

TRANS WOMEN CONNECTED (TWC)

STUDY PROTOCOL WITH IMPACT ANALYSIS PLAN

Purpose (Brief description)

The purpose of this study protocol with the analysis plan is to document the research questions, study design, and programmatic information along with the planned impact and supplemental analyses. All sections in this analysis plan are intended to elicit text that can be directly copied into final evaluation reports or journal articles. Deviations from these plans are to be discussed and documented for transparency.

Primary Author(s)

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TWC Clinical Trials Registration #: NCT03897049

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1) Research Questions That Address Program Effectiveness on Behavioral Outcomes

These are consistent with outcomes listed on the www.ClinicalTrials.gov website.

a. Primary research question(s):

- i. What is the impact of the full TWC app relative to the TWC COVID only app on the **number of times participants report having been tested for STI and HIV in the past 3 months at follow-up**, approximately three- and six-months post baseline?
- ii. What is the impact of the full TWC app relative to the TWC COVID only app on the **number of times participants report receptive condomless anal or vaginal intercourse at follow-up**, approximately three- and six-months post baseline?

b. Secondary research question(s): Grouped by timepoints at which they are to be assessed per Clinical Trials Registration

Assessed at all three follow-up timepoints

- i. What is the impact of the full TWC app relative to the TWC COVID only app on the **perceptions of social support (based on mean score) at follow-up**, approximately one-month, three-months, and six-months post baseline?
- ii. What is the impact of the full TWC app relative to the TWC COVID only app on **self-reported uptake of PrEP** since last measurement period, approximately one-month, three-months, and six-months post baseline?
- iii. What is the impact of the full TWC app relative to the TWC COVID only app on **self-efficacy in decisions around safer sex behavior (i.e., the HIV & Safer Sex: Self Efficacy Scale)** at follow-up, approximately one-month, three-months, and six-months post baseline?
- iv. What is the impact of the full TWC app relative to the TWC COVID only app on **patient communication self-efficacy within clinical encounters** (i.e., Ask ,Understand, and Remember, AURA, Scale) at follow-up, approximately one-month, three-months, and six-months post baseline?
- v. What is the impact of the full TWC app relative to the TWC COVID only app on participants' **degree of comfort with external appearance as it relates to gender identity** (i.e., the **Transgender Congruence Scale, or TCS**) at follow-up, approximately one-month, three-months, and six-months post baseline?

Assessed at three- and six-months post intervention only

- vi. What is the impact of the full TWC app relative to the TWC COVID only app on whether participants reported **using a condom at last receptive anal intercourse or vaginal intercourse** at follow-up, approximately three- and six-months post baseline?
- vii. What is the impact of the full TWC app relative to the TWC COVID only app on the **self-reported number of visits to a health care provider (of any type and by type) at follow-up**, approximately three- and six-months post baseline?
- viii. What is the impact of the full TWC app relative to the TWC COVID only app on the **self-reported number of contacts as/with a mentor/mentee for guidance or support at follow-up**, approximately three-months and six-months post baseline.

Reaction outcome—one-month follow-up full TWC app sub-group only

- ix. What are participants' reactions to the full TWC app at immediate follow-up (one-month post baseline)?

Dropped outcomes

Several outcomes were dropped before the study launch and were not included on the survey or asked in a way on the survey that allowed calculation. These include:

- The Gender Identity Reflection and Rumination Scale: Scale measures rumination in the context of gender identity among transgender persons. Average of 15 items on a 4-point scale, with a range of 15 - 60, with a lower score indicating less rumination and better outcomes [Time Frame: Baseline, Immediate post, 3- month post, 6-month post]. Note: Scale dropped after pilot test.
- Ask ,Understand, and Remember (AURA): Scale measures patient communication self-efficacy within clinical encounters. Average of 4 items on a 4-point scale, with a range of 4 - 16, with a greater higher score indicating better outcomes [Time Frame: Immediate post, 3- month post, 6-month post]. Note: Scale dropped after pilot test.
- Sexual partners, unprotected, in last 3 months: # partners with whom had anal or vaginal sex without using condoms or PrEP in past 3 months [Time Frame: 3- and 6-months post intervention]. Note: Study survey asked each separately (# partners and times unprotected, but not the intersection per feedback during pilot test).

2) Description of the Intended Intervention and the Attention Control Conditions

- a. **Intervention condition:** The intervention is a mobile app delivered sexual health promotion program designed specifically for transgender women. The mobile app includes 42 interactive activities plus resource maps, opportunities for mentoring, and

communication forums for connecting with other transgender women (see Table 1 for content summary). The intervention/app is intended to be used regularly (e.g., two times per week) though participants control how often and when they use the app.

