

Adapting a group-level PrEP promotion intervention trial for transgender Latinas during the COVID-19 pandemic: Recruitment, screening, enrollment, data collection, implementation, and retention

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Abstract

The COVID-19 pandemic has profoundly affected the conduct of community-based and community-engaged HIV research. Prior to the pandemic, our community-based participatory research partnership was testing *ChiCAS*, an in-person, group-level behavioral intervention designed to promote uptake of pre-exposure prophylaxis (PrEP), condom use, and medically supervised gender-affirming hormone therapy among Spanish-speaking transgender Latinas who report having sex with men during the past 6 months. However, the pandemic required adaptations to ensure the safe conduct of the *ChiCAS* intervention trial. In this paper, we describe adaptations to the trial within critical five domains: (1) participant recruitment, (2) screening and enrollment, (3) baseline data collection, (4) intervention implementation, and (5) participant retention for follow-up data collection. Transgender women continue to be disproportionately affected by HIV; therefore, it was essential to find ways to continue important research designed to support their health and wellbeing within the context of the COVID-19 pandemic. These adaptations offer guidance for ongoing and future community-based and community-engaged research during the COVID-19 pandemic and/or potential subsequent pandemics.

Introduction

Transgender women are disproportionately affected by HIV in the United States. Current estimates suggest that about 14% of transgender women are living with HIV,¹ and it is estimated that fewer than half of transgender women with HIV in the United States know their status.²⁻⁴ Some subgroups are particularly affected by HIV, including transgender Latinas.⁵⁻⁷ A number of factors contribute to high rates of HIV among transgender Latinas, including lack of knowledge and misconceptions regarding HIV transmission and prevention strategies,⁸⁻¹⁰ a lack of available sexual health education and other preventive services specifically designed for transgender Latinas;⁸⁻¹¹ and perceptions that sex is more enjoyable without condoms or that “being in love” means not using condoms.¹²

Transgender Latinas may also face challenges negotiating condom use with sexual partners. They may lack adequate sexual communication skills and self-efficacy,¹¹ and they may worry that their partner will think that they have HIV or a sexually transmitted infection (STI) if they request condom use.¹² Furthermore, male partners of transgender Latinas tend to be at increased risk for HIV. Compared to Latino men who have sex with men (MSM) who do not have sex with transgender partners, Latino MSM who have sex with transgender partners are three times more likely to have had sex without a condom in the past three months and are more likely to be HIV positive.¹³ Transgender Latinas and their sexual partners tend to have high rates of having sex while using drugs and alcohol, and substance use during sex is associated with incorrect condom use and an increased number of sexual partners.^{2,11}

In addition, transphobia and discrimination may create a heightened need for transgender Latinas to feel safe and affirmed through sex. High rates of violence and victimization may affect transgender Latinas' ability to engage in prevention behaviors, causing them to be willing to take sexual risks if requested by

partners who make them feel accepted or if they feel unsafe refusing to do so.^{12,14-16} Some transgender Latinas also engage in sex work or exchange sex for money or drugs,^{2,11,12} often resulting from being forced out of their homes due to family rejection based on gender identity, discrimination when pursuing work and hiring bias, and/or a need to pay for gender affirmation services.^{6,15,17,18} Further, systemic and institutional discrimination reduce access to education, employment, housing and health services.^{19,20} Consequently, many may rely on sex work for survival,^{12,21,22} where they may experience additional power imbalances or financial pressure to have sex without condoms.^{11,15} Issues related to immigration may further impact condom use among transgender Latinas. Undocumented status, for example, has been found to be associated with less control over sexual relationships, and fear of exposure and deportation may result in a reluctance to deny partner and/or client demands and aversion to seeking out legal protections.^{7,23,24}

Pre-exposure prophylaxis (PrEP) is a critical biomedical strategy to prevent new HIV infections. PrEP clinical practice guidelines recommend combination tenofovir/emtricitabine as safe and effective in reducing the risk of HIV infection in adults and adolescents. Research suggests that overall awareness and knowledge of PrEP, as well as actual use of PrEP, are relatively low among transgender women,^{8,25-27} particularly transgender Latinas.^{8,28} Currently, CDC's Prevention Research Synthesis group has not identified any behavioral HIV prevention interventions for transgender Latinas as being efficacious, and no efficacious interventions for this population are listed in the *Compendium of Evidence-Based HIV Prevention Interventions* (<https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html>). There is a profound need for culturally congruent, efficacious HIV prevention interventions, particularly within the context of emerging biomedical strategies (such as PrEP), to reduce the disproportionate impact of HIV among transgender Latinas.

