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## Project Moxie: Results of a feasibility study of a telehealth intervention to increase HIV testing among binary and nonbinary transgender youth

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### Abstract

Transgender youth have low rates of engagement in HIV prevention, shaped in part by experiences of transphobia and lack of access to culturally competent care. Project Moxie tested the feasibility of an intervention that provides home-based HIV self-testing coupled with video-chat counseling. A diverse sample of 202 binary and nonbinary transgender youth (TY) were recruited online, and randomized 2:1 to receive the intervention or a control condition of only home-based HIV self-testing. TY were willing to order HIV self-testing kits and report their results. Half of those in the intervention arm opted to use the video-chat counseling and, among those who did, levels of satisfaction were high. Project Moxie demonstrates the ability to recruit TY online and provide them with access to home HIV testing. Further work is required to develop online interventions for youth who do not wish to receive counseling through video-chat formats.

### INTRODUCTION:

Transgender individuals (those whose gender identity does not match their sex assigned at birth) are over three times more likely to be diagnosed with HIV than cisgender individuals

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(those whose current gender identity aligns with their sex assigned at birth)(1). Rates of other sexually transmitted infections (STIs) are significantly higher in transgender individuals compared to cisgender individuals(2–4), with 27%(5) of transgender women and approximately 13%(6, 7) of transgender men self-reporting a history of STI diagnosis in recent years. It is estimated that the percentage of youth (15–24 years) in the United States (US) who identify as transgender is between 0.2% and 1.3%(8). There is a dearth of literature that has examined HIV risk behaviors and outcomes for transgender youth (TY). In a recent study with a sample of 181 TY, 12% were unaware of their HIV status and 8% had never been tested for HIV(9). More young transgender women (63.3%) had accessed HIV prevention services than young transgender men (38.1%)(9). While there is scant data available on the use of pre-exposure prophylaxis (PrEP) among TY, or among transgender individuals generally, a 2016 study found that 62% of young transgender women met the Centers for Disease Control and Prevention's (CDC's) PrEP needs while only 31% had any PrEP awareness.(10) For these reasons, there is an urgent need to develop interventions that recognize the lived realities of TY and provide support for engagement in HIV prevention.

Stigma against transgender people is rooted in social structures and norms that reinforce a gender binary corresponding to biological sex and marginalize those who seek to affirm their gender identity (11–13). In the recent United States Transgender Survey (USTS), over half of the respondents reported interpersonal stigma via verbal or physical abuse in the past year(14). Rates of both anticipated and internalized stigma are consistently high (11, 15, 16). Across all gender identities, TY report high levels of exposure to stigma and resultant poor health outcomes (12, 17). Experiencing high rates of economic hardship coupled with social stigma, TY face barriers to accessing healthcare and engaging in recommended health screenings for their gender and age(18, 19). Additionally, TY have an increased probability of being diagnosed with depression than their cisgender peers (50.6% vs. 20.6%) and are more likely to experience anxiety (26.7% vs. 10.0%)(20). Depression, anxiety, and other mental health problems can contribute to risky sexual behaviors and an increased likelihood of engaging in condomless sex.(11, 21) Sexual risk taking may be a behavioral response to stress (as a means of gender affirmation from partners) or a response to structural inequalities (e.g., employment discrimination) which may result in engaging in transactional sex(22).

Sexual health research among transgender populations, including work on HIV and STI prevention, has focused heavily on transgender women.(8, 23) Research on transgender men's sexual health often addresses their sexual identities, and how they conceptualize their bodies when having sex(24), but not with whom they are engaging in sex. This fails to consider transgender men who have sex with cisgender men and other transgender sexual partners assigned a male sex at birth (AMAB), who may be at an increased risk for HIV and other STIs. A recent report by the San Francisco Department of Public Health placed transgender men within the same risk group as cisgender men who have sex with men, among whom HIV prevalence is estimated to be 24.3%.(25) At least one study found that, compared to transgender women, transgender men had less knowledge of HIV transmission and prevention, and were more likely to engage in risky sexual behaviors.(26) Another study found that, when having sex with cisgender men, over 60% of transgender men engaged in condomless vaginal sex and 27% had engaged in condomless anal sex.(27)

Similarly, much of what is known about the risk factors for HIV and other STIs for gender nonbinary individuals has been obtained from research with transgender women.(28) Gender nonbinary individuals are those who feel like they exist between or outside the binary genders of man or woman, or do not identify with any gender(28), and are commonly categorized incorrectly with binary transgender individuals. There is little to no literature assessing the risk determinants and mitigating factors for HIV and other STIs in this population. The 2008 National Transgender Discrimination Survey gave respondents a write-in option if the response options of “transgender woman” or “transgender man” were not appropriate descriptions of their gender(14). Individuals who wrote in their gender were 2.9% more likely to be living with HIV than transgender women and men. Moreover, 11% did not know their HIV status, compared to 9% of transgender women and men.(29) The recent LISTs finds that nonbinary individuals were less likely to be tested for HIV (45%) than either transgender women (62%) or transgender men (58%).(14)

There is clearly a need to develop HIV prevention interventions that not only recognize the HIV prevention needs of TY, but that also recognize the heterogeneity of TY identities. The Compendium of Evidence-Based Interventions (EBIs) and Best Practices for HIV Prevention lists 63 complete risk reduction evidence-based behavioral interventions.(30) Of these, only one intervention, Couples HIV Intervention Program (CHIP), provides HIV prevention for transgender people. As is common with transgender HIV prevention work, this intervention examines transgender women in their sexual relationships with cisgender men. No current EBIs are recommended for transgender people, regardless of gender identity, that do not relate transgender individuals to a cisgender male partner.