Table 1. TWC Intervention App Content.

Activity or Feature Name	Brief Description of Focus	App functionality
1-800-SEX-TALK Sexual Feedback	Increase skills to talk about sex and give sexual feedback; Increase confidence in talking about sex with partners	This activity describes approaches to providing feedback successfully, illustrates a variety of couples providing sexual feedback, then provides an opportunity for the user to add their own feedback in scenarios using the new techniques
Affirmations	Short messages of affirmation are sent to users to reinforce gender identity, social support, and HIV prevention messages.	A database of affirming and motivational quotes are sent at random intervals to users as push notifications.
A Trip to the Clinic - Getting Tested	Increase knowledge of STI/HIV facts and misconceptions; Differentiate STI/HIV test types	This activity uses a persona, Adriana, to allow the user to explore the HIV/STI testing process. Here the user learns about misconceptions about STIs and STI/HIV testing; the before, during; and after of testing; and the different types of testing that may be done
Assertiveness Super Hero Academy	Increase knowledge of assertive communication skills; increase comfort and skill in how to communicate assertively	Users are introduced to nine custom trans women superhero characters who each have an assertiveness superpower they demonstrate in a scenario. Users self-select the technique they would like to focus on improving through practice in a scenario.
Boundaries - My Life, My Way	Increase awareness of why boundaries are important; increase skills and strategies to set boundaries	Users are introduced to the importance of boundaries and are introduced to a video vignette of three friends and the three steps to address boundaries in relationships.
Can You Hear Me Now	Increase awareness and skills for assertive communication and navigating difficult conversations	Users see examples of passive, aggressive, passive-aggressive, and assertive communication styles in relationship scenarios and practice the steps to be able to respond assertively to challenging relationship scenarios.
Cards Against COVID	Increase awareness of self care practices; increase ability to identify personal strengths in face of obstacles	Users play a card game to practice different supportive strategies to respond to potentially stressful situations.
Cleaning House - Breaking Up	Increase confidence to end an unhealthy relationship; increase awareness of strategies to end a relationship in a healthy way	Users are encouraged feel empowered to end a relationship if it no longer feels right. Using the analogy of cleaning up a messy room, users learn nine tips to improve their skills to end a relationship safely and calmly.
Coping With Clocking	Increase awareness and confidence to validate feelings about misrecognition; Increase understanding of	Users view "social media story" style experiences of trans women who have faced

Activity or Feature Name	Brief Description of Focus	App functionality
	different responses to misrecognition; Increase social support by share the experiences of other women	and addressed misrecognition. Users identify their own feelings about non-affirming encounters and hear from other trans women how they have overcome these feelings.
COVID Connections	Increase knowledge of strategies to prevent COVID transmission while dating and sex. Increase skill to develop a personal intimacy plan to identify what feels safe and appropriate dating during COVID.	Users watch a simulated dating game show and select their preferred responses from the contestants to help construct their own intimacy plan that can be saved to My Creations.
COVID Slam	Increase knowledge of COVID transmission and prevention strategies.	Users watch a simulated game show with a host and 3 trans women participants answer questions about COVID transmission and prevention.
Cumming Soon...Orgasm!	Increase knowledge about how orgasms work; Increase awareness of other trans women's experiences of orgasm; Increase knowledge of different ways orgasm may change during transition	User is introduced to features related to orgasm using a movie poster theme and are asked to create their own poster to identify what matters most to them for their own orgasm. The customized movie poster can be saved to My Creations.
Forums	A bulletin board feature where users can have conversations and discussions on a variety of topics.	Users can post and comment on communication topics started by the forum moderator or other forum participants.
Healthy Relationship Roots	Increase knowledge and comfort to distinguish a healthy relationship from an unhealthy relationship	Using a gardening theme, users learn qualities that are most important to healthy relationships and then reflect on different relationship scenarios and identify their own feelings in response to the situation. They also reflect on their own past relationship experiences to identify their feelings of what is healthy and unhealthy.
Hook Me Up - HIV Linkage	Increase knowledge of HIV care services; Increase confidence to get what you need from HIV care	User view a video of a clinic walkthrough to illustrate the process of HIV testing and linkage.
I Care About Me	Increase awareness of why self-care is important; Increase knowledge of self-care activities; Increase confidence in identifying self-care activities they can participate in	Users learn about different self-care practices and are asked to create their own "Self-care Playlist" by identifying activities that can help them reduce stress and replenish their energy.
It's My Health and I'm in Charge	Increase assertive communication skills when talking with healthcare provider; identify question to prepare for healthcare appointments.	User hears from the assertiveness superhero characters about specific strategies to use with health care providers. Users complete their own assertive communication "prescription pad" to

