

**HIV prevention among Latina transgender women:
Evaluation of a locally developed intervention**

OMB 0920-New

Section B: Supporting Statement

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1. Respondent Universe and Sampling Methods

City Selection

The goal of this study is to evaluate the efficacy of ChiCAS (Chicas Creando Acceso a la Salud [Chicas: Girls Creating Access to Health]), a locally developed and culturally congruent two-session Spanish-language small-group combination intervention designed to promote consistent condom use, and access to and participation in PrEP and medically supervised hormone therapy by HIV seronegative Hispanic/Latina transgender women who have sex with men. 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. It is estimated that about 1 in 4 transgender women has HIV;¹⁻³ and the odds of becoming HIV positive are estimated to be 34.2 times higher for transgender women than other US adult populations.² As noted by the CDC, because HIV-related surveillance data are not uniformly collected, data on HIV infection among transgender women is lacking.⁴ While local surveillance of HIV infection among transgender women in North Carolina 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.

The ChiCAS intervention was developed in North Carolina by Triad Health Project in close conjunction with local Latina transgender women. The initial intervention was a compilation of activities partially adapted from other interventions carried out over the last 15 years by a local community-based participatory research (CBPR) partnership that included representatives from Triad Health Project, local health departments, representatives from the Latina transgender community, and Wake Forest University. Our research team at Wake Forest School of Medicine and Triad Health Project has extensive community networks in North Carolina and is very well trusted.

ChiCAS intervention sessions will be implemented at 7 locations (in 5 cities) across NC that are safe and convenient for participants. Screening of potential participants for eligibility, HIV testing to verify their eligibility, and completion of the informed consent process and baseline assessments may also occur at these locations unless potential participants prefer to complete these processes at another location of their choosing. All locations are owned or operated by organizations with which we have collaborated in the past and provide HIV and STI testing, PrEP, and/or medically supervised hormone therapy, or provide referrals to sources of these services. The locations and the organizations are listed below.

- In Asheville, we will implement the intervention at the Western North Carolina AIDS Project (WNCAP) (#1). WNCAP offers HIV testing, prevention and adherence counseling, PrEP services, and case management for transgender persons. We will also implement at the Western North Carolina Community Health Services (WNCCHS) (#2). WNCCHS offers HIV and STI testing, PrEP services, and medically supervised hormone therapy for transgender persons.
- In Charlotte, we will implement the intervention at the Regional AIDS Interfaith Network (RAIN) (#3). RAIN offers HIV testing, prevention and adherence counseling, PrEP services, case management, and medically supervised hormone therapy for transgender persons.
- In the Triad (metropolitan area of Greensboro, Winston-Salem, and High Point), we will implement the intervention at the Triad Health Project (#4). Triad Health Project offers HIV testing, prevention and adherence counseling, PrEP services, and case management for transgender persons. There are several providers in the Triad area that provide medically supervised hormone therapy for transgender persons on a sliding scale, and for those with insurance.
- In Raleigh, we will implement that intervention at the Alliance of AIDS Services – Carolina (AAS-C) (#5). AAS-C offers HIV testing, prevention and adherence counseling, PrEP services, and case

management for transgender persons. There are several providers in Raleigh that provide medically supervised hormone therapy for transgender persons on a sliding scale and for those with insurance.

- In Wilmington, we will implement the intervention at the Wilmington Health Center (#6) and the New Hanover Regional Medical Center (#7), which offer HIV and STI testing, PrEP services, and transition-related services for transgender women. Several providers in Wilmington provide medically supervised hormone therapy for transgender persons on a sliding scale and for those with insurance.

Target population:

This study plans to sample 140 persons living in or near five metropolitan areas in North Carolina: Asheville, Charlotte, Research Triangle, Raleigh and Wilmington. The target population of interest is HIV-negative Hispanic/Latina transgender women at least 18 years of age who have sex with men and are at risk of HIV infection. We anticipate that study participants will be comprised mainly of racial/ethnic minority participants under 35 years of age, consistent with the epidemiology of HIV infection among transgender women.

Inclusion criteria:

- * Aged 18 or over
- * Self-identify as Hispanic or Latina
- * Self-identify as male-to-female transgender or report having been born male and identifying as female
- * Report sex with at least one man in the past six months
- * HIV negative based on self-report and verified by HIV testing at baseline
- * Fluent in Spanish
- * Provide informed consent

Exclusion criterion:

- * Participation in any HIV prevention intervention within the past 12 months prior to enrollment

Exhibit 1.1: Summary of Recruitment Targets

Participant Type	Total
Transgender women <ul style="list-style-type: none"> • Adult • Hispanic/Latina • HIV-negative • Have sex with men • Spanish-speaking • Willing to provide informed consent 	140
Total study enrollment	140

We will recruit transgender women into the study through a combination of approaches, including active recruitment at local gathering places of Hispanic/Latina transgender women such as bars and nightclubs. Participants will also be asked to refer friends or others who may be eligible. Passive approaches include posting study flyers (**Attachment 3a and 3b**) in businesses that serve and/or employ large numbers of Hispanics/Latinos including tiendas (shops or stores that cater to Hispanic/Latino populations), laundromats, construction sites, hotels, ESL classes, restaurants, housing communities and apartment complexes.