Within the Compendium, there are components of efficacious interventions that could be adapted for transgender people, and more specifically for TY. Counseling and motivational interviewing (MI) have proven effective in delivering HIV and other STI prevention techniques to various populations.(31, 32) However, the Compendium does not list any interventions using MI to engage TY.(33) Of the 63 risk-reduction EBIs, only two of the three which provide counseling and MI employ an online facilitator to interact with the participant.(33)

TY often rely on online technologies to build their social networks, receive support, and search for health information. Recent data show that reliance on smartphones to access the Internet has increased dramatically for youth(34). Telehealth includes the provision of information, education, referrals and counseling via an Internet platform, offering the opportunity to reach TY who are currently underserved by HIV prevention services and for whom structural or stigma-related barriers prevent them from accessing testing services. Telehealth formats commonly include text-messaging, audio- and video-conferencing platforms, social media, or smart-phone applications that aim to circumvent traditional impediments to healthcare access.(35) In recent years, telehealth formats have been adapted for use in transgender populations where stigma and a lack of LGBTQ-friendly healthcare providers contribute to reduced access to care(36). These interventions, however, are mostly focused on linkage to care and adherence to medication for people living with HIV, and fail to account for the lack of prevention outreach needed by TY(9). Recently, there has been an increase in online interventions that promote HIV testing or offer options to access testing,

but none of these focus specifically on TY (37–39). Online interventions are seen as convenient for LGBTQ youth and allow for home-based access to health messaging, thereby reducing fears of embarrassment or ‘outing’ by connecting with local resources(39).

To begin to fill this critical gap in HIV prevention interventions for TY, Project Moxie developed and tested an online HIV prevention intervention for TY in the US. The piloted intervention combined telehealth and home-based HIV self-testing to provide comprehensive, gender-affirming HIV testing and counseling for TY. This paper describes the results of the pilot study, and reports lessons learned and future recommendations for HIV prevention interventions for TY.

## **METHODS:**

### **Study design:**

Project Moxie was a two-arm pilot randomized control trial (RCT), which employed a sample of approximately 200 self-identified TY aged 15-24 years, recruited online via a range of social media platforms. TY in the control arm received one HIV self-testing kit by mail and were asked to report their results via a study website. TY in the intervention arm received one HIV self-testing kit via mail, and conducted this test under the supervision of a remotely-located counselor during a prescheduled video-chat session. Additional details regarding the study protocol have been published previously.(40)

### **Trial Registration and Institutional Board Approval:**

The Institutional Review Board of the University of Michigan has approved this study (HUM00123412). The study has also been registered on [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03185975).

### **Sample size:**

Pilot studies are a way to carry out exploratory activities(41), for which sample sizes between 24 and 50 have been recommended(42). Project Moxie aimed to test the feasibility of recruiting, retaining, and delivering an online HIV prevention intervention for a diverse sample of TY. A target sample size of 200 was established based on costing, resource, and time factors.

### **Eligibility:**

Eligibility criteria included the following: (1) self-identification as non-cisgender, indicated by a current gender identity differing from sex assigned at birth; (2) aged 15 to 24 years; (3) negative or unknown HIV status; (4) current US residency; (5) willingness to receive an at-home HIV self-testing kit; and (6) access to a computer, smartphone, or tablet that supports VSee, a HIPAA compliant video-conferencing software to implement the intervention. Pronouns and recruitment route were also asked at the time of eligibility screening.

### **Recruitment and retention:**

Recruitment of TY took place from June 2017 to June 2018, using advertisements and postings placed on the following social media platforms: Facebook, Instagram, Twitter, Tumblr, and Craigslist. Recruitment advertisements featured photos representing a spectrum

of transgender and gender diverse persons, and directed interested individuals to the Project Moxie website to earn up to \$150 for participating. The Project Moxie landing page provided basic study information, including a short description of activities. Those interested in the study were then directed to a comprehensive online informed consent form. Those who provided consent were directed to an eligibility screener. A waiver of need for parental consent to screen and enroll those under the age of 18 years was approved by the IRB. Participants received email and/or SMS message reminders once a week for up to 4 weeks to complete study activities (e.g. follow-up survey, scheduling an intervention session, reporting test results).

**Study process:**

Eligible participants registered for the study by creating an account and providing their contact information. This information included an e-mail address, telephone number, physical mailing address, and preferred name and pronouns. Many TY may have unstable housing or may not feel comfortable receiving mail, even in discreet packaging, at their home address. For this reason, the registration form asked for a physical address at which the participant felt safe and comfortable receiving mail. All identifying information was stored on a password protected server accessible only to IRB-approved study staff. Duplicate accounts and those which could be linked across inconsistent IP address, name, physical address, email, or phone number were flagged for verification. The information from these accounts was verified by staff using Spokeo, an online information aggregator; if the search was inconclusive, participants were contacted and asked to confirm their account information. If multiple accounts were detected for a verified individual, they were notified by staff that their longest standing account would be retained while any others would be deleted. In the case of fraudulent activity—the persistent creation of numerous accounts with inconsistent information—the associated IP address was restricted from accessing the study server. Following verification, participants were given the opportunity to refer friends into the study.

Once the consent process, eligibility screening questionnaire, and study registration were complete, the participant received an e-mail with instructions on accessing the baseline survey. After completing the baseline survey, each participant was randomized to either the intervention arm (video-based counseling in conjunction with home-based HIV self-testing) or control arm (home-based HIV self-testing only), using a 2:1 (intervention to control) treatment allocation. A 2:1 allocation was used to gain greater perspective on the user experience of the intervention arm. The randomization process generated one of two emails to study participants, indicating whether they would be receiving video-based counseling plus a home-based HIV self-testing kit (intervention) or only a home-based HIV self-testing kit (control).

**Control condition:**

TY in the control arm received one home-based HIV self-testing kit (OraQuick In-Home HIV Test®) delivered in discreet packaging. In addition to this oral fluid rapid HIV test, the package contained condoms, water-based lubricant packets, and a pair of ear buds (a token gift). All OraQuick tests were assigned an ID number that links to the participant's study ID

number. Upon taking the test, participants were directed to enter their results on the study website. For those who reported a positive result, a message was automatically sent to the study coordinator. Study staff then called the participant to offer information regarding places where the participant may acquire a confirmatory HIV test, as well as HIV care services and counseling either in their local area or another area of their choice. Within 48 hours, these participants were sent a discreet email listing confirmatory testing sites and treatment facilities near their residential or other desired zip code and based on their insurance status through the use of AIDSVu or United Way 211.(43, 44) Study staff followed up with these participants two more times, one month and three months following the reporting of their results, to evaluate linkage to care status and address any barriers identified.

