

Adaptation of a Protocol to Evaluate Online Recruitment Strategies for Mailing HIV Self-Tests and Pilot an Intervention to Improve Linkage to HIV Prevention and Care among Transgender Women

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Abstract

Background: Transgender women are disproportionately affected by HIV in the United States. Evidence shows that HIV self-testing increases awareness of HIV status, preventing transmission. Culturally appropriate strategies are needed to provide HIV self-tests (HIVSTs) to transgender women.

Objective: We present the adaptation of materials used in an HIVST distribution study designed for Black or African American and Hispanic or Latino MSM (iSTAMP).

Methods: The ADAPT-ITT framework guided the adaptation. Project staff worked with consultants and a community advisory board (CAB) to revise all study materials (i.e., intervention web content, marketing text and images, and language used in the surveys) to be tailored to, and inclusive of, health topics relevant to transgender women. We conducted a pilot study of transgender women recruited through online venues. Participants were randomly assigned 2:1 to the intervention arm or control arm, respectively. All participants were mailed two HIVSTs, the OraQuick® In-Home HIV Test, and had access to a standard resource list including information on how to find a nearby testing location, HIV prevention, and sexual health. Only intervention arm participants had access to the study website, "Know@Home.org." Incorporating recommendations from the consultants and CAB, we tailored the mobile app provided to MSM in the intervention arm of the main iSTAMP study into the Know@Home website redesigned for transgender women. The Know@Home website allowed participants in the intervention arm to order sexually transmitted infection test kits, condoms, lubricant, and provided HIV prevention information, service locators, and risk assessment tools. Changes to the intervention included modifying language, images, and links to outside resources to be trans-specific or gender neutral. Online surveys were adapted by removing inappropriate gender terms and replacing them with culturally appropriate terms for gender identity, genitalia, and condom use. Four months after completing the baseline (enrollment) survey, all participants were asked to complete a final follow-up survey. Upon completing the 4-month survey, participants were mailed a dried blood spot collection kit to be returned by mail for laboratory testing of the sample. The results of all HIVSTs could be reported in real time into an online survey. Video health counseling was available, upon request, for all participants during study participation.

Results: Enrollment into the pilot study began on April 22, 2021, and concluded on July 7, 2021, yielding a total of 102 transgender women participants, with data collection completed in January 2022.

Conclusions: By using the ADAPT-ITT model, we produced materials to be culturally and linguistically appropriate for transgender women. The findings of this study have the potential to inform future research studies among transgender women

and underscores the importance of involving subject matter experts and community members in the development of tailored materials. Clinical Trial: Registered at ClinicalTrials.gov (NCT04219878).

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Abstract

Background:

Transgender women are disproportionately affected by HIV in the United States. Evidence shows that HIV self-testing increases awareness of HIV status, preventing transmission. Culturally appropriate strategies are needed to provide HIV self-tests (HIVSTs) to transgender women. We present the adaptation of materials used in an HIVST distribution study designed for Black or African American and Hispanic or Latino MSM (iSTAMP).

Methods:

The ADAPT-ITT framework guided the adaptation. Project staff worked with consultants and a community advisory board (CAB) to revise all study materials (i.e., intervention web content, marketing text and images, and language used in the surveys) to be tailored to, and inclusive of, health topics relevant to transgender women. We conducted a pilot study of transgender women recruited through online venues. Participants were randomly assigned 2:1 to the intervention arm or control arm, respectively. All participants were mailed two HIVSTs, the OraQuick® In-Home HIV Test, and had access to a standard resource list including information on how to find a nearby testing location, HIV prevention, and sexual health. Only intervention arm participants had access to the study website, "Know@Home.org." Incorporating recommendations from the consultants and CAB, we tailored the mobile app provided to MSM in the intervention arm of the main iSTAMP study into the Know@Home website redesigned for transgender women. The Know@Home website allowed participants in the intervention arm to order sexually transmitted infection test kits, condoms, lubricant, and provided HIV prevention information, service locators, and risk assessment tools. Changes to the intervention included modifying language, images, and links to outside resources to be trans-specific or gender neutral. Online surveys were adapted by removing inappropriate gender terms and replacing them with culturally appropriate terms for gender identity, genitalia, and condom use. Four months after completing the baseline (enrollment) survey, all participants were asked to complete a final follow-up survey. Upon completing the 4-month survey, participants were mailed a dried blood spot collection kit to be returned by mail for laboratory testing of the sample. The results of all HIVSTs could be reported in real time into an online survey. Video health counseling was available, upon request, for all participants during study participation.

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Conclusions:

By using the ADAPT-ITT model, we produced materials to be culturally and linguistically appropriate for transgender women. The findings of this study have the potential to inform future research studies among transgender women and underscores the importance of involving subject matter experts and community members in the development of tailored materials.

Trial Registration:

Registered at ClinicalTrials.gov (NCT04219878).

Keywords:

HIV; HIV prevention; transgender women; linkage to care; HIV self-testing; protocol

Introduction

The Ending the HIV Epidemic in the United States (U.S.) initiative is built on four science-based strategies, the first is diagnosing all individuals with HIV as early as possible. HIV testing allows people to learn their HIV status and to initiate pre-exposure prophylaxis (PrEP) or antiretroviral treatment (ART), thereby preventing new infections. HIV self-testing (HIVST) is one component of this testing strategy [1–3].