Activity or Feature Name	Brief Description of Focus	App functionality
Keep My Fire Lit	Increase knowledge of the connection between compassion fatigue and risk factors like isolation, substance use, and sexual risk taking; Increase knowledge of the causes and symptoms of compassion fatigue; Increase skill to assess self for symptoms of compassion fatigue; Increase skill to identify next steps to address compassion fatigue	prepare for conversations that can be saved to My Creations.
Let Me Tell You Something - STI Disclosure	Increase confidence in talking to current, former, and future partners about STI status	Users complete a compassion fatigue quiz to identify their level of fatigue. They receive a score and suggestions on how to address their own level of compassion fatigue. The customized quiz results can be saved to My Creations.
Let's Put it Together - My Boundaries Plan	Increase skills to set boundaries in relationships.	Users follow a character through a “maze” to practice the four steps of disclosing an STI diagnosis to current or future partners.
Let's Talk About Sex - Getting on the Same Page	Increase skills to talk about sex and consent; Increase confidence in talking about sex	Users follow a video vignette of three friends talking about the three steps to address boundaries in relationships.
Life's a Beach	Increase self-awareness about life trajectories and the opportunities and challenges that may occur at different time periods in one's life	Users help a character practice talking about sex with a new partner, identify the topics that should be discussed, the timing for discussions, and examples of ways to talk about the topics.
Loud and Clear: Communicating Boundaries	Increase skills to communicate boundaries in relationships.	Users reflect on the current, past, and future selves and to identify what mattered most, their accomplishments, challenges, and transitions during different decades of their lives.
Love Shouldn't Hurt	Increase awareness that IPV happens in relationships and that it is not OK and that everyone deserves love in a relationship; increase ability to make a plan to leave or cope with IPV.	Users follow a video vignette of three friends talking about the three steps to address boundaries in relationships.
Map	Locator map of resources specifically relevant to the trans community across several categories.	In this activity, the incidence of IPV in trans women's relationships is discussed and their right to have a safe and loving relationship is emphasized. User creates a safety plan for coping with IPV.
Mentoring	To encourage connection and support between users, mentors and mentees are matched based on survey results and encouraged to create their own informal mentoring relationship.	When the user opens the map feature, their geo location data opens the resources available in their region. Users can click on the resource and obtain the google maps information about the resource.
		Users complete a mentoring survey to request to be a mentor or a mentee. To be a mentor, users need to have completed a set number of activities in the TWC app.

Activity or Feature Name	Brief Description of Focus	App functionality
Messaging	To encourage connection and support between users, individuals can connect with other users individually.	Users can send private messages to other users in the app.
My Creations	Screenshots of all of the personalized activity summaries are stored in one location on the individual user's profile.	If the user chooses to save their personalized activity products (e.g. the orgasm movie poster, the assertive communication prescription, the list of sexual boundaries), they are privately stored. The user can choose to share, download, or review their own creations.
My Gender Journey	Increase awareness that each trans woman's transition is an individual process that looks different; increase comfort to identify success and barriers in transition	Users take a virtual journey through a map of fantasy style kingdom, identifying their own priorities and barriers along the journey. The customized map can be saved to My Creations.
My Play Palette	Increase knowledge of safer sex options; Increase decision-making skills; increase confidence to choose safer sex steps	This activity describes 6 steps to support decision making for safer sex. Users then select a type of sex and practice using the six steps to make safe sex decisions in that situation.
My Pleasure Box	Increase confidence to talk about safer sex and different types of sex; Increase knowledge of resources for exploring sexual pleasure and safer sex	This activity uses a chocolate shop setting to give users the opportunity to select and learn about different types of sex.
My Umbrella - HIV Social Support	Increase knowledge of qualities needed in a person/group for social support; Increase comfort to identify people/groups in current social network or outside current social network to strengthen and/or grow social support system; Increase knowledge how to navigate a conversation to express social support need(s) to another person	The activity addressing the need for social support systems and types of social support. Alongside the character Alex, the user decides what they need in a person and what kind of social support that they need.
PEP'd Up!	Increase knowledge of the difference between PEP and PrEP;	This activity presents essential facts about when and how to access and use PEP as well as ways to increase support and decrease stigma.
Pick Your Protection - The Condom Lab	Increase knowledge of the various condom types; Increase awareness of how to modify condoms for a variety of sex practices; Increase comfort to utilize condom types	Three trans health care provider custom characters walk users through various types of condoms and lubricant and ways to increase the effectiveness of use.
Pleasure Map	Increase comfort with identifying where you do and don't like being touched; Increase comfort with your own body; Increase confidence to discuss sex and sexual pleasure with a partner	This activity guides users to explore and map their own preferences for their bodies and pleasure (with or without partners). The customized map can be saved to My Creations.
Prep'n for PrEP	Increase knowledge of the how PrEP can protect women from HIV; increase awareness that PrEP is safe and effective for trans women	This activity presents a video of a trans woman talking to the user directly about the benefits of PrEP.