### **Intervention condition:**

The intervention arm was a combination of home-based HIV self-testing and HIV test counseling offered remotely via a HIPAA-compliant video-chat software, VSee. Participants in the intervention arm also received an oral fluid rapid HIV test, condoms, lubricant packets, and earbuds, but were informed to leave their package *unopened* until directed by the counselor during the video-chat session. They were instructed via email on how to download the VSee software prior to the video-chat session. VSee is available as downloadable software for Windows and Macintosh and as an application in the iOS and Android marketplaces(45). This allowed participants to login to the video-chat from a desktop, laptop, tablet, or smartphone. Both the software and application versions contain audio, video, and screen-sharing capabilities, enabling the provision of a comprehensive counseling session across platforms and devices. VSee provides high-quality video at speeds as low as 50 Kbps(45), allowing full functionality in areas without access to broadband or high-speed cellular data networks. Participants received reminders one week and the day before their scheduled intervention session. The one-time counseling session lasted approximately 30-45 minutes and consisted of two consecutive phases.

**Phase one:** The first phase used elements of MI to ascertain barriers to HIV testing (e.g., structural barriers, lack of information/misinformation on HIV testing). The counselor asked about some of the participant's recent sexual behaviors (e.g., number of partners, use of condoms, sexual activities) to establish those that may pose a risk for acquiring HIV. The answers to these questions formed the basis for the problem-solving portion to follow. In this portion, the counselor attempted to provide solutions to mitigate each of the participant's concerns regarding HIV testing.

For structural barriers, such as lack of transportation or cost of testing, the counselor may have talked about locating local HIV testing services, venues that sell subsidized HIV self-testing kits, and options for free HIV testing in their local area. If the participant reported not testing because of a lack of knowledge of where to test or fear of being recognized at local testing sites, the counselor would have assisted the participant in finding testing options in gender-affirming spaces and helped to establish a transportation plan. The screen-sharing function in VSee allowed the counselor to share online resources and instruct the participant on their use.

For participants who reported fear of stigma or discrimination, the counselor provided advice on their rights as a patient, including their right to confidentiality, respect, and privacy. The counselor may also have shared the Gay & Lesbian Medical Association (GLMA) resource list with the participant, which includes *'10 Things Transgender Persons Should Discuss with their Health Care Providers'*(46). Through role-playing with the counselor, the participant practiced talking about sex and HIV with a healthcare provider. The counselor helped the participant formulate and practice specific talking points to use with their provider. The counseling placed emphasis on providing the participant with the skills necessary to routinely test for HIV by addressing individual barriers to testing and giving each participant a supportive and affirming HIV testing experience.

**Phase two:** The second phase of the session consisted of testing for HIV. Prior to the test, counselors offered standard content for risk elicitation and identification of safer sex goal behaviors. The participant, directed by the counselor, conducted their own test and read their own results. They then showed the counselor their test result for confirmation. Based on the results of the test and the information gathered in Phase I, the counselor assisted the participant in developing a prevention or care plan to reduce risk of acquiring or transmitting HIV. The counselor described the behavioral and biomedical interventions appropriate for each participant, such as antiretroviral therapy, condom use, partner reduction, decreasing drug or alcohol use, and/or PrEP.

At the end of the video-chat session, participants with a preliminary positive result were counseled on the need for timely confirmatory testing and linkage to care if necessary. The counselor arranged a time within one week of the initial session to conduct a second video-chat session with the participant testing preliminary positive. Within 48 hours of the video-chat session, participants testing preliminary positive were sent an email listing confirmatory testing sites and treatment facilities near their residential or other desired zip code and based on their insurance status through AIDSvu and United Way 211. During the second session, the counselor discussed confirmatory testing and care status and determined other resources from which the participant may benefit, such as medical case management, mental health care, and/or more comprehensive psychological counseling and services. Counselors were to follow up with these participants two more times, one month and three months following the initial video-chat counseling session, to evaluate linkage to care status and address any barriers identified.

#### **Interventionist training:**

Three lay counselors were trained to use MI during a two-day training session. The training involved didactic presentations on the history, science, and spirit of MI, as well as role-plays with other counselors acting as study participants. The counseling session protocol was developed with the input of transgender-identified staff members and community members. All counselors were trained in HIV testing and counseling and received training on the importance of gender affirmation and working with TY prior to delivering the intervention.

**Data collection:**

Participants in both arms completed a baseline survey upon recruitment, with repeat surveys being administered at three and six months. Participants in the intervention arm also completed a satisfaction survey within one week of completing the intervention. All surveys were completed online via Qualtrics, delivered via links sent to the participants' emails. Counselors completed a case report form (CRF) after each intervention session detailing the content of the session. The CRF included details on the HIV testing process and results, MI techniques employed, and any referrals or follow-up visits that were scheduled.

**Incentives:**

All participants received \$30 for completion of the baseline survey and an additional \$50 after completing each of the three- and six-month surveys, for a total of \$130 upon completion of all surveys.

**Measures:**

**Demographics:** The demographics section included measures of age, education, race, ethnicity, sexual orientation, employment, and state of residence. Both the respondent's sex assigned at birth and gender identity were collected. Gender identity included options for male, female, transmasculine/male, trans-feminine/female, as well as categories for genderqueer/gender non-conforming, agender/gender fluid individuals, and an open-ended response option.

**HIV and STI Testing:** History of HIV and other STI testing, including measures of frequency, place of testing, method of testing, and linkage to care (if HIV-positive), was collected at baseline. Questions included location of most recent test (e.g., home, AIDS Service Organization, Department of Public Health, or physician), test result, care received (specifically for HIV positive participants), and reason for testing (i.e., routine care versus episodic exposure). The baseline survey also assessed knowledge and use of PrEP(47). Follow-up surveys did not ask about repeat HIV testing: all participants were sent an HIV self-testing kit at baseline and, given a maximum follow-up period of only 6 months, it would be unlikely that participants would repeat an HIV test in such a short period. This is in line with current CDC guidelines(48) for HIV testing of high-risk individuals at least annually. Follow-up surveys did include questions on other STI testing.