In 2019, approximately 2% of HIV infection diagnoses were among transgender persons. The majority (93%) of these were among transgender women [4]. Transgender women in the U.S. are disproportionately affected by HIV with a prevalence of 14.1%, compared with an estimate of less than 0.5% for all U.S. adults [5–7].

Underutilization of HIV testing may contribute to the disproportionate impact of HIV among transgender women [7] as HIV testing is the entry to engagement with HIV prevention and treatment [9–11]. Barriers to HIV testing reported by transgender women include low risk perception, lack of access to HIV testing, and concerns of HIV-related stigma and transphobia in healthcare settings [9,12,13]. Providing HIVSTs to transgender women may help to overcome some barriers they experience when seeking transgender-affirming HIV testing services by expanding routine testing options and partially mitigating the barrier of medical mistrust [14]. Self-testing allows the users the flexibility of not having to present to a clinical care or community-based testing sites where providers may not be culturally competent. This testing approach provides an alternative service to those who are distrustful of medical settings or do not wish to be seen attending testing sites, due to stigma, discrimination, homophobia, transphobia, and racism [15].

Preliminary evidence indicates that technology-based behavioral health interventions, such as using social media to promote HIV testing, have the potential to be a key strategy towards addressing HIV testing and prevention disparities [9]. However, the use of social media channels to reach transgender women has not been evaluated [16]. Not all sexual and gender minority groups have been equally engaged in research, as Poteat et al. noted, "Historically, HIV studies have conflated men who have sex with men with trans [transgender] women, explicitly excluded trans individuals, or included sample sizes of trans people that are too small to reach meaningful conclusions" [16–18].

Adapting and implementing interventions originally designed for one population for a second population is an important strategy to expedite the creation and deployment of effective interventions, and improves public health outcomes for the second population [19]. Mailing HIVSTs to gay, bisexual, and other men who have sex with men (MSM) increased rates of testing and awareness of infection status [20]. This paper presents the adaptation of the study protocol and materials from the Implementation of Rapid HIV Self-Testing Among MSM Project (iSTAMP). The iSTAMP study evaluated strategies to reach participants for distributing HIVST, and incorporated a pilot evaluation of an HIV prevention phone application to improve linkage to HIV prevention and care designed for Black and Hispanic MSM [20]. To address the needs of transgender women, an adaptation of the original protocol was necessary to consider social and behavioral characteristics unique to this population.

Through an existing cooperative agreement with the Centers for Disease Control and Prevention (CDC), we obtained funds for conducting pilot activities for transgender women. This pilot project was funded separately from the original iSTAMP study at the end of year 3 of the 4-year project period.

We describe a community-engaged process to adapt the iSTAMP protocol to be culturally appropriate for transgender women, which included revising recruitment materials, survey tools, and the interactive intervention website.

Methods

This pilot study assessed whether the iSTAMP protocol, online advertisements and recruitment materials [20], originally designed for recruiting and engaging Black and Hispanic MSM, could be adapted for, and implemented with transgender women. Most study procedures were the same as those described in the iSTAMP protocol paper [21]. Briefly, the iSTAMP RCT was implemented to evaluate a program that distributed HIVST kits to MSM. iSTAMP included a nested randomized component assessing the utility of a comprehensive prevention mobile app (Know@Home [22]) to support related HIV prevention services for those assigned only to the intervention arm. Four months after completing the baseline (enrollment) survey, all participants were asked to complete a final follow-up survey. Upon completing the 4-month survey, participants were mailed a dried blood spot collection kit to be returned by mail for laboratory testing of the sample. The results of all HIVSTs could be reported in real time into an online survey. Video health counseling was available, upon request, for all participants during study participation.

This paper focuses on materials effecting the transgender participant, rather than internal staff documents, such as standard operating procedures, and email, text, or phone scripts.

Our adaptation was guided by the 8 phases of the ADAPT-ITT model [23,24] (Table 1), which are: Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, and Testing. We chose the iSTAMP study for assessment, reviewed literature, identified domains of the study for adaptation, and developed a list of needed adaptations. Topical experts provided input on marketing and recruitment materials and recommended changes to intervention materials and survey assessments. Suggested changes were integrated into all study materials. The testing phase of the pilot study and associated data analyses occurred as the final phase.

Table 1. Use of ADAPT-IT Framework for the development of a protocol for distribution of HIV self-test kits for transgender women, United States, 2020

Phase	Staff Roles	Activity	Outcomes
Assessment	Researchers	Literature review	Determined need for increased HIV testing options
Decision	Researchers	Literature review	Selected the iSTAMP protocol
Adaptation	Community Consultants	Review of iSTAMP materials	Identified questions, images, and content for revision
Production	Researchers	Review of input from community consultants	Created required changes in recruitment materials, images, intervention materials, and survey assessments
Topical Experts	Subject Matter Experts	Recommend revisions	Provided feedback on intervention materials and survey assessment
	Community Advisory Board	Formative discussion to provide feedback	Provided feedback on marketing, images, and recruitment materials
Integration	Research Staff	Create new website and modify study	Revised marketing materials, recruitment materials, intervention

		assessments	materials, and assessment
Training/ Testing	Researchers, Research Staff	Implement Pilot study	Analyzed preliminary data on feasibility, acceptability, recruitment, retention, and HIV testing outcomes

- ADAPT-ITT: Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, and Testing
- iSTAMP: Implementation of Rapid HIV Self-Testing Among MSM Project

Assessment

In the Assessment phase, we reviewed relevant literature and decided to adapt an intervention to promote HIV self-testing to increase HIV testing and awareness of HIV status for transgender women. An informal literature review indicated that transgender women were disproportionately affected by HIV [6,7,23]. Transgender women's unique experiences and their desire for HIV interventions and services necessitated specialized research to assess risks that differentiate transgender women from MSM [26].