Activity or Feature Name	Brief Description of Focus	App functionality
Relationship Bouquet	Increase confidence to identify what is important to you in a relationship; Increase knowledge of skills to nurture intimacy	This activity asks users to select the behaviors and actions that make them feel safe in a relationship. Their personalized bouquet of characteristics is summarized at end of activity.
Safely Securing Your Bag	Increase knowledge of ways to remain safer when exchanging sex for money or other goods	Videos of trans women speaking to user providing practical and actionable tips to stay safe when engaging in sex work.
Salad Greens and COVID Vaccines	Increase awareness of vaccines and trans specific concerns; increase understanding of what a vaccine is and how they have been developed/used historically	The user experiences a virtual interview-style chat with four characters introduced in other activities discussing the COVID-19 vaccine. They reference the C.R.A.P. test to evaluate vaccine information
Sex Dice	Increase confidence to explore sexual pleasure; Increase comfort with your own body; Increase confidence to have conversations with partners about sex and sexual pleasure	This activity simulates rolling dice of body parts and types of touch to explore ways to experience pleasure. The user can customize which items are included on the dice and they are encouraged to try out the combinations on themselves or with a partner.
Sex My Way	Increase knowledge of sexual boundaries; Increase confidence to identify some of your own sexual boundaries	This activity lists different types of sexual boundaries and the user is asked to swipe left or right to indicate if that is an important sexual boundary for themselves. Their personalized list of boundaries is summarized at end of activity and can be saved to My Creations.
STI University	Increase knowledge of different STIs; increase knowledge of safer sex options for specific STIs; Increase confidence and skills through practice telling a partner that you have an STI.	This activity introduces the categories of STIs and common symptoms. The user hears a summary of someone recently diagnosed with 3 different common STIs responds to questions about symptoms and treatments.
Sticking With It: ART	Increase motivation and encouragement for ART adherence; increase understanding of U=U	This activity introduces the user to the benefits of anti-retroviral treatment for those living with HIV through vector characters speaking to the user.
Super U & Telehealth	Increase knowledge of the benefits of telehealth; increase awareness of how telehealth helps to fulfill healthcare needs; Increase awareness of telehealth's usefulness in the user's health routine(s)	This activity introduces the user to telehealth through a virtual, first person experience where the character explores what telehealth is, its pluses and challenges, the user reflects upon how they will address these challenges, sees how other trans women have identified their healthcare needs through telehealth, and

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Activity or Feature Name	Brief Description of Focus	App functionality
The Adventures of Sleutherella	Increase confidence and skills to find and evaluate health/COVID-related information to support informed decisions related to COVID mitigation, sexual health and health-care seeking practices.	ultimately provides the user with a greater sense of self-efficacy about telehealth.
Vision Board	Identify goals for the future; visualize the realization of the goals by creating an image to guide and inspire the process.	The users follow a detective character to identify and apply the "Current-Reliable-Authority-Purpose Test" to assess the reliability of COVID messaging.
Where I Draw the Line - Deciding My Boundaries	Increase knowledge of how to set relationship boundaries; increase confidence to set boundaries.	Users create a vision of the future they want using pictures, art, words, colors in a graphic interface to make a collage of what their goals look like.

b. **Attention Control Condition:** An alternate mobile app (TWC COVID only) was designed specifically for transgender women. The mobile app includes 7 interactive activities focused on COVID and COVID resources (see Table 2 for app content). The intervention/app is intended to be used regularly (e.g., two times per week) though participants control how often and when they use the app.

Table 21. TWC Control App Content.