**Transphobia and social marginalization:** Experiences of transphobia were assessed at baseline using subscales from the Gender Minority Stress and Resilience (GMSR) measure(49). Consisting of eight psychometrically validated scales, this measure was conceptualized as an assessment of potential facilitators and barriers to engaging in routine HIV testing. Participants were asked about lifetime and recent (< 6 months) experiences of homelessness and incarceration. Recent (< 3 months) participation in commercial sex work was assessed by items from the *National Transgender Discrimination Survey*(50).

**Sexual behaviors:** Measures were adapted from the National HIV Behavioral Surveillance (NHBS) inventory (51, 52). Participants were asked to estimate the number of anal intercourse (and vaginal, if applicable) partners, as well as condom use or non-use at



each encounter and the number of times they were the insertive (if applicable) versus receptive partner. The disclosure of HIV status and reported sero-status, or lack thereof, for each partner was also assessed.

**Linkage to care:** Participants self-reporting an HIV-positive test result in any of the surveys, or as part of the intervention or control condition activities, were asked about their engagement in HIV care. Per recommendations of the Institute of Medicine (IOM)(53), indicators of linkage to care included: (1) attending at least one clinical care appointment; (2) having at least one CD4 test performed; and (3) having at least one viral load test performed within three months of HIV diagnosis(54, 55).

**Intervention acceptability and satisfaction:** Participants in the intervention arm completed a satisfaction survey within one week of the date of intervention. The survey assessed participants' attitudes towards the counselor (i.e., friendliness, credibility, and knowledge), the ease of using the home-based HIV self-testing kit, the ease of using the video-chat software, and their willingness to repeat the intervention or to recommend the intervention to others.

#### **Data Analysis:**

Analysis examined data from surveys completed at baseline, 3 and 6 months, the satisfaction surveys completed by participants randomized to the intervention arm and study record data tracking participant recruitment and retention. The analyses focused primarily on measures of feasibility, conceptualized as rates of recruitment and retention, rates of ordering of HIV testing kits (for control and intervention arms), rates of uptake of the intervention and levels of satisfaction reported by those exposed to the intervention. Demographic, recent behavioral characteristics and measures on the GMRS were compared between control and intervention arm at baseline (using Chi-Square, Fisher's Exact or Kruskal-Wallis tests) to assess failures in randomization. Although not powered to detect changes in HIV risk behavior, tests for trends in HIV risk were conducted across baseline, 3 and 6 months by arm, to explore directions of potential effect of the intervention.

#### **RESULTS:**

Project Moxie social media advertisements generated 1,113,955 impressions (the total number of times the ads were displayed to any user) resulting in 33,182 (3.0%) clicks. Electronic consent to screen for eligibility was obtained from a sample of 2,707 individuals, 1,365 (50.4%) of whom started the eligibility screener. No data were collected to assess differences between those who did and did not screen for eligibility. Of these individuals, 698 (51.1%) met the study eligibility criteria. Reasons for ineligibility included self-identification as cisgender (275, 20.1%), age (303, 22.2%), HIV status (12, 0.9%), unwillingness to receive a home-based HIV self-test (61, 4.5%), and lack of access to a computer, smartphone, or tablet (7, 0.5%). Of the 698 eligible individuals, 480 (68.8%) consented for participation and created an account. Information from 216 (45%) accounts was verified, while 264 (55%) accounts were determined duplicate or fraudulent and

dropped from the study. Of the 216 verified individuals who created accounts, 202 (93.5%) took the baseline survey via the study website and were randomized.

The participant sample was composed of mostly nonbinary individuals (41.1%) and transgender men (40.6%), with transgender women comprising 18.3% of the sample (Table I). A majority of participants were assigned a female sex at birth (AFAB; 76.2%). Age distribution was 15 to 17 (32.7%), 18 to 21 (46.5%), and 22 to 24 (20.8%). Most identified as lesbian, gay, bisexual, or queer (LGBQ; 75.7%), non-Hispanic white (66.8%), were employed and/or a student (80.7%), had a high school education or GED (70.8%), and reported currently having stable housing (93.1%). Amongst the four Census-designated US regions, the sample was distributed as follows: 70 from the South (34.6%), 58 from the Midwest (28.7%), 43 from the West (21.3%), and 31 from the Northeast (15.4%). A significantly greater portion of the control arm (80.0%) identified as non-Hispanic white, compared to the intervention arm (58.7%;  $P=0.006$ ).

The majority of participants were currently living in their affirmed gender (87.1%) and had accessed, or planned to access, medical gender affirmation services of some sort (e.g., hormone replacement therapy; 77.7%). In the past 90 days, 36.1% reported having smoked tobacco, 66.3% reported having drunk alcohol, and 47.1% reported having used marijuana. Approximately half (53%) had engaged in condomless penetrative intercourse in the past 90 days. Only 5.5% reported ever having ever been arrested, and the majority (87.4%) reported currently having health insurance. At baseline, 22.4% of participants had ever previously tested for HIV and 23.1% had tested for STIs in the past 12 months. The percentage of participants reporting having tested for STIs in the past 12 months was significantly lower in the control arm (16.2%) than in the intervention arm (27.1%;  $P=0.001$ ).

Table II shows the baseline measure for the GMSR, life stress and resilience, healthcare affirmation, and psychological distress. There were no significant differences between control and intervention arm participants on any of these measures.

Seventy-six (76) participants were randomized to the control condition. Of these, 100% ordered HIV self-testing kits and 69 (91%) reported their HIV test results via the study portal. Two control participants reported a preliminary-positive HIV test result. Both of these participants were contacted within 48 hours and linked to care within 30 days. Retention rates for control condition participants were 87% at 3 months and 83% at 6 months.