The literature review indicated that additional behavioral health survey items, which are not typically included in HIV research with MSM, would be relevant for transgender women. These items were chosen and included in the survey tool. Research staff determined their capacity to adapt and implement the HIV counseling and referral component of the study and assessed the availability of transgender-specific referral resources for HIV testing and prevention services.

Decision and Adaptation

In the Decision phase, we selected the iSTAMP study because the distribution of HIV self-test kits has shown to increase HIV testing in MSM [27], and there were specifically designed materials and processes available that could be adapted.

Although many aspects of the original iSTAMP study protocol remained the same (e.g., OraQuick® In-Home HIV test, the recruitment and mailing systems), some key aspects needed to be adapted to accommodate population differences noted in the assessment phase.

For the Adaptation phase, we identified domains that would require revision. These domains included the recruitment materials (images and text), survey questions, and an intervention website. In March 2020, five members of the community and several culturally competent iSTAMP study staff identified language in existing survey materials that was not culturally appropriate for transgender women. They provided alternative appropriate language. A \$50 gift card was provided for the community members' time.

Production

During the Production phase, staff reviewed the relevant literature from the assessment phase and created a list of required changes. This was a preliminary list of potential adaptations required to tailor the iSTAMP study for transgender women.

Topical Experts: Recruitment and Advertising Materials

We convened an online meeting of consultants to identify effective recruitment strategies and to tailor advertising materials specifically for transgender women. Consultants were either transgender women, trans-feminine identifying individuals, or non-binary identifying individuals. We recruited the consultants through social media and flyers sent to Lesbian, Gay, Bisexual, Transgender, and

Queer (LGBTQ) organizations located in the eleven states from which we planned to recruit participants. Consultants were provided a \$50 e-gift card for their time. Four consultants participated in the online videoconference held in November 2020. The videoconference was recorded with the consent of the consultants.

The consultants discussed the suitability of recruiting transgender women from online dating websites and social media platforms. Further discussion explored other potential platforms that may have had a greater transgender women user base than those already under consideration. The facilitator presented a slide presentation composed of advertising images and text messages to assess the cultural acceptability for the transgender women community. Consultants were asked how representative stock images depicting transgender women were, how they would react if they saw these advertising images on social media, and what qualities made some advertisements more appealing than others. The facilitator queried the consultants on relevance of assuring participants confidentiality, and how beneficial free HIV and STI tests are for transgender women.

After the online consultation, study staff reviewed the videoconference recording and compiled notes that were gathered into a set of themes to be incorporated into actionable recommendations for the recruitment campaign. Consultants' comments identified text being pop cultural references more relevant to MSM and the drag community than to transgender women. Examples include texts such as "Demon time" that references horniness and "Faster than beating your mug" that references applying makeup. The use of drag references with transgender women was deemed to be offensive and inappropriate.

Additional language that alluded to using sex-seeking applications (apps) (e.g., "You host, we're mobile" appearing to reference the dating app Grindr, or "Plan for your fans" appearing to reference the website OnlyFans, which is often used by sex workers) was viewed negatively by consultants. The consultants stated that the transgender women's community has often been portrayed as hypersexualized within mainstream media and the text messages and images reinforced the stereotype. Advertisement text that focused on respecting transgender identities and intimated themes of empowerment were preferred.

Consultants emphasized the importance of using photographs with transgender women. Images that appeared to showcase a cisgender woman were rated poorly by consultants. Images where the individual's transgender or gender non-conforming identity was more prominent were rated higher. Consultants stated that text specifically used to provide assurances of data security or confidentiality (e.g., "Your identity is safe here") increased skepticism of data protections and how participant information may be used. Another identity concern the consultants discussed was that the study should consider developing procedures to allow participants to use different names in different contexts. For example, some participants may prefer to use their legal name or "deadname" at home because they are not "out." The participant may want to use a chosen name on email and text communications but use their legal name or "deadname" on postal packages to avoid disclosing their transgender identity to the people with whom they live.

There was a consensus among consultants that obtaining free HIVSTs and STI home collection kits would be viewed as beneficial by transgender women. Lastly, consultants agreed that the financial token for the participant's time should be included in the advertisement because it may be viewed by many potential participants as immediately beneficial. Figures 1 and 2 provide examples of recruitment advertisements that resulted in greater response from possible participants during the study.

Topical Experts: Intervention Website

In this pilot study we substituted the Know@Home mobile app, provided for the MSM intervention arm of the main iSTAMP trial, into a website named Know@Home. The website contained HIV prevention information and free materials (e.g., condoms and STI self-collection kits), risk assessment tools, and service locators for HIV testing, HIV treatment, and PrEP services.

A subject matter expert (SME) on transgender health reviewed the Know@Home website intervention content and supporting materials. This person proposed revisions to make the content suitable for transgender women based on recommendations from the Provincial Health Services Authority of British Columbia [28]. The reviewed intervention sections included written and video messaging components, risk-assessment quizzes to help assess one's risk for HIV infection, embedded links to external pages, and the static informational pages consisting of the "About Us" page, and STI and HIV information.