Our long-standing community-based participatory research (CBPR) partnership, known as the North Carolina Community Research Partnership, comprised of local Latine^[1] community members; representatives from AIDS service organizations, public health departments, and other community organizations; federal partners, and academic researchers,^{8,29} is currently implementing and evaluating the *ChiCAS: Chicas Creando Acceso a la Salud* [*ChiCAS: Girls Creating Access to Health*] intervention. *ChiCAS* is designed to increase uptake of PrEP, consistent and correct condom use, and medically supervised gender-affirming hormone therapy among Spanish-speaking HIV seronegative transgender Latinas who have sex with men. We began the *ChiCAS* trial prior to the onset of the COVID-19 pandemic in July of 2019; however, we had not yet reached the *a priori* sample size established to adequately test the intervention (N=100-140) before the beginning of the pandemic in March of 2020, when we paused the trial.¹⁸ Thus, in this paper, we describe how we adapted the *ChiCAS* trial to conduct it in the context of the COVID-19 pandemic, focusing on: (1) participant recruitment, (2) screening and enrollment, (3) baseline data collection, (4) intervention implementation, and (5) participant retention for follow-up data collection.

[1] The term “Latine” uses a gender-neutral “e”, which replaces the gendered endings “a” and “o” as in “Latina” and “Latino” and is similar to “Latinx”. This term is increasingly used within Latine LGBTQ+ communities.

Background On The Chicas Intervention

The *ChiCAS* intervention was originally designed to be implemented in person, as a group-level intervention, in two four-hour sessions.¹⁸ The intervention is informed by social cognitive theory³⁰ and the theory of empowerment education,³¹ and aims to: (1) increase awareness of HIV and other STIs and of the benefits of medically supervised gender-affirming hormone therapy; (2) increase knowledge of types of STIs, modes of transmission, signs and symptoms, and prevention strategies (including PrEP and condom use); (3) offer guidance on PrEP and medically supervised hormone therapy services, including eligibility requirements for accessing these services, information about resources to cover the cost of these services, and “what to expect” within healthcare encounters; (4) build condom use skills and skills for negotiating condom use with sexual partners; (5) help to overcome barriers to accessing PrEP and medically supervised gender-affirming hormone therapy services; (6) change health-compromising norms and expectations (e.g., decrease internalized transphobia); and (7) build supportive relationships and sense of community among transgender Latinas.¹⁸

ChiCAS has nine core elements. As defined, core elements of behavioral interventions are those components of the intervention that are essential to effectiveness and that should not be altered.^{32,33} *ChiCAS* core elements include: a transgender Latina serving as a peer instructor; use of culturally congruent transgender-positive messages and materials; identifying and addressing the challenges transgender Latinas face; teaching and practicing skills through modeling, role-play, and feedback; Spanish-language implementation; and uptake of PrEP, condom use, and medically supervised gender-affirming hormone therapy as the intervention focus (Table 1).

[Table 1 About Here]

Prior to COVID-19, we advertised the intervention trial through flyers posted in *tiendas*, laundromats, Latine restaurants, businesses that employ large numbers of Latine persons (such as hotels), housing communities and apartment complexes, English as a Second Language (ESL) classes, organizations that offer services to the Latine community, and LGBTQ+ organizations. Research team members made brief presentations about the project at local bars and clubs known to be frequented by transgender Latinas and set up and staffed recruitment tables with flyers to discuss the project and enroll potential participants. We also actively advertised and interacted with potential participants on social media platforms (e.g., Facebook). Furthermore, we recruited participants through word-of-mouth; enrolled participants were encouraged to share information about the trial with others in their social networks, including how to contact the research team. We have successfully used these strategies previously in multiple studies within Latine communities.³⁴

Since the onset of the COVID-19 pandemic, we adapted recruitment to occur through advertisement on social media platforms and word-of-mouth using social media. Former participants use social media platforms (predominately Facebook messenger) to explain the project to their friends, refer potential participants to the project Facebook page, and provide the phone number of a research team member if a potential participant expresses further interest in the trial.