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. Because Hispanic/Latina transgender women are a unique and hidden population for which there is no study sampling frame, we will use multiple convenience and referral-based sampling techniques to identify and recruit participants to the study.

Rationale for proposed number of subjects

ChiCAS study power calculations 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 may re-estimate the sample size in light of interim results during the ChiCAS trial study. In order to avoid increasing the Type I error rate at the time of the final analysis, we will use the sample size reassessment approach of Mehta and Pocock.⁵ Once we have recruited and completed follow-up assessments for 80 participants, we will calculate the conditional power based on participant data accumulated by that point. The use of 80 participants will enable us to maximize the precision of our interim estimate. If power based on our review of outcome data 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. This approach does not discontinue a study due to futility. At a minimum, it continues to the original sample size. Please note that we have strong and diverse experiences with high rates of participant retention using various strategies. Based on our recruitment protocol, 20 additional individuals will have been recruited and will be awaiting follow-up assessments at the time of this reassessment and will therefore be assured follow-up and inclusion in our final analysis.

We will randomly select a subset of up to 30 participants from the total study sample who will be categorized into three groups of 10 persons each based on their self-reported behavioral outcomes relative to those expected from the intervention. We will administer qualitative interviews to these persons in order to obtain information concerning their general experiences while participating in the intervention and intervention outcomes, and any recommendations they may have for improving the intervention content or delivery. We chose this number based on qualitative research literature suggesting that a sample size of 30 is sufficient for our purposes. We describe the categorization of qualitative interview participants in greater detail below.⁶

2. Procedures for the Collection of Information

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

Interested participants will be screened for eligibility either in person or over the telephone prior to enrollment (**Attachments 4a and 4b**). After potential participants have been identified, screened for eligibility, and confirm their willingness to participate, study staff will schedule a meeting with them to complete an HIV test to confirm their eligibility, administer informed consent and the baseline assessment. The screening form includes a detachable section in which contact information is collected. (**Attachments 4a and 4b**). By enrolling participants in waves of 20, we expect to avoid long delays between recruitment, randomization, and participation.

Screening, HIV testing to verify eligibility, and completion of the informed consent process and baseline assessments may be conducted at one of the seven community-based organizations (CBOs) or health service delivery organizations in NC that are listed above (see page 4) and have agreed to make their facilities available during the study. All organizations provide spaces that are safe and convenient for participants. Alternatively, if potential participants prefer, these steps in the study screening and enrollment processes may be completed at locations that are selected by the individuals. Examples of alternative locations include private and safe areas of homes, bars and clubs, Hispanic/Latino-owned businesses, and at community events (e.g., gay pride and Hispanic/Latino cultural events) by staff. Immediately following enrollment, participants will be randomized into one of two groups, the intervention or the delayed-intervention group, and interviewers will administer the quantitative baseline assessment to both groups (**Attachments 4c and 4d**). All participants will repeat the assessment, using the same data collection instrument, 6 months after enrollment and completion of the baseline assessment. Study assessments will collect information on sociodemographic factors; the primary outcomes (PrEP use, consistent condom use and use of medically supervised hormone therapy); psychosocial factors including awareness and knowledge about HIV and PrEP, barriers to care, condom use skills, healthcare provider trust and communication skills; and other variables including self-reported health status and history of health care use. The assessment also includes a detachable section in which contact information is collected (**Attachments 4c and 4d**).

As noted above, we will also identify and explore the strengths and weaknesses of the ChiCAS intervention through the use of qualitative in-depth interviews with up to 30 intervention participants (**Attachment 4e and 4f**). For this portion of the study, we will randomly select and interview three groups of 10 participants each from the intervention group after they complete the 6-month follow-up. These groups will include ten participants who reported an increase in at least one HIV prevention behavioral outcome (PrEP or condom use) and who reported an increase in the use of medically supervised hormone therapy; ten participants who did not report an increase in at least one HIV prevention behavioral outcome (PrEP or condom use) and did not report an increase in the use of medically supervised hormone therapy; and ten participants with mixed results. The qualitative assessment will collect information from selected participants on their general intervention experiences and recommendations, and their experiences and lessons learned regarding PrEP, condom use and use of medically supervised hormone therapy.