Materials that directly referred to sexual anatomy were revised to use gender-neutral anatomical terms [29]. Materials were revised with the gender-neutral terms "person" and "people." Video messages and external links to study materials were reviewed, and those appropriate for MSM were replaced with gender-neutral alternatives. Content that featured only MSM were replaced with content that featured transgender women or people that would be appropriate for all audiences regardless of gender identity. Table 2 lists the four core themes identified as requiring revisions and examples of appropriate terminology replacements. The four core themes included: 1) gendered terminology referring to the participant, 2) gendered terminology referring to the participant's sex partners, 3) terminology describing genitalia and sexual acts, and 4) condom use.

Table 2. Thematic content from the iSTAMP study identified as not suitable for HIV Self-test Distribution for transgender women, 2020.

Theme Identified	iSTAMP terms and phrases	Revised terms and phrases	Reasons text modified	Study Materials Updated
Participant Gender Identity	Men, Man, MSM, Guys	People, Person	Avoids misgendering transgender women	Website, Surveys, Advertisements, Videos, Images
	Gay and Bisexual Men	Transfeminine People, Transgender Women		
Sex Partner(s) Gender Identity	Men, Man, MSM, Guys	Partner, Partners, Sex Partner(s)	Avoids potentially misgendering a participant's sex partner(s) Avoids assumption that a participant has sex with only cisgender men	Website, Surveys
Terms Describing Genitalia and Sex Acts	Penis, Scrotum, Testicles	Outer Parts	Avoids biological terms associated with a specific gender that may cause discomfort or gender dysphoria for a participant or their partner(s)	Website, Surveys
	Penis, Vulva	External Pelvic Area		
	Vagina	Internal Pelvic Area		
	Vaginal Fluids, Semen	Genital Fluids	Avoids biological terms that may not be the preferred term of the participant or participant's partner(s)	

Condom Use	Male or Female Condoms	External or Internal Condoms	Avoids assumptions about a participant or sex partner's body parts and how the condoms are used (e.g., female condoms may be used rectally rather than vaginally)	Website, Surveys
	"Are you happy with the condoms you are currently using with your partner(s)?"	"Are you happy with the condoms you and your partner(s) are using?"	Avoids specifying which partner wears the condom as this could trigger gender dysphoria	

- iSTAMP: Implementation of Rapid HIV Self-Testing Among MSM Project
- MSM: gay, bisexual, and other men who have sex with men

Topical Experts: Survey Assessments

A SME on transgender health reviewed the online surveys and identified items that needed to be rephrased with culturally appropriate terminology based on current best practices [29]. The SME identified and recommended survey domains that were relevant to transgender health that were not included on the original surveys designed for MSM.

Similar to the intervention materials, baseline and follow-up surveys were revised to ensure clarity and appropriateness of questions pertaining to the gender, sex, and genitalia of respondents and their sexual partner(s). The four core themes identified that were considered inappropriate for transgender women were removed from questions for MSM. Supplemental questions related to experiences of transgender women were developed using appropriate terminology for transgender women. These questions were provided to participants directly after they completed the baseline and follow-up surveys.

The supplemental questions obtained data on the following domains: gender identity, sexual orientation, gender presentation, mental health and suicidality, sexual behavior (using affirming language for genitalia), gender confirmation surgeries, hormone replacement therapy, electrolysis, hormonal and medical gender affirmation, gender-based stigma, and history of intimate partner violence (IPV). For transgender-specific IPV, we used Peitzmeier's T-IPV scale which is specifically for transgender women and consists of four domains: 1) coercive control of gender transition or gender presentation, 2) emphasizing the undesirability of transgender individuals as intimate partners, 3) blackmail via "outing", and 4) sabotaging transition [30]. This tool has demonstrated adequate internal consistency ($KR-20 = 0.56$) [30]. To measure gender-based stigma, we used a 13-question scale developed by Maksut et al. (2020) that assessed perceived, anticipated, and enacted stigmas due to gender identity [31,32]. This gender identity stigma scale has demonstrated acceptable internal consistency (Cronbach's $\alpha = 0.79$) [31].

Integration and Testing

With the deployment of the redesigned website and the implementation of the revised materials for transgender women, we conducted a RCT in which we aimed to recruit up to 200 participants. This pilot study was approved by the Emory University Institutional Review Board (IRB00099710) and is registered at ClinicalTrials.gov (NCT04219878). The eligibility criteria are described in Table 3.

Table 3. Eligibility and exclusion criteria for an HIV self-test pilot study of transgender women

living in 11 U.S. states, 2020-2021.