Furthermore, because we had the contact information of and permission to contact some potential participants whom research team members interacted with before the pandemic but were unavailable to participate in *ChiCAS* in person, we reached out to them to gauge their interest in participating in a virtual implementation of *ChiCAS*.

Screening And Enrollment

Eligibility to participate in the *ChiCAS* trial is limited to those who: (a) self-identify as male-to-female transgender or report having been assigned male at birth and self-identify as female; (b) self-identify as Hispanic or Latina; (c) are ≥ 18 years of age; (d) report having sex with at least 1 man in the past 6 months; (e) are HIV negative (based on self-report and verified by HIV testing); (f) are fluent in Spanish; and (g) provide informed consent. Those who have participated in any HIV prevention intervention within the past 12 months, including HIV prevention interventions that our CBPR partnership previously implemented (e.g., *HOLA en Grupos*³⁵ and *HOLA*⁸), are excluded. These interventions included transgender Latinas.

Adaptations to the screening process as a result of the pandemic include completing the screening process by phone or videoconferencing (if the participant is already familiar and comfortable with videoconferencing). However, verifying that a potential participant is HIV negative requires an onsite HIV test. Prior to the onset of the pandemic, a trained member of the research team would administer the rapid (60-second) INSTI HIV Test (by bioLytical; <https://www.insti.com/hiv-test/>). This test requires a finger prick to obtain sufficient blood. If the INSTI HIV Test result was negative, the potential participant was eligible to participate; if the result was positive, the potential participant was provided referrals to and logistical support for HIV care engagement. However, we now use the 20-minute OraQuick In-Home HIV Test (<http://www.oraquick.com/>) to allow for physical distancing between the research team member and potential participant. This FDA-approved test is self-administered by the potential participant and requires a minimally invasive and relatively simple gum swab.

After verifying all other eligibility criteria by phone or videoconferencing, a research team member schedules a physically distanced appointment with the potential participant at the participant's home to obtain informed consent, provide and oversee completion of the HIV test, and, if eligible, complete the interviewer-administered assessment. Twenty-four hours before the appointment, a research team member screens each potential participant by phone or videoconferencing for coronavirus exposure, asking the potential participant: "(1) Have you had a fever, cough, or shortness of breath in the last 7 days?"; "(2) Have you had vomiting or diarrhea in the last 7 days?"; and "(3) Have you had contact with

someone who was diagnosed to have COVID-19?” If the potential participant responds negatively to all three questions, the research team member proceeds with the scheduled appointment. If the potential participant responds affirmatively to one or more questions their appointment is rescheduled, and the potential participant is referred to a primary care provider and/or to a local respiratory assessment clinic, including options for those without insurance. The research team member also provides the number for a hotline for phone consultation to help determine if the potential participant needs to be seen or evaluated for COVID-19.

The research team member also reminds the potential participant that during the appointment, they will follow recommended physical distancing guidelines and wear a face covering, and the participant will be expected to maintain physical distancing and wear a face covering as well. Potential participants may feel that these safety precautions are in place because they are assumed to be “unhealthy” or infectious, and thus, expectations about the appointment must be managed. The research team member makes it clear that the safety precautions are to protect the potential participants as well as the research team. Members of marginalized communities and populations are often stigmatized, and building and maintaining trust requires careful consideration of their perceptions and feelings.³⁶⁻³⁸

When the research team member arrives at the potential participant’s home, they call the potential participant from their car and repeat the coronavirus exposure screening process. If the potential participant again responds negatively to all questions, the scheduled appointment proceeds; if the potential participant responds affirmatively to one or more questions the appointment is rescheduled. The research team member, wearing a face covering and maintaining physical distancing, then places the (1) two-part consent form (section one for the HIV test and section two for participation in the trial), (2) a bag that contains an unopened OraQuick In-Home HIV Test kit, and (3) a face covering that has the *ChiCAS* logo on it at the potential participant’s door. The research team member reminds the potential participant that section one of the consent form must be signed before performing the self-test. The research team member returns to their car and videoconferences with the potential participant, reading section one of the consent form for the HIV test to the potential participant and answering any questions. The research team member then watches the potential participant sign section one of the consent form and provides guidance to the potential participant to complete the HIV test step-by-step. After 20 minutes (the time it takes for the test results to appear), the potential participant shows the research team member the result, again by videoconferencing. If the result is positive, the research team member explains to the potential participant that she is not eligible for the trial, terminates the informed consent process, obtains the consent form with the first section signed, and links her to local HIV care services for follow-up. If the result is negative, the research team member watches the participant sign section two of the consent form for participation in the trial.

