be collected in a de-identified format. The audio-recorder and audio recordings will be password-protected. Computer data files will be maintained by ID number only, and are password protected and encrypted. Only study investigators and the study data manager will have access to survey and interview data. All identifying information will be destroyed as soon as possible at the end of the study and no longer than three years from the closure of the study protocol with the Lurie Children's IRB. There will be no video recording of any aspect of intervention delivery or data collection.

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Active recruitment will be carried out by study front-line staff, who will be members or allies of the target population.
- A $50 token of appreciation will be provided to respondents upon completion of each assessment ($150 total for all three assessments), and a $50 token of appreciation will be provided upon completion of the semi-structured interview.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from individual respondents.

4. Tests of Procedures or Methods to be Undertaken

Our team includes experts with the transgender population, HIV prevention, quantitative and qualitative research, including screening and survey and interview development and testing. The grantee study team will conduct pretesting of the screening tool, assessment survey and qualitative interview on three to five qualified mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the data collection tools and to estimate response burden for each respondent.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The staff will neither collect data from nor interact with research participants. Data will be collected by members of grantee project staff listed. Participant names and contact information will not be shared with nor accessible by CDC staff.

Exhibit 5.1: Statistical Consultants

Name	Title	Organization	Phone	Email
Damian Denson	Project Officer	CDC	404-639-6125	dvd5@cdc.gov
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Josie Lynne Paul	Project Director	Chicago House & Social Service Agency	773-248-5200 ext. 317	jpaul@chicagohouse.org

References

1. Centers for Disease Control and Prevention (CDC). HIV among transgender people 2015 [Available from: http://www.cdc.gov/hiv/group/gender/transgender/.
2. Wilson EC, Garofalo, R., Harris, D. R., Belzer, M. Sexual Risk Taking Among Transgender Male-to-Female Youths with different Partner Types. American Journal of Public Health. 2009:e1-e6.
3. Garofalo R, Osmer E, Sullivan C, Doll M, Harper G. Environmental, psychosocial, and individual correlates of HIV risk in ethnic minority male-to-female transgender youth. Journal of HIV/AIDS Prevention in Children & Youth. 2006;7(2):89-104.