Eligibility Criteria	Exclusion Criteria
• Provided informed consent online • At least 18 years of age • Identifies as a transgender woman or transgender female • Assigned male sex at birth • Has an Android or iOS mobile smartphone with active service • Resides in AL, CA, FL, GA, LA, MS, NC, NV, NY, SC, TX • Provides valid contact information • Successfully completed the baseline survey	• Declined consent to participate • Currently participating in another HIV prevention research study or program • Has a bleeding disorder • Participant in an HIV vaccine study • Currently taking PrEP for HIV prevention • Reported a prior positive HIV test result • Plans to move out of a study state during the 4 months study period

- AL: Alabama; CA: California; FL: Florida; GA: Georgia; LA: Louisiana; MS: Mississippi; NC: North Carolina; NV: Nevada; NY: New York; SC: South Carolina; TX: Texas
- PrEP: Pre-exposure Prophylaxis

The goal of the pilot study was to provide preliminary data on recruiting transgender women online and the feasibility of enrolling transgender women into an HIV self-testing study. Data would provide estimates for the length of time needed to recruit participants, effectiveness of online recruitment strategies, cost of recruitment, retention rates, the use and acceptability of video counseling services, and the proportion of transgender women who reported using the HIVSTs and STI self-collection kits. These data can be used in conducting power calculations for future HIV self-testing research studies with transgender women.

We planned to use the data to identify key considerations for programmatic implementation of a mail-out HIV self-testing program for transgender women that could be implemented by local health departments or community-based service providers. Factors that are relevant for implementation by these providers relate to online recruitment and cost to implement.

For this pilot study, potential participants were recruited through online venues such as social networking sites (e.g., Facebook), and dating apps (e.g., Adam4Adam) completed an initial eligibility screening survey, provided electronic informed consent, and completed a baseline survey. An initial validation process was conducted to determine enrollment status. Participants were considered fully enrolled into the study and mailed two HIVST after they had provided the required contact information and duplicate accounts were excluded. Personal identifying information was only stored at Emory University. Confidential information was stored off-site on secure web servers. All data files were encrypted with strong password protection. Access to personally identifying information was restricted to Emory study staff.

We used a two-stage randomization procedure. First, we grouped participants based on race/ethnicity (Black, White, Other, Hispanic/Latina) for a total of 4 strata. Next, we randomly assigned participants from each strata to the intervention arm (mailed self-test kit + provided link to the Know@Home website) or control arm (mailed self-test kit only) with a 2:1 ratio. Enrollment for the Know@Home pilot for transgender women began April 22, 2021 and concluded July 7, 2021.

Results

The main research outcomes from this pilot study are summarized in Table 4. During the enrollment period, 2,014 people consented to be screened for the study, most of whom were ineligible for multiple reasons, with not identifying as female or a transgender woman being the most common reason for ineligibility. Of 217 people who were eligible based on screening criteria, 169 provided contact information. Of these, 108 participants passed the initial validation process, responded to a text message to complete the validation process, and completed the baseline survey. Subsequently, we determined that an additional six people had provided false information and were excluded from the analyses. A total of 102 transgender women constituted the sample for this pilot study and 81 provided follow-up information.

Table 4. Research outcomes, data types, and relevance to study design implementation for HIV self-test kit distribution for transgender women, 11 states, 2020

Research outcomes	Types of data	Relevance to study design
Feedback on sample advertisements	Qualitative report from consultant's conference	Allows for more effective and culturally appropriate recruitment
Proposed recruitment strategies for transgender women (specific online sites, influencers, ad images, language)	- Cost data - Advertisement click-through rates - Eligibility and enrollment counts based on venue and ad copy	Allows for cost analysis for recruitment venues.
Feasibility of online enrollment of transgender women	- Characteristics of transgender women enrolled - Ability to obtain target enrollment	Allows for assessment of potential biases in recruitment of transgender women (for example, by age, region, race/ethnicity) and development of plans to mitigate selection biases and allows ability to determine if sample size will be met
Time to recruit	Time required to recruit transgender women	Allows for planning of appropriate recruitment period and funds for recruitment
Retention rates	- Stratified retention estimates by age - Region - Race/ethnicity	Allows for planning of sample size of a large-scale trial, accounting for retention
Percent of participants using study HIVSTs	Reported use of HIVST	Allows for sample size calculations and budgeting and number of HIVST

	kits • Distribution of HIVST kits to others • Reasons for using or not using kits	kits required for distribution
HIV prevalence among pilot study participants	• Reported results of HIV self-testing	Allows for estimation of initial sample size to develop a cohort of transgender women who have a negative HIV status for prospective research; allows planning for needs for video counseling resources
Percent of participants using video counseling services	• Number of counseling sessions requested, scheduled, and attended • Client preferences for time of day and day of week.	Allows for planning of the number of counselors needed and meeting the capacity for counseling sessions each week based on preferences for time of day and day of week

Discussion

This paper documents the process of adapting the iSTAMP protocol developed for Black and Hispanic MSM to be appropriate for engaging transgender women, using the eight phase-ADAPT-ITT model. The purpose of this adaptation is to ensure that study procedures and materials presented to the participants are culturally and linguistically appropriate, and do not cause discomfort or harm. In our adaptation process we strived to ensure that study materials would not misgender participants, and questions and responses would be culturally relevant and inclusive [33–36]. These adaptations were crucial to ensure the data obtained were relevant for transgender women who participated in the study and allow us to gain a comprehensive understanding of the experiences of transgender women. The resources developed in this protocol can be used to provide preliminary data and tools for further development and evaluation of a robust trial HIVST distribution and linkage to prevention services for transgender women in the U.S.

Limitations

We encountered several challenges during the development and implementation of this pilot study. This activity was conducted after completion of a trial for MSM with supplemental funding awarded in the final year of the primary study. Consequently, the achieved sample size was half of what was originally planned because there were time constraints in which all activities had to be completed. Only four of the nine consultants were able to participate in the online videoconference due to scheduling conflicts, limiting the input on the adaptation process; however, we had co-authors who are SMEs who contributed to the adaptation. The study was conducted in 11 States, predominately located in jurisdictions with high prevalence of HIV in the U.S. The sample does not represent all

transgender women in the U.S.