Baseline Data Collection

After the participant has provided consent to participate, the research team member administers the baseline assessment to the participant. Before the onset of the pandemic, data were collected in-person

using an interviewer-administered baseline and follow-up assessment. However, adapting to the pandemic, a research team member collects these data by phone call or videoconferencing. After the baseline assessment is completed, the research team member informs the participant that they will be placing the participant's token of appreciation and a receipt for the participant to sign at her door. The participant is instructed to place the signed consent form and the used HIV test kit materials (for disposal offsite), as well as the signed receipt, at her door for the research team member to collect. The research team member, wearing gloves as well as a face covering and maintaining physical distancing, retrieves these materials.

Virtual *ChiCAS* Implementation

After baseline data are collected, participants are randomized into the intervention or delayed-intervention group using a block randomization scheme (block size=4) generated with SAS version 9.3. Prior to the pandemic, *ChiCAS* was implemented in person, as a group-level intervention with about 10 participants at a time. Subsequently, the intervention curriculum¹⁸ and key characteristics were slightly adapted for virtual implementation (Table 2). For example, we found that limiting the number of participants during virtual sessions to about six was more deliverable than 10 participants given the challenges associated with participating in discussions with large numbers of participants by videoconferencing. The core elements did not require adaptation.

[Table 2 About Here]

Because of the virtual nature of the intervention, the research team works with each participant regarding the logistics of participation. A research team member contacts each participant who has been randomized to the intervention group by phone or videoconferencing and again reminds her that the sessions will be conducted virtually using the videoconferencing app Zoom and that she will not go to a specific community-based venue to attend but instead will attend the session using her phone, tablet, or laptop computer (most participants use their phones to participate). The research team member also advises each participant to select a location where she plans to participate in the virtual session. In selecting a location, the research team member advises each participant to consider her comfort and most importantly, her privacy. Ideally, the location, whether inside or outside the home, should have minimal interruptions and the participant should be able to speak freely. The participant is reminded to have her charger close in case the battery charge on her phone or other device runs low during the session. Most participants have used their phones to "video chat" with others within their social networks via apps such as Facebook Messenger or FaceTime but have not attended a group-level educational session with other participants whom they had not met before. Thus, the research team member explains the virtual group-level implementation to each participant in advance, so she knows what to expect. The research team member also makes sure that the participant feels comfortable using the Zoom app to participate in the session, particularly if the participant has not used the Zoom app much previously. This explanation includes how to manage the gallery view options, change backgrounds, use the chat and mute/unmute features, and change one's display name and preferred pronouns. If the participant does

not already have the Zoom app installed on the phone or other device she plans to use during implementation, a research team member talks the participant through the process for installing the app and practices using the app with the participant.

The activities in the *ChiCAS* curriculum include role plays, games, and group discussions that are designed to be interactive and promote active participation. However, we anticipated that even the most interactive four-hour sessions might be too long for virtual implementation. Thus, some activities were either eliminated (e.g., meals during sessions and a night simulator box activity that allows participants to practice putting a condom on a penis model in the dark³⁹) or made shorter (e.g., PowerPoint presentations and the graduation celebration). We also adapted the sessions and activities in other ways to be more conducive to virtual implementation, and creativity was needed to ensure that virtual intervention sessions remained interesting and engaging for participants.

The research team members who deliver the intervention (hereafter referred to as interventionists) use multiple strategies to create a friendly and welcoming atmosphere to maintain participant attention. At the beginning of the first session, for example, the interventionists use an adapted icebreaker titled “Find Someone Who...” In this activity, participants must find someone in the group who has certain characteristics or experiences such as someone who has a tattoo, prefers hairy men, met one’s boyfriend or partner online, or had a crush on a teacher while in school. The original intervention activity instructs participants to move around the room to find and meet other participants who have the characteristic or experience described in the activity. However, the virtual implementation required us to adapt this activity to be one in which an interventionist reads out each characteristic and participants use Zoom reactions to indicate that they share the described characteristic or experience. The interventionists spend time acknowledging reactions, encouraging laughter and dialogue for participants to feel comfortable and start connecting with one another.