One hundred and twenty-six (126) participants were randomized to the intervention condition. Of these, only 61 (48%) participants took part in the intervention: all 61 ordered HIV self-testing kits and underwent a video-chat counseling session. There were no differences in age, race, ethnicity or residential location between those who did and did not opt into the intervention (ordered testing kits and attended a video-chat counseling session). Although we did not systematically assess the reasons why TY opted not to take part in video-based counseling, anecdotal evidence from communications with participants suggests that participants were worried about having to be seen physically on camera by a person they did not know (even though study materials noted they could use voice-only options), and reported hesitation around talking about sensitive issues (e.g., recent sexual behavior). The

home-based HIV self-test was performed in-session by 59 of the 61 (96%) intervention participants: two gender nonbinary participants conducted the test themselves before the scheduled video-chat session. These two participants both self-reported the results of their test as negative during the video-chat session, although counselors were unable to visually confirm the test result. Of the 59 who conducted the HIV test in view of the counselor, 100% received a non-reactive result. Retention rates for intervention condition participants were 62% at 3 months and 58% at 6 months.

Satisfaction with the intervention across gender identities was uniformly high (Table III). Participants reported finding the counselors friendly (98-100%), knowledgeable (100%), experienced (87-100%) and professional (97-100%). Very few participants reported issues in using the video-chat software, most reported a good audio/visual quality (67-77%), and the majority felt it was easy to use (78%). The majority of participants felt that the home-based HIV self-testing kit was easy to use (97-100%) and easy to interpret (67-100%). Most participants reported a neutral feeling to the length of the session, with 2-5% reporting that the session was too long and 0-8% reporting that it was too short. Participants were overwhelmingly willing to repeat the intervention session later (86-100%), recommend the intervention to others (68-100%), and recommend home-based HIV self-testing to others (95-100%). Overall satisfaction levels with the intervention were high: 98% for the entire intervention sample (n=61), with the lowest levels of satisfaction (97%) reported among transmasculine participants.

Table IV shows sexual behavior, PrEP, and STI testing data at baseline, 3 months, and 6 months. Several of the items measured on the follow-up surveys suffered from a high degree of missing data, with participants not answering questions regarding sexual behavior in particular. Levels of PrEP use were very low and did not change significantly over the follow-up period. Willingness to use PrEP increased significantly from baseline (39.0%) to 3 months (74.8%) and 6 months (74.2%): the increase in willingness to use PrEP was significant overall ( $P=0.000$ ), and in the intervention ( $P=0.000$ ) and control ( $P=0.002$ ) arms. By 3 months, the percentage of participants testing for STIs in the past 3 months was significantly greater in the intervention (72.5%) than the control (42.9%) arm ( $P=0.001$ ), but declined again by 6 months (intervention arm 19.2%, control arm 15.3%). The overall change in STI testing over the entire 6-month period was only significant for participants in the control arm ( $P=0.025$ ). The percentage of those reporting condomless sex in the past 90 days was high at baseline (overall 53.2%, control 51.1%, intervention 54.7%) and by 3 months had increased to 69.1% overall (control 82.6%, intervention 62.2%). By 6 months, the percentage reporting condomless sex in the past 90 days was 35.7% (control 36.8%, intervention 33.6%). The change in reporting of condomless sex was only significant for those in the control arm ( $P=0.005$ ). The percentage of those using alcohol, tobacco, and other drugs (ATOD) while having condomless sex also did not change significantly throughout the follow-up period (baseline 60.0%, 3 months 50.0%, 6 months 50.0%). The change in the number of sex partners in the last 90 days did change significantly over the follow-up period, and was driven by shifts from no sex partners to one sex partner over the 6-month follow-up (total  $P=0.000$ , control  $P=0.027$ , intervention  $P=0.002$ ).

## DISCUSSION:

TY face significant structural and interpersonal barriers to effective engagement in HIV prevention, and currently utilize HIV testing at sub-optimal rates. (9, 10) Interventions to encourage uptake of HIV prevention (i.e., testing, condom use, and PrEP) must recognize the complex lived realities of TY and create opportunities for engagement that simultaneously address many of the barriers they experience. Providing interventions via telehealth might be a feasible approach to addressing these barriers.

Results from this pilot intervention demonstrate that TY are willing to order home-based HIV self-testing kits online: 100% of participants in the control arm ordered kits and reported their results. However, when asked to test at home during a video-based counseling session, only half of the intervention arm opted to do so, and this decision did not vary significantly by age or race / ethnicity. Anecdotal evidence from communications with participants suggests that participants were worried about having to be seen physically on camera by a person they did not know (even though study materials noted they could use voice-only options). However, for participants who did opt into the intervention, levels of satisfaction were extremely high, with almost all participants who received the intervention reporting they would do it again and recommend it to a friend.

The results suggest that participants fell into two groups: those who wanted to test themselves at home and benefited from access to ordering HIV self-testing kits, and those who wanted the opportunity to talk to a counselor via video-chat. This demonstrates the importance of creating flexible interventions that recognize the diverse needs of TY. Future iterations of telehealth interventions for TY may consider providing TY with a menu of options (i.e., testing only or access to counseling), allowing TY to choose testing modalities that meet their level of comfort and own perceived needs. There may be other formats of telehealth that are feasible and desired among TY: further work is warranted to fully understand the forms and functions of telehealth delivered HIV testing that are desirable to TY.

The recruitment strategies employed by Project Moxie were successful in enrolling a relatively large sample of TY with a diverse range of gender identities. This is in contrast to many HIV prevention studies for transgender individuals that have largely focused on transfeminine populations, (56–59) limiting our understanding of best intervention practices for transmasculine and gender nonbinary individuals. The current study also employed fraud detection strategies based on the standards recommended by Bauermeister et al.(60), and was able to successfully identify 264 fraudulent accounts, saving significant study resources. The sample reported high levels of recent risk taking (53% reported recent condomless intercourse) and low levels of recent HIV and other STI testing. Advertisements for Project Moxie were developed in collaboration with TY, several study staff were transgender identifying, and experts in transgender health reviewed all study materials. The attention to ensuring that transgender voices were included at all stages of the research process, in particular the marketing and branding of the study, assisted in enabling the study to reach diverse communities of TY. The sample was, however, majority white, despite the use of

images featuring a range of young people of color. Future attention is required to identify messaging and imagery that appeals to TY of color.