Due to time constraints, we created a web-based version from the original intervention developed for use on a mobile phone. We used the same questions in the eligibility screener from the MSM trial, and participants were required to identify as “male to female transgender.” This language may have discouraged some transgender women from participating in the study if they did not identify with this terminology. To earn trust among the community it is necessary to use appropriate language [31,37] and future studies can incorporate an expanded eligibility criterion to include transgender women who may identify with alternative terminologies, such as transgender woman, transfeminine individual, or other terms that are commonly used at the time of study implementation.

Future Adaptations

During the adaptation process, we identified several key principles that may be useful for future adaptations of protocols or interventions for transgender women. When collecting names and pronouns, researchers can inform participants that legal names may not be required to participate, and when possible, collect both the legal name and the name the participant wishes to use during study participation. There is limited research regarding tailoring study materials and procedures for transgender populations; therefore, there are not widely accepted best practices for this process. Engaging members and representatives of the community in planning the research design and materials can mitigate this issue [33–36]. Involving SMEs on transgender women, particularly when the experts are a part of the intended study population, can be incorporated into future studies for transgender women.

Mixed methods approaches can provide an opportunity for increasing cultural competency of materials and survey instruments. Qualitative methods can be used to allow transgender women to provide detailed feedback on materials and terminology before implementation.

Linguistic choices that pathologize or marginalize people have been determined to be potentially harmful to participants during research and publication of findings [31,37]. As languages and cultures evolve it is necessary to adapt terminology so that terms are culturally appropriate for the proposed populations. This may require modifying demographic terminology used to collect data to reflect the culture of the population. Finally, while this pilot engaged transgender women, there is little information on how best to reach other populations who may also benefit from HIV self-test programs, such as nonbinary people, gender nonconforming people, transgender men, and transmasculine people.

Conclusions

In conclusion, this paper outlines the adaptation of study materials for transgender women. By using the ADAPT-ITT model, we produced materials to be culturally and linguistically appropriate for transgender women. The findings of this study have the potential to inform future research studies among transgender women and underscores the importance of involving subject matter experts and community members in the development of tailored materials.

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Conflict of Interest

None declared.

Abbreviations

ADAPT-ITT: Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, and Testing

ART: Anti-Retroviral Treatment

iSTAMP: Implementation of Rapid HIV Self-Testing Among MSM Project

CAB: community advisory board

EHE: Ending the HIV Epidemic

HIVST: HIV self-test

HIV: human immunodeficiency virus

IPV: Intimate partner violence

LGBTQ: Lesbian, Gay, Bisexual, Transgender, and Queer

MSM: gay, bisexual, and other men who have sex with men

PrEP: Pre-Exposure Prophylaxis

RCT: randomized control trial

STI: Sexual Transmitted Infections

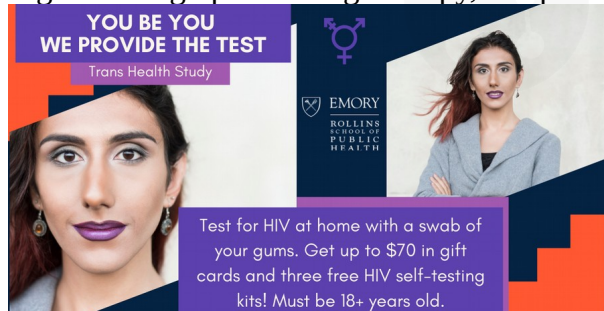
U.S.: United States

Figures:

Figure 1. High performing ad copy, sample #1.



Figure 2. High performing ad copy, sample #2.



References

1. Ending the HIV Epidemic. Hiv.gov. Available from: <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/> [accessed Jun 18, 2024]
2. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV epidemic: a plan for the United States. *JAMA* 2019;321(9):844–845.
3. Centers for Disease Control and Prevention. Issue Brief: The Role of HIV Self-Testing in Ending the HIV Epidemic. 2022. Available from: <https://www.cdc.gov/hiv/policies/data/self-testing-issue-brief.html> [accessed Sep 8, 2023]
4. Centers for Disease Control and Prevention. CDC HIV surveillance report, 2019. 2021. Available from: <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-updated-vol-32.pdf> [accessed Jun 18, 2024]
5. Centers for Disease Control and Prevention. Issue Brief: HIV and Transgender Communities. 2024. Available from: <https://www.cdc.gov/hiv/policies/data/transgender-issue-brief.html> [accessed Jun 26, 2024]
6. Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2010–2016. Cdc.gov. 2019. Available from: [cdc.gov/hiv/library/reports/hiv-surveillance.html](https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html) [accessed Feb 1, 2019]
7. Centers for Disease Control and Prevention. HIV Surveillance Supplemental Report: Estimated HIV Incidence and Prevalence in the United States, 2018–2022. 2024 May 21; Available from: <https://stacks.cdc.gov/view/cdc/156513> [accessed Dec 16, 2024]
8. Myers JE, Braunstein SL, Xia Q, Scanlin K, Edelstein Z, Harriman G, Tsoi B, Andaluz A, Yu E, Daskalakis D. Redefining Prevention and Care: A Status-Neutral Approach to HIV. *Open Forum Infect Dis* 2018 Jun;5(6):ofy097. PMID:29977957
9. Olakunde BO, Pharr JR, Adeyinka DA, Conserve DF. Nonuptake of HIV Testing Among Transgender Populations in the United States: Results from the 2015 U.S. Transgender Survey. *Transgender Health* Mary Ann Liebert, Inc., publishers; 2021 Jul 19; doi: 10.1089/trgh.2020.0141
10. Poteat T, Wirtz AL, Reisner S. Strategies for engaging transgender populations in HIV prevention and care. *Curr Opin HIV AIDS* Ovid Technologies (Wolters Kluwer Health); 2019 Sep;14(5):393–400. PMID:31219887
11. Sevelius JM, Patouhas E, Keatley JG, Johnson MO. Barriers and facilitators to engagement and retention in care among transgender women living with human immunodeficiency virus. *Ann Behav Med* Oxford University Press (OUP); 2014 Feb;47(1):5–16. doi: 10.1007/s12160-013-9565-8
12. Frye V, Wilton L, Hirshfield S, Chiasson MA, Usher D, Lucy D, McCrossin J, Greene E, Koblin B, All About Me Study Team. “just because it’s out there, people aren’t going to use it.” HIV