In the virtual environment, interventionists cannot rely on body language (as they had been able to during in-person implementation) to gauge and promote engagement. Thus, they developed and use non-threatening ways to encourage participants to answer questions, ask questions, and make comments. For example, when interventionists want participant input, they “call on” each participant by name; every participant is given an opportunity to speak. Because participants expect to be called on, we have learned that participants feel less pressure than if they were called on sporadically; interventionists also explain to participants that they can say nothing when called on or indicate that they would prefer to say nothing. This process also limits the confusion and awkward moments that can arise during videoconferencing when two or more attendees try to speak at the same time.

Several other adjustments were made to translate in-person activities to the virtual context, including using the screen sharing feature on Zoom to project PowerPoint slides and videos and typing notes on a shared screen rather than writing on newsprint during group discussions. The Zoom breakout room feature is used for the role-play activities focused on communication with providers about PrEP and gender-affirming hormone therapy and condom negotiation with partners. Each participant is paired with

a partner and then assigned to a breakout room, where they practice and perform their role plays, and the interventionists rotate throughout the breakout rooms to answer questions and provide feedback to participants. Participants enjoy the novelty of “traveling” to the breakout room and then rejoining the larger group after the activity to report back about their experiences; interventionists add lightheartedness and ease any technical difficulties that occur by describing participants as being “teleported” to their breakout rooms, assuring participants that they will be brought back “safe and sound” to the larger group, and joking that participants who arrive back to the Zoom main room later than others were probably given a “faulty parachute”. Participants also particularly enjoy the role play activities because these activities provide an opportunity to interact one-on-one with other participants, create bonds, and promote a sense of community. In the in-person implementation of our partnership’s interventions, we have seen the building of community among participants,^{35,40} and we were gratified that we were able to recreate this critical component of the *ChiCAS* intervention¹⁸ during virtual implementation.

In order to further facilitate engagement in activities, prior to implementation, a set of session-specific materials is delivered to each participant’s home by a research team member following physical distancing procedures similar to those used during screening and enrollment. These materials include a penis model and condoms for practicing correct condom use, brochures with information about STIs/HIV, cards with descriptions of characters for role plays, lists of local providers of PrEP and medically supervised hormone therapy, and handouts with copies of all PowerPoint slides used. In addition, a set of cards, each describing a different step in the process for accessing services and obtaining PrEP, are provided for an activity in which participants are instructed to put the steps in the correct order. During in-person implementation, participants were divided in to two teams that “raced” to see which team could put the cards in correct order first. During virtual implementation, however, participants are given time during the session to put their cards in order individually and then led by an interventionist, participants review the order together as a group.

The two intervention sessions are delivered on consecutive Sunday afternoons, which we have found is the time that is most convenient for the majority of participants’ schedules. After each session, a research team member goes to each participant’s home (again, following similar physical distancing procedures to those previously described) to deliver their tokens of appreciation, the materials to be used for the following session, and a t-shirt and tote bag with the *ChiCAS* logo. After the second (final) session, a research team member delivers a framed and personalized *ChiCAS* graduation certificate. A research team member contacts participants during the week between the first and second session to find out what they thought of the first session (including the virtual delivery platform) and ask them to confirm the name they would like on their certificates. Some participants request two certificates (e.g., one with the name that appears on their government identification card and the other with the name that they use). After attending the first session, participants have often begun to bond with the other participants, have seen that the information provided in the sessions is interesting and useful and the atmosphere is empowering and fun, and have built trust in the research team. They see that the intervention is

“legitimate” and that the team has no “hidden agenda”, increasing the likelihood that participants will return for the second session.

Retention For Follow-up Data Collection

In order to retain participants over time for follow-up data collection, an interventionist stays in touch with both intervention and delayed-intervention participants by phone, text messaging, and social media. A research team member checks-in on participants monthly, which helps to ensure that the contact information for each participant is up to date; congratulates participants on their birthdays; and sends seasonal greetings, such as wishing them happy holidays. The trust and rapport built between participants and the research team during recruitment, screening and enrollment, baseline data collection, and intervention implementation (for those in the intervention group) helps to facilitate these retention strategies, and for the most part, these strategies did not change because of the pandemic.