Although not powered for efficacy, the pilot trial of Project Moxie showed that willingness to use PrEP increased substantially across both the control and intervention arms. In the intervention arm, counselors talked to participants about PrEP, and this information sharing in the context of a HIV test may have created interest in future PrEP use. For the control arm, reading about PrEP in the surveys – which included a description of PrEP as “*a pill taken every day that can reduce your risk of getting HIV by over 90%*” coupled with the experience of HIV testing at home may have initiated interest in PrEP use. Participants in the intervention group experienced significantly greater increases in STI testing by 3 months relative to those in the control group, suggesting that exposure to the intervention has the potential to create proximal gains in STI testing. During the video-chat sessions, counselors encouraged participants to pursue STI testing and helped them locate local services. In terms of sexual risk, the intervention showed no impact on reporting condomless intercourse or sex with alcohol or substances, yet there was a shift from participants reporting zero to one sex partners. This increase may reflect time, with participants more likely to have a sex partner over the follow-up period, or participants may become more comfortable answering questions about sexual behavior over time.

While only two HIV-positive results were identified—both of which were in the control arm—both participants were contacted and linked to care within a short period. Although more work is needed with larger samples of TY, this preliminary result does suggest the potential for telehealth to identify and successfully link HIV-positive TY to care.

There are several limitations to the results. While Project Moxie was successful in reaching a large, diverse sample of TY, retention rates across the pilot test were sub-optimal (58%-87%). Retention rates were lower in the intervention arm, shaped by participants who were reluctant to undertake the intervention. These retention rates did not vary by age or race/ethnicity. Although the primary intent of the study was to identify the feasibility of providing the intervention, sub-optimal retention and missing data limited the ability to identify changes in behavior associated with the intervention. In addition, this was a convenience sample recruited from a limited number of social media platforms and, therefore, findings from this study do not represent the experiences of all TY. The sample likely also underrepresent TY who are experiencing housing instability or do not have access to the internet. Future work should continue to expand efforts to identify TY through a variety of online and offline recruitment channels to optimize representation in intervention studies. Two significant differences were identified post-randomization: participants in the control arm had lower baseline prevalence of recent STI testing and therefore this may be driving the finding that the intervention group had more significant gains in STI testing than the control group. Participants in the control group were more likely to be non-Hispanic White than the intervention arm. Future efficacy trials should consider stratifying by race/ethnicity to ensure balanced groups for comparison.

## CONCLUSION:

Project Moxie aimed to test the feasibility and acceptability of an innovative telehealth intervention with the potential to fill a significant gap in HIV prevention interventions for TY. The intervention was created to assist TY in overcoming structural and interpersonal barriers to HIV testing by providing a positive experience of home-based HIV self-testing, facilitated remotely by a competent and affirming counselor. The intervention showed promisingly high levels of satisfaction among those who opted to participate. Those who opted not to access video-based counseling still reported high levels of willingness to order at-home HIV testing kits and to report their results online, in line with the overall sample. These results indicate that further work is required to understand the approaches best suited to engaging TY in the use of telehealth platforms for optimal benefits in HIV testing and prevention.

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Table I.

Demographic characteristics of 202 transgender youth, United States, June 2017 – June 2018

	Total n = 201 % (n)	Intervention n = 126 % (n)	Control n = 75 % (n)	p
<b>Characteristics</b>				
Gender Identity				0.479
Transmasculine	40.6 (82)	40.8 (51)	41.3 (31)	
Transfeminine	18.3 (36)	19.8 (25)	14.7 (11)	
Nonbinary AFAB	27.7 (56)	26.2 (33)	30.7 (23)	
Nonbinary AMAB	13.4 (27)	13.5 (17)	13.3 (10)	
Age				0.103
15-17	32.7 (66)	27.0 (34)	42.7 (32)	
18-20	32.1 (64)	33.3 (42)	29.3 (22)	
21-24	35.2 (71)	39.7 (50)	28.0 (21)	
Identifies as LGBTQ	75.7 (152)	76.2 (96)	74.7 (56)	0.826
Race				<b>0.006</b>
Non-Hispanic White	66.8 (134)	58.7 (74)	80.0 (60)	
Other Race/Ethnicity <sup>1</sup>	33.2 (67)	41.3 (52)	20.0 (15)	
Employment				0.752
Employed, and/or a student	80.7 (162)	79.4 (100)	82.7 (62)	
Unemployed, not a student	19.3 (39)	20.6 (26)	17.3 (13)	
Region				0.785
Midwest	28.7 (58)	28.6 (36)	29.3 (22)	
Northeast	15.4 (31)	13.5 (17)	18.7 (14)	
South	34.7 (69)	36.5 (46)	30.7 (23)	
West	21.3 (43)	21.4 (27)	21.3 (16)	
Accessed any medical interventions to affirm their gender, or planned to	77.7 (156)	77.0 (97)	78.7 (59)	0.833
Currently living as the gender that most affirms them	87.1 (175)	86.5 (109)	88.0 (66)	0.886
Currently has stable housing <sup>2</sup>	93.1 (187)	92.1 (116)	94.7 (71)	0.752
Engaged in transactional sex in the past 90 days	5.5 (11)	6 (4.8)	5 (6.7)	0.566
ATOD <sup>3</sup> use				
Has used tobacco in the past 90 days	36.1 (72)	33.3 (42)	40.0 (30)	0.262
	<b>n = 187</b>	<b>n = 119</b>	<b>n = 67</b>	
Has used alcohol in the past 90 days	66.3 (124)	66.4 (79)	67.2 (45)	0.370
Has used alcohol and is under 21 in the past 90 days	85 (70.3)	53 (72.6)	32 (66.7)	0.485
Has used marijuana in the past 90 days	47.1 (87)	44.5 (53)	50.8 (34)	0.408
Has used other drugs <sup>4</sup> in the past 90 days	51.3 (95)	48.7 (58)	55.2 (37)	0.433
	<b>n = 182</b>	<b>n = 115</b>	<b>n = 67</b>	
Ever been arrested	5.5 (10)	3.5 (4)	9.0 (6)	0.175
	<b>n = 199</b>	<b>n = 174</b>	<b>n = 25</b>	
Has health insurance coverage	87.4 (173)	86.3 (107)	89.2 (66)	0.779