- self-testing among young, black MSM, and transgender women. *AIDS Patient Care STDS* Mary Ann Liebert Inc; 2015 Nov;29(11):617–624. PMID:26376029
13. Adams LM, Simoni JM. The need for multi-level mitigation of medical mistrust among social network members contributing to antiretroviral treatment nonadherence in African Americans living with HIV: Comment on Bogart et al. (2016). *Soc Sci Med*. 2016. p. 58–60. PMID:27173741
 14. Arnold EA, Rebchook GM, Kegeles SM. “Triply cursed”: racism, homophobia and HIV-related stigma are barriers to regular HIV testing, treatment adherence and disclosure among young Black gay men. *Cult Health Sex* 2014 Jun;16(6):710–722. PMID:24784224
 15. Horvath KJ, Walker T, Mireles L, Bauermeister JA, Hightow-Weidman L, Stephenson R. A systematic review of technology-assisted HIV testing interventions. *Curr HIV/AIDS Rep* Springer Science and Business Media LLC; 2020 Aug;17(4):269–280. PMID:32507984
 16. Poteat T, German D, Flynn C. The conflation of gender and sex: Gaps and opportunities in HIV data among transgender women and MSM. *Glob Public Health* 2016 Aug;11(7–8):835–848. PMID:26785751
 17. McKleroy VS, Galbraith JS, Cummings B, Jones P, Harshbarger C, Collins C, Gelaude D, Carey JW, ADAPT Team. Adapting evidence-based behavioral interventions for new settings and target populations. *AIDS Educ Prev Guilford Publications*; 2006 Aug;18(4 Suppl A):59–73. PMID:16987089
 18. Baumann AA, Cabassa LJ, Stirman SW, Brownson R. Adaptation in dissemination and implementation science. *Dissemination and implementation research in health: translating science to practice* Oxford University Press New York, NY; 2017;2:286–300. Available from: <https://books.google.com/books?hl=en&lr=&id=pWU9DwAAQBAJ&oi=fnd&pg=PT461&dq=adaptation+of+interventions+implementation+science&ots=UBMMHljAvN&sig=jw6ycSbzByfZS3CW3eL3rKS85qA>
 19. MacGowan RJ, Chavez PR, Borkowf CB, Owen SM, Purcell DW, Mermin JH, Sullivan PS, eSTAMP Study Group. Effect of internet-distributed HIV self-tests on HIV diagnosis and behavioral outcomes in men who have sex with men: A randomized clinical trial. *JAMA Intern Med American Medical Association (AMA)*; 2020 Jan 1;180(1):117–125. PMID:31738378
 20. Dana R, Sullivan SP, MacGowan R, Chavez P, Wall K, Sanchez T, Stephenson R, Hightow-Weidman L, Johnson JA, Smith A, Sharma A, Jones JS, Hannah M, Trigg M, Luo W, Caldwell JA, Sullivan P. Engaging Black or African American and Hispanic or Latino men who have sex with men for HIV testing and prevention services through technology: Protocol for the iSTAMP comparative effectiveness trial. *JMIR Res Protoc* 2023 Jan 6;12. PMID:36607707
 21. Sullivan PS, Stephenson R, Hirshfield S, Mehta CC, Zahn R, Bauermeister JA, Horvath K, Chiasson MA, Gelaude D, Mullin S, Downing MJ Jr, Olansky EJ, Wiatrek S, Rogers EQ, Rosenberg E, Siegler AJ, Mansergh G. Behavioral Efficacy of a Sexual Health Mobile App for Men Who Have Sex With Men: Randomized Controlled Trial of Mobile Messaging for Men. *J Med Internet Res JMIR Publications Inc.*; 2022 Feb 2;24(2):e34574. PMID:35025755
 22. Wingood GM, DiClemente RJ. The ADAPT-ITT model: a novel method of adapting evidence-based HIV Interventions. *J Acquir Immune Defic Syndr* 2008;47 Suppl 1:S40–6.