However, three slight adaptations to participant retention for follow-up data collection were made to accommodate the pandemic. Prior to the pandemic, the tokens of appreciation were \$30 for the baseline and \$40 for the follow-up assessment, unless the follow-up was completed by phone, in which case, compensation remained \$30. Because all follow-ups were completed by phone or videoconferencing because of the pandemic, the token of appreciation for completing the follow-up assessment remotely was changed from \$30 to \$40. We did this to acknowledge that there was no longer another option for follow-up completion; to maintain a graduated increase in the token of appreciation between baseline and follow-up; and to recognize and respect the profound needs that communities had in light of the pandemic. Second, rather than calling a participant to schedule an appointment to complete the follow-up assessment at another time, the research team member asks the participant whether they would be willing to complete the assessment by phone at that very moment. This strategy is highly effective. We have found that participants are likely to change dates and times of their scheduled follow-up assessments and, that each time an appointment is rescheduled, there is increased chance that the participant will be lost to follow-up. We have also found that participants are likely to say yes to completing the assessment directly when contacted by phone. Finally, because follow-up data collection is conducted remotely, participants are given the option to receive their token of appreciation for their follow-up assessment via mobile payment apps such as CashApp or Venmo; if a participant chooses not to use one of these apps a research team member delivers their token of appreciation to their home following similar physical distancing procedures to those previously described.

Discussion

The COVID-19 pandemic has profoundly affected the conduct of community-based and community-engaged research, which are critical research approaches to promote health equity and reduce health disparities among underserved and vulnerable communities and populations. Designed to be implemented in-person and among small groups of Spanish-speaking HIV-negative transgender Latinas who report having sex with men, *ChiCAS* offers a promising approach to increase uptake of PrEP and

medically supervised gender-affirming hormone therapy. However, the COVID-19 pandemic has required swift changes to in-person research activities to ensure the safety of community members, community partners, and research team members and investigators. Our adaptation of the *ChiCAS* intervention trial provides an example of how shifts can be made to continue critical community-based intervention research among communities and populations experiencing disproportionate negative health outcomes.

While we have been successful in adapting our trial of the *ChiCAS* intervention to the restrictions resulting from the pandemic, we faced important challenges. First, the pandemic is unpredictable, and early in the pandemic, we paused our research and waited for a more favorable time to reinitiate our research as it had been conducted previously. We naively assumed that there would be a post-COVID-19 world soon, we could get back to “research as usual”, and our *ChiCAS* intervention trial would resume and resemble what it had looked like previously. In time, however, it became apparent that we did not know what the future held; there were increased COVID-19-related hospitalizations and deaths, questions about the timeline for vaccine development and approval, and worsening financial impacts of the pandemic (e.g., unemployment and housing instability). Thus, our team spent much time thinking about and planning next steps and how the trial could be completed safely, while keeping in mind the importance of being both flexible and patient.

Second, it became clear by June 2020 that we needed to adapt our protocol to move the trial forward. Adapting the protocol was challenging; we were in uncharted waters with no examples on how we could proceed within the new context of the COVID-19 pandemic. For example, it was unclear whether we would be able to recruit transgender Latinas without the in-person community engagement that we had harnessed prior to the pandemic and the personal connections we made in communities to build trust. We also did not know whether transgender Latinas would use videoconferencing and find a virtual intervention engaging, and we had no examples in the literature to guide the adaptation of an in-person intervention trial to a virtual setting to meet the safety needs of a pandemic. Previous qualitative research by our team has shown that accessing health information online is common in this population, suggesting that a digital platform might be acceptable.⁷

Third, the pandemic also meant more travel for our team, as materials are delivered to each participant’s home on several separate occasions: at screening and enrollment, immediately prior to intervention sessions to deliver intervention materials to be used during each session, and post-intervention to deliver tokens of appreciation and final graduation certificates.

Finally, one of the benefits of participation in the in-person version of *ChiCAS* is development of a sense of community among participants and social support. The missed opportunity for in-person interactions required the team to be more intentional about the activities and their facilitation to help participants get to know one another and bond (e.g., ice breakers, small-group interactions, and jokes). We are certain that the lack of informal interactions (e.g., chatting during breaks) during virtual implementation changed the dynamic considerably; however, we are hopeful that the participant interactions with members of the research team (e.g., delivery of materials to participant homes) are a helpful alternative.