	<b>Total n = 201 % (n)</b>	<b>Intervention n = 126 % (n)</b>	<b>Control n = 75 % (n)</b>	<b>p</b>
Ever tested for HIV	<b>n = 50</b> 22.4 (45)	<b>n = 30</b> 19.8 (25)	<b>n = 20</b> 26.7 (20)	0.098
Tested for STIs <sup>5</sup> in the past 12 months	<b>n = 186</b> 23.1 (44)	<b>n = 118</b> 27.1 (32)	<b>n = 68</b> 16.2 (11)	0.001
Heard of PrEP	<b>n = 190</b> 55.8 (106)	<b>n = 121</b> 57.0 (69)	<b>n = 69</b> 53.6 (37)	0.482

<sup>1</sup>Includes 16 Hispanic, 12 Black, 7 Asian, 3 Middle Eastern, 2 Native American/Alaskan Native, and 27 multiracial individuals

<sup>2</sup>Stable housing includes having own house/apartment, family member's house/apartment, friend's house/apartment, or foster home

<sup>3</sup>Alcohol, tobacco, and other drug use

<sup>4</sup>Includes synthetic marijuana, cocaine, amphetamine type stimulants, Amyl nitrates, sedatives, hallucinogens, and opioids

<sup>5</sup>Includes having been tested for genital herpes, chlamydia, syphilis, human papillomavirus(HPV), and Gonorrhea

**Table II.**

Descriptive statistics of GMSR scales by study arm

		(min, max)	Total (median, SD)	Intervention (median, SD)	Control (median, SD)	<sup>6</sup> P
<b>Scales</b>						
<b>Gender Minority Stress and Resilience</b>						
Discrimination	n = 187	(0, 5)	(2, 1.59)	(3, 1.57)	(2, 1.62)	0.581
Rejection	n = 185	(0, 6)	(4, 1.83)	(4, 1.74)	(4, 2.01)	0.459
Victimization	n = 185	(0, 5)	(2, 1.66)	(2, 1.63)	(2, 1.70)	0.389
Non-affirmation	n = 187	(0, 21)	(17, 5.59)	(17, 5.41)	(16, 5.97)	0.934
Internalized Transphobia	n = 183	(0, 31)	(18, 8.48)	(16, 8.46)	(20, 8.58)	0.370
Anticipated Stigma	n = 186	(0, 36)	(27, 10.32)	(22, 10.17)	(22.5, 10.63)	0.388
Pride	n = 187	(0, 28)	(20, 6.96)	(16, 6.58)	(14, 7.47)	0.528
Community Connectedness	n = 185	(0, 20)	(16, 4.56)	(13, 4.56)	(13, 4.57)	0.444
<b>Life Stress and Resilience</b>	n = 183	(10, 40)	(17, 6.57)	(17, 6.84)	(18, 6.12)	0.596
<b>Healthcare Affirmation</b>	n = 195	(0, 24)	(9, 6.60)	(9, 6.79)	(8.5, 6.27)	0.932
<b>Psychological Distress (BSI-18)</b>	n = 171	(0, 72)	(28, 18.68)	(30.5, 17.26)	(24, 20.86)	0.772

<sup>6</sup>Results from Kruskal-Wallis equality-of-populations rank tests

**Table III.**

Satisfaction survey data reported by intervention participants (N=61) separated by gender identity

	<b>Total % (n)</b>	<b>Transfeminine % (n)</b>	<b>Transmasculine % (n)</b>	<b>NB-AMAB % (n)</b>	<b>NB-AFAB % (n)</b>
<b>Measures</b>					
<b>Counselor Attributes</b>	<b>n = 60</b>	<b>n = 8</b>	<b>n = 30</b>	<b>n = 3</b>	<b>n = 19</b>
<b>Friendly</b>	98.3 (59)	100 (8)	96.7 (29)	100 (3)	100 (19)
<b>Knowledgeable</b>	100 (60)	100 (8)	100 (30)	100 (3)	100 (19)
<b>Experienced</b>	98.3 (59)	87.5 (7)	100 (30)	100 (3)	100 (19)
<b>Professional</b>	98.3 (59)	100 (8)	96.7 (29)	100 (3)	100 (19)
<b>VSee Ease of Use</b>					
<b>Difficult</b>	15.0 (9)	— (0)	10.0 (3)	33.3 (1)	26.3 (5)
<b>Neutral</b>	6.7 (4)	— (0)	10.0 (3)	33.3 (1)	— (0)
<b>Easy</b>	78.3 (47)	100 (8)	80.0 (24)	33.3 (1)	73.7 (14)
<b>VSee Quality</b>					
<b>Poor</b>	6.7 (4)	12.5 (1)	3.3 (1)	33.3 (1)	5.3 (1)