Personal identifying information will not be attached to the data obtained from participants during the assessments. Immediately after completing the assessments, personal contact information will be separated from the questionnaire. The signed consent form will also be stored separately. A code will link the two assessments and the consent form. During data collection outside of the offices of the Wake Forest Health Services, completed assessments, participant contact information, and the consent forms will be stored in 3 separate locked boxes to ensure that each participant's information is not easily linked to their responses. The locked boxes will never be left in the car of a data collector overnight. Within 48 hours, all assessments, contact information, and consent forms will be transferred to Wake Forest School of Medicine.

3. Methods to Maximize Response Rates and Deal with Non-responses

We expect attrition in this study to be minimal because studies that are based on community member priorities and planned and conducted in partnership with community members and organizations they trust (e.g., Triad Health Project) tend to have lower attrition rates.⁷⁻¹² We have used this approach in all of our studies. Often assumed to be “unstable” or “in transition,” the Hispanic/Latino communities

involved in our studies have had low attrition rates, with much of this success due to our community-engaged approach.

In our recent CDC-funded intervention study HOLA en Grupos (U01PS001570; OMB 0920-0942, exp. 3/31/2018) to reduce HIV risk among Hispanic/Latino gay and bisexual men, MSM, and transgender women, we retained 100% of the 304 participants at 6-month follow-up.¹¹ In another recent study of Hispanic/Latino gay and bisexual men, other MSM, and transgender women (R01MH087339; no OMB number),¹³ we had a 95% retention rate at 24-month follow-up; although the numbers of transgender women were low in these 2 studies, there was no difference in retention rates between transgender women and MSM.

We have calculated the statistical power for our study based on a 10% dropout rate at the 6-month post-intervention follow-up. Although we have not experienced such high dropout rates, we have used 10% as a worst-case scenario. Attrition will be followed by the partnership to provide important insights for retention efforts in subsequent studies. We have strong and diverse experiences in participant retention using various strategies.

At the baseline assessment with each participant we will obtain: current address, personal cellphone number, other telephone numbers, e-mail addresses, the contact information of others (e.g., friends and family) who may know how to find the participant if she becomes difficult to find, and Facebook names/aliases. We will also obtain permission to use these resources to reach the participant if we cannot locate them through other means. Each participant also will be given a toll-free number on a stay-in-touch card that she can call to provide updated contact information (**Attachment 9a & 9B**). If necessary, the 6-month follow-up assessment can be completed by telephone, and the token of appreciation mailed to the participant. We have successfully provided a cellphone number to Hispanic/Latino participants previously, and they have used it to notify us their contact information has changed or if they are temporarily or permanently out of the area.

To enhance retention, we will provide tokens of appreciation for participation in the different stages of the study. We will provide \$30 for completion of the baseline assessment, \$40 for completion of each of the two intervention sessions, \$40 for completing the 6-month follow-up assessment in person (\$30 in the rare cases that study participants complete the follow-up assessments by phone). In addition, \$40 will be provided to those participants from the intervention group who are selected and complete qualitative in-depth interviews. Additional retention-promoting measures will include the following: (1) providing a meal during each intervention session; (2) giving participants Spanish-language appointment cards with the date and time of the next intervention session (**Attachment 10a and 10b**), (3) bags and cosmetic bags bearing the study logo; (4) a two-sided laminated card that will include a toll-free cellphone numbers (answered by the interventionist) to stay in contact with the study and report changes in contact information (i.e., the stay-in-touch card previously described); (5) a graduation dinner upon successful completion of the intervention; and (6) a certificate acknowledging completion of the intervention.

Study staff will make a maximum of five attempts to contact study participants to administer 6-month follow-up assessments and the in-depth interviews.

4. Tests of Procedures or Methods to be Undertaken

Study staff have considerable experience collecting sensitive data (including sexual health and risk data and healthcare access) from Hispanic/Latino heterosexual individuals, MSM, and transgender women.^{8, 11, 12, 14-56} The interviewers will be trained in issues particularly salient to research with Hispanic/Latina transgender women, and within Hispanic/Latino communities. This training will develop their knowledge of these communities and sexuality within these communities and refine their interviewing skills. Interviewing skills to be developed include asking questions, listening instead of talking, expressing verbal interest in the respondent, and showing interest by eye contact and other nonverbal cues.⁵⁷ The grantee study team will facilitate interview role playing with Hispanic/Latina transgender women (N=5) from the steering committee, who represent the target community, and use various challenging scenarios to develop the skills of the interviewers. These mock interviews will be videotaped to allow the interviewers to see and hear how the interview went and debrief with study team leads and learn from the process. Mock interviews will allow interviewers to identify opportunities for silence, probing for detail, etc. Pretesting instruments also will serve as opportunities to refine and practice skills.