These adaptations led to several (sometimes unexpected) benefits. First, the virtual implementation of the *ChiCAS* intervention is appealing to many participants for a variety of reasons. It reduces time burden for participants with the removal of travel time to an intervention site; it does not require driving or obtaining transportation, and they can participate from any place they chose. Furthermore, the virtual platform may feel safer than an in-person intervention because many Latine persons fear putting themselves at risk for discrimination and racial profiling associated with local immigration policy enforcement,⁴¹ and virtual implementation allows our participants to join the intervention from locations where they feel secure such as their own homes. Finally, virtual implementation allows us to expand the breadth of our trial catchment area (e.g., not only recruiting from one area for an intervention wave but instead implementing intervention sessions with participants from across North Carolina).

If the *ChiCAS* intervention is efficacious, organizations will have the flexibility to deliver the intervention, and others like it, via in-person or virtual formats. This flexibility may support the scalability of the intervention. *ChiCAS* may reach more transgender Latinas and thus increase safer sex practices reducing HIV disparities.

Conclusions

Transgender women are disproportionately affected by HIV and bear significant consequences of the COVID-19 pandemic (e.g., increased unemployment and housing instability) that may affect their HIV risk and/or HIV care engagement.⁴² As such, it is crucial that public health researchers and practitioners ensure that the COVID-19 pandemic does not inhibit our efforts to reduce the impact of HIV. We must continue to make critical advances in HIV prevention, care, and treatment through ongoing research despite the challenges posed by the pandemic. Moreover, virtual implementation of behavioral interventions may be a powerful tool to reach underserved and vulnerable communities and populations. While access to home computers and Wi-Fi may not be pervasive within all communities and populations, the proliferation of smartphones have become a “lifeline” for members of some underserved and vulnerable communities and populations (including transgender women and Spanish speakers) to access information and communicate with others.^{43–49}

Declarations

Disclosure: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Ethics approval: Trial approval and oversight is provided by Wake Forest School of Medicine Institutional Review Board.

Consent to participate: All trial participants provided written informed consent.

Availability of data and material: NA

Conflict of interest: The authors have no conflicts to disclose.

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Authors' Contributions: SDR, JA, LMJ, and BAR designed the *ChiCAS* intervention trial in partnership with members of the North Carolina Community Research Partnership. SDR oversaw and documented adaptations to the trial resulting from the onset of the COVID pandemic and drafted and reconciled edits to the manuscript. AET, JA, LMJ, LAR, MG, and BAR adapted the trial and edited iterations of the manuscript. CAR, PAB, CCQ, BDS, and TG edited iterations of the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1. *ChiCAS* core elements

Core Elements of the <i>ChiCAS</i> Intervention
<ol style="list-style-type: none"> 1. Transgender Latina from the community serves as a peer instructor, trained in facilitation and <i>ChiCAS</i> implementation, and is knowledgeable about HIV, PrEP, gender-affirming hormone therapy, condom use, and existing local resources to access PrEP and medically supervised hormone therapy. 2. Participants are transgender Latinas. 3. Culturally congruent and trans-positive messages and materials are used. 4. The challenges transgender Latinas face in the socio-cultural environment (focusing on machismo, transphobia, and discrimination) are identified, acknowledged, and addressed. 5. Modeling, role-play, and feedback are strategies used to teach and practice skills and build participant self-efficacy. 6. Implementation is in Spanish. 7. Two locally produced video segments provide information and teach and role model skills and behaviors. 8. Implementation occurs in a setting where transgender Latinas feel safe and comfortable. 9. Uptake of pre-exposure prophylaxis (PrEP), condom use, and medically supervised gender-affirming hormone therapy are main focuses.

Table 2. Key characteristics of the original in-person *ChiCAS* intervention and of the virtual intervention

Key Characteristics	Adapted Key Characteristics of Virtual <i>ChiCAS</i>
<ol style="list-style-type: none"> 1. Implementation occurs in community-based venues. 2. All activities are interactive and encourage group discussion. 3. Include about 10 participants per session. 4. Implemented in 2 sequential small-group sessions. 5. Sessions are about 4 hours each. 	<ol style="list-style-type: none"> 1. Implementation occurs virtually. 2. All activities are interactive and encourage group discussion. 1. Include about 6 participants per session. 2. Implemented in 2 sequential small-group sessions. 3. Sessions are about 120 minutes each.