**Table IV.**

Testing and sex behaviors across study arms at baseline, 3 months, and 6 months

	Baseline				3 months				6 months				Change over time				
	Total	Intervention	Control	Total	Intervention	Control	Total	Intervention	Control	Total	Intervention	Control	Total	Intervention	Control	p	p
<b>Sex Partners</b>	<b>n = 201</b>	<b>n = 126</b>	<b>n = 75</b>	<b>n = 143</b>	<b>n = 93</b>	<b>n = 50</b>	<b>n = 136</b>	<b>n = 87</b>	<b>n = 49</b>	<b>n = 87</b>	<b>n = 49</b>	<b>n = 87</b>	<b>n = 49</b>	<b>n = 87</b>	<b>n = 49</b>		
	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)	% (n)		
0	18.1 (31)	21.2 (22)	13.6 (9)	1.1 (1)	1.8 (1)	0.0 (0)	1.2 (1)	1.7 (1)	0.0 (0)	1.7 (1)	0.0 (0)	1.7 (1)	0.0 (0)	1.7 (1)	0.0 (0)	0.000	0.002
1	50.6 (86)	54.8 (57)	43.9 (29)	66.7 (58)	68.4 (39)	63.3 (19)	70.7 (58)	69.0 (40)	75.0 (18)	69.0 (40)	75.0 (18)	69.0 (40)	75.0 (18)	69.0 (40)	75.0 (18)		
2	15.9 (27)	12.5 (13)	21.2 (14)	17.2 (15)	15.8 (9)	16.7 (5)	15.9 (13)	13.8 (8)	20.8 (5)	13.8 (8)	20.8 (5)	13.8 (8)	20.8 (5)	13.8 (8)	20.8 (5)		
3+	15.3 (26)	11.5 (12)	21.2 (14)	16.1 (14)	14.0 (8)	20.0 (6)	12.2 (10)	15.5 (9)	4.2 (1)	15.5 (9)	4.2 (1)	15.5 (9)	4.2 (1)	15.5 (9)	4.2 (1)		
<b>Condomless sex in the past 90 days<sup>J</sup></b>	<b>n = 111</b>	<b>n = 64</b>	<b>n = 47</b>	<b>n = 68</b>	<b>n = 45</b>	<b>n = 23</b>	<b>n = 56</b>	<b>n = 38</b>	<b>n = 18</b>	<b>n = 38</b>	<b>n = 18</b>	<b>n = 38</b>	<b>n = 18</b>	<b>n = 38</b>	<b>n = 18</b>	0.001	0.062
	53.2 (59)	54.7 (35)	51.1 (24)	69.1 (47)	62.2 (28)	82.6 (19)	35.7 (20)	36.8 (14)	33.3 (6)	36.8 (14)	33.3 (6)	36.8 (14)	33.3 (6)	36.8 (14)	33.3 (6)	0.001	0.062
<b>Had condomless sex and ATOD use in past 90 days</b>	<b>n = 50</b>	<b>n = 30</b>	<b>n = 20</b>	<b>n = 22</b>	<b>n = 15</b>	<b>n = 7</b>	<b>n = 14</b>	<b>n = 11</b>	<b>n = 3</b>	<b>n = 11</b>	<b>n = 3</b>	<b>n = 11</b>	<b>n = 3</b>	<b>n = 11</b>	<b>n = 3</b>	0.654	0.417
	60.0 (30)	66.7 (20)	50.0 (10)	50.0 (11)	46.7 (7)	57.1 (4)	50.0 (7)	54.6 (6)	33.3 (1)	54.6 (6)	33.3 (1)	54.6 (6)	33.3 (1)	54.6 (6)	33.3 (1)	0.654	0.417
<b>Using PrEP</b>	<b>n = 190</b>	<b>n = 121</b>	<b>n = 69</b>	<b>n = 142</b>	<b>n = 92</b>	<b>n = 50</b>	<b>n = 135</b>	<b>n = 86</b>	<b>n = 49</b>	<b>n = 86</b>	<b>n = 49</b>	<b>n = 86</b>	<b>n = 49</b>	<b>n = 86</b>	<b>n = 49</b>	0.246	0.253
	1 (0.5)	0.0 (0)	1 (1.5)	2.8 (4)	2.2 (2)	4.0 (2)	2.2 (3)	2.3 (2)	2.0 (1)	2.3 (2)	2.0 (1)	2.3 (2)	2.0 (1)	2.3 (2)	2.0 (1)	0.246	0.253
<b>Willing to use PrEP</b>	<b>n = 77</b>	<b>n = 46</b>	<b>n = 31</b>	<b>n = 132</b>	<b>n = 84</b>	<b>n = 48</b>	<b>n = 132</b>	<b>n = 84</b>	<b>n = 48</b>	<b>n = 84</b>	<b>n = 48</b>	<b>n = 84</b>	<b>n = 48</b>	<b>n = 84</b>	<b>n = 48</b>	0.000	0.000
	39.0 (30)	39.1 (18)	38.7 (12)	74.8 (107)	77.2 (71)	70.0 (35)	74.2 (98)	77.4 (65)	33 (68.8)	77.4 (65)	33 (68.8)	77.4 (65)	33 (68.8)	77.4 (65)	33 (68.8)	0.000	0.000
<b>No</b>	9.1 (7)	4.4 (2)	16.1 (5)	14.7 (21)	10.9 (10)	22.0 (11)	17.4 (23)	14.3 (12)	22.9 (11)	14.3 (12)	22.9 (11)	14.3 (12)	22.9 (11)	14.3 (12)	22.9 (11)		
<b>I don't know</b>	52.0 (40)	56.5 (26)	45.2 (14)	10.5 (15)	12.0 (11)	8.0 (4)	8.3 (11)	8.3 (7)	8.3 (4)	8.3 (7)	8.3 (4)	8.3 (7)	8.3 (4)	8.3 (7)	8.3 (4)		
<b>Tested for STIs in past 90 days</b>	-	-	-	<b>n = 140</b>	<b>n = 91</b>	<b>n = 49</b>	<b>n = 140</b>	<b>n = 91</b>	<b>n = 49</b>	<b>n = 91</b>	<b>n = 49</b>	<b>n = 91</b>	<b>n = 49</b>	<b>n = 91</b>	<b>n = 49</b>	0.144	0.128
	-	-	-	62.1 (87)	72.5 (66)	42.9 (21)	16.7 (22)	15.3 (13)	19.2 (9)	15.3 (13)	19.2 (9)	15.3 (13)	19.2 (9)	15.3 (13)	19.2 (9)	0.144	0.128

<sup>J</sup> Condomless sex includes receptive and/or insertive anal sex and receptive and/or vaginal sex