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. CDC staff will neither interact with nor collect data from study participants. Data will be collected by members of grantee project staff listed. No individual identifiers will be linkable to collected data shared with or accessible by CDC staff, and no individually identifiable private information will be shared with or accessible by CDC staff.

6. Analysis Plan

Individuals who are eligible to participate in the intervention study will be randomly assigned to receive the intervention (intervention condition) shortly after collection of baseline data from them, or to receive the intervention (waitlist comparison condition) after completion of the 6-month post-intervention follow-up assessments by intervention condition participants and before comparison participants receive the intervention.

Individuals who are eligible to participate in the ChiCAS intervention study will be randomly assigned to receive the intervention shortly after collection of baseline data from them (intervention condition), or to receive ChiCAS after (waitlist comparison condition) intervention condition participants complete their 6-month follow-up assessments.

Analysis of quantitative data from baseline and 6-month follow-up questionnaires

Data analysis will involve general descriptions of the study groups and analysis of the intervention effects.

General description of the study groups. Absolute numerical values and percents will be calculated for categorical variables; means, medians, standard deviations, and ranges will be calculated for continuous variables to describe the overall characteristics of study participants and to compare ChiCAS intervention and comparison participants. Correlational analyses will be used to evaluate associations

between variables, and nonparametric statistics will be used as appropriate to assess the significance of the observed associations.

Evaluation of intervention effects. The effects of the ChiCAS intervention will be evaluated by comparing use rates for PrEP, medically supervised hormone therapy, and consistent condom use by intervention and waitlist participants at baseline and six months later. We will adjust for baseline use rates at the follow-up, as doing so has the advantage of being unaffected by baseline differences.

The intervention outcomes will be assessed using an intent-to-treat approach in which participants are included in the analysis as originally assigned to the intervention or comparison conditions, regardless of whether they actually attended their assigned session. Statistical analysis will be performed using generalized linear mixed modeling for binary outcomes, sometimes termed random effects logistic regression. This approach will produce estimates of PrEP use, medically supervised hormone therapy use, and consistent condom use while adjusting for covariates, which will be compared to unadjusted estimates. Individual-level covariates may include age, country of origin, education level, and length of time in US. To assess the importance of covariates, a backwards elimination model building approach will be used, with primary consideration on assessment of confounding on the intervention-group difference. If confounding is present (defined to be greater than a 10% change in the regression estimate of the intervention-group effect), the confounder will be retained in the multivariable model. Interactions with intervention group will be tested first and retained if significant at the 5% level. All analyses will be two-sided.¹⁴¹

Adherence. Some participants in rigorous evaluations such as that planned for the ChiCAS intervention study may be “non-adherent;” that is, they do not attend all sessions as expected. This can introduce bias when estimations of intervention effects are based solely on data collected from participants who attend all intervention sessions. The intent-to-treat method described above addresses this bias. In addition, adherence will be assessed by estimating the proportion of participants who complete both of the intervention’s two sessions and the average number of completed sessions. In secondary analyses, adherence data will be used as a predictor variable in modeling intervention efficacy. Differences between intervention and waitlist participant outcomes will be assessed at the ≤ 0.05 significance level.

Data management. Study staff will develop a standardized data collection manual/codebook for use with the identical baseline and 6-month follow-up assessment questionnaires. Completed assessments will be reviewed by study staff and entered using TELEform software (Verity, Inc, Sunnyvale, CA).

Analysis of qualitative data from in-depth Interviews

Analysis of qualitative data will include eight analytic steps: (1) After each interview, study staff will document general impressions about its content and potentially emerging themes and new areas of information; (2) They will listen to the digital recording and take general notes; (3) The digital recordings will be professionally transcribed verbatim and then verified, and any personally identifying information will be removed from the transcription; (4) Digital recordings will be erased after verification; (5) Transcriptions will be entered into the NVivo software (Chicago, IL) for purposes of data management; (6) A common coding system and data dictionary will be developed; (7) All transcripts will be coded using this coding scheme, while allowing for new codes to emerge. Similarities and differences across transcripts will be examined and codes and themes revised accordingly. Finally (8), findings will be presented to the Community-Based Participatory Research partnership for final review, revision, and interpretation. We have used this approach to qualitative data analysis successfully previously

Characteristics of study locations. As noted above, the seven study locations are similar insofar as they all have safe community rooms where the intervention can be delivered and provide or provide referrals for HIV and STI testing, PrEP, and/or medically supervised hormone therapy. Data will be collected to describe cross-site differences in study outcomes, but the study is not sufficiently powered to compare the sites.

Exhibit 5.1: Statistical Consultants

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Teri Wellendorf	Project Manager	Wake Forest University	336-713-5074	twellend@wakehealth.edu

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