PMID:18301133

23. Everhart AR, Boska H, Sinai-Glazer H, Wilson-Yang JQ, Burke NB, LeBlanc G, Persad Y, Ortigoza E, Scheim AI, Marshall Z. 'I'm not interested in research; i'm interested in services': How to better health and social services for transgender women living with and affected by HIV. *Soc Sci Med* 2022 Jan 1;292:114610. doi: 10.1016/j.socscimed.2021.114610
24. Sevelius JM, Keatley J, Calma N, Arnold E. 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Rethinking MSM, Trans* and other Categories in HIV Prevention* Routledge; 2018. p. 242–257. doi: 10.4324/9781315151120-17ISBN:9781315151120
25. MacGowan RJ, Chavez PR, Gravens L, Wesolowski LG, Sharma A, McNaghten AD, Freeman A, Sullivan PS, Borkowf CB, Michele Owen S, for the eSTAMP Study Group. Pilot evaluation of the ability of men who have sex with men to self-administer rapid HIV tests, prepare dried blood spot cards, and interpret test results, Atlanta, Georgia, 2013. *AIDS Behav Springer Science and Business Media LLC*; 2018 Jan;22(1):117–126. PMID:29058163
26. Department of Health and Human Services. Minority HIV/AIDS Fund Background. *Hiv.gov*. 2023. Available from: <https://www.hiv.gov/federal-response/smaif/background/> [accessed Jun 18, 2024]
27. TransCare BC. Gender Inclusive Language: Building relationships. In: Provincial Health Services Authority. www.phsa.ca. 2022. Available from: http://www.phsa.ca/transcarebc/Documents/HealthProf/Gender_Inclusive_Language_for_Every_one.pdf [accessed Feb 8, 2022]
28. Bauer GR, Braimoh J, Scheim AI, Dharma C. Transgender-inclusive measures of sex/gender for population surveys: Mixed-methods evaluation and recommendations. *PLoS One journals.plos.org*; 2017 May 25;12(5):e0178043. PMID:28542498
29. Peitzmeier SM, Hughto JMW, Potter J, Deutsch MB, Reisner SL. Development of a novel tool to assess intimate partner violence against transgender individuals. *J Interpers Violence SAGE Publications*; 2019 Jun;34(11):2376–2397. PMID:30735080
30. Maksut JL, Sanchez TH, Wiginton JM, Scheim AI, Logie CH, Zlotorzynska M, Lyons CE, Baral SD. Gender identity and sexual behavior stigmas, severe psychological distress, and suicidality in an online sample of transgender women in the United States. *Ann Epidemiol Elsevier BV*; 2020 Dec;52:15–22. PMID:32768521
31. Adams N, Pearce R, Veale J, Radix A, Castro D, Sarkar A, Thom KC. Guidance and ethical considerations for undertaking transgender health research and Institutional Review Boards adjudicating this research. *Transgend Health* 2017 Oct 1;2(1):165–175. PMID:29098202
32. Tebbe EA, Budge SL. Research with trans communities. *Couns Psychol SAGE Publications*; 2016 Oct;44(7):996–1024. doi: 10.1177/0011000015609045
33. Katz-Wise SL, Pullen Sansfaçon A, Bogart LM, Rosal MC, Ehrensaft D, Goldman RE, Bryn Austin S. Lessons from a community-based participatory research study with transgender and gender nonconforming youth and their families. *Action Res (Lond) SAGE Publications*; 2019 Jun;17(2):186–207. doi: 10.1177/1476750318818875

34. Singh AA, Richmond K, Burnes TR. Feminist participatory action research with transgender communities: Fostering the practice of ethical and empowering research designs. *Int J Transgend Informa UK Limited*; 2013 Jul;14(3):93–104. doi: 10.1080/15532739.2013.818516
35. Andrasik MP, Yoon R, Mooney J, Broder G, Bolton M, Votto T, Davis-Vogel A, HVTN 505 study team, NIAID HIV Vaccine Trials Network. Exploring barriers and facilitators to participation of male-to-female transgender persons in preventive HIV vaccine clinical trials. *Prev Sci Springer Science and Business Media LLC*; 2014 Jun;15(3):268–276. PMID:23446435
36. Mann-Jackson L, Alonzo J, Garcia M, Trent S, Bell J, Horridge DN, Rhodes SD. Using community-based participatory research to address STI/HIV disparities and social determinants of health among young GBMSM and transgender women of colour in North Carolina, USA. *Health Soc Care Community Wiley*; 2021 Sep;29(5):e192–e203. PMID:33369811
37. Martin JI, Meezan W. Applying Ethical Standards to Research and Evaluations Involving Lesbian, Gay, Bisexual, and Transgender Populations. *J Gay Lesbian Soc Serv Routledge*; 2003 Apr 1;15(1–2):181–201. doi: 10.1300/J041v15n01_12

Supplementary Files

Figures

High performing ad copy, sample #1.



**YOU BE YOU
WE PROVIDE THE TEST**

Trans Health Study

EMORY
ROLLINS
SCHOOL OF
PUBLIC
HEALTH

Test for HIV at home with a swab of your gums. Get up to \$70 in gift cards and three free HIV self-testing kits! Must be 18+ years old.

The advertisement is a rectangular graphic with a dark blue background and orange geometric shapes. It features a portrait of a woman with long brown hair and purple lipstick. The text is in white and purple. The Emory Rollins School of Public Health logo is visible in the upper right. A large, light gray watermark reading 'Preprint JMIR Publications' is overlaid diagonally across the bottom half of the image.

High performing ad copy, sample #2.