Activity or Feature Name	Brief Description of Focus	App functionality
Super U & Telehealth	Increase knowledge of the benefits of telehealth; increase awareness of how telehealth helps to fulfill healthcare needs; Increase awareness of telehealth's usefulness in the user's health routine(s)	This activity introduces the user to telehealth through a virtual, first person experience where the character explores what telehealth is, its pluses and challenges, the user reflects upon how they will address these challenges, sees how other trans women have identified their healthcare needs through telehealth, and ultimately provides the user with a greater sense of self-efficacy about telehealth.
The Adventures of Sleutherella	Increase confidence and skills to find and evaluate health/COVID-related information to support informed decisions related to COVID mitigation, sexual health and health-care seeking practices.	The users follow a detective character to identify and apply the "Current-Reliable-Authority-Purpose Test" to assess the reliability of COVID messaging.
COVID Connections	Increase knowledge of strategies to prevent COVID transmission while dating and sex. Increase skill to develop a personal intimacy plan to identify what feels safe and appropriate dating during COVID.	Users watch a simulated dating game show and select their preferred responses from the contestants to help construct their own intimacy plan that can be saved to My Creations.
COVID Slam	Increase knowledge of COVID transmission and prevention strategies.	Users watch a simulated game show with a host and 3 trans women participants answer questions about COVID transmission and prevention.
Cards Against COVID	Increase awareness of self care practices; increase ability to identify personal strengths in face of obstacles	Users play a card game to practice different supportive strategies to respond to potentially stressful situations.
My Creations	Screenshots of all of the personalized activity summaries are stored in one location on the individual user's profile.	If the user chooses to save their personalized activity products (e.g. the orgasm movie poster, the assertive communication prescription, the list of sexual boundaries), they are privately stored. The user can choose to share, download, or review their own creations.
Salad Greens and COVID Vaccines	Increase awareness of vaccines and trans specific concerns; increase understanding of what a vaccine is and how they have been developed/used historically	The user experiences a virtual interview-style chat with four characters introduced in other activities discussing the COVID-19 vaccine. They reference the C.R.A.P. test to evaluate vaccine information

3) Study Design

a. Sample

The study is open to participants who self-identify as transgender women; report having had 2 or more sexual partners in the past 90 days with at least one of those partners having a penis; report being age 18-49 at baseline; own a smartphone; and reside in any state in the United States.

b. Screening criteria and process

Participants were invited to complete a screening survey (via Qualtrics) that assessed eligibility for the study. Those who did not meet eligibility criteria received an immediate message thanking them for this interest in the study and informing them that they were not eligible for participation. Those who met eligibility criteria were forwarded to the study consent form and asked to read and complete the form to indicate their interest in taking part.

c. Consent process

Participants who screened into the study were directed to an online consent form that explained the study expectations along with risks and benefits. Participants were asked to provide their consent if interested in taking part by clicking “yes” on the consent form and providing (add). Those who provided affirmative consent went through a further confirmation protocol to reduce the risk for bots, scams, or those out of the country to enroll. Once participants’ eligibility, consent, and geographic location (US) were confirmed, participants received a link to the baseline survey.

d. Random assignment process

The 2-arm randomized controlled trial involves randomizing individual participants using an equal allocation (allocation ratio 1:1) to receive the full TWC app or an attention control app. Participants were randomized after completing their baseline surveys using the randomizer feature of Qualtrics.

e. Baseline and follow-up data collection

The primary source of data for the outcome analyses is the self-report survey. The survey is administered four times: Baseline and at three follow-up timepoints, including 1-month, 3-months, and 6-months post-baseline.

Data collection was ongoing due to rolling enrollment. On a weekly basis, prospective participants who were screened in, consented to participate, and were determined to be a unique respondent in the United States were emailed invitations to participate in the study. These invitations sent through the Qualtrics platform contained links to the baseline survey. Weekly, study staff would review all baseline survey completions and set up invitations to take the survey 1 month later, 3 months later, and 6 months later. Qualtrics survey invitations for baseline, 1-month, 3-month and 6-month surveys were set-up with 5 automated reminders going out to non-completers (3 emails at 3, 5, and

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10 days after the survey link was sent and text message reminders at 7 and 12 days after the survey link was sent).

For those not responding to automated reminders, we used multiple follow-up strategies to encourage survey completion, including more intense follow-up by engagement specialists (trans women who did more intense follow-up via phone calls and texting), and extra time-anchored incentives to promote survey completion by a set date.

4) Analysis

Table 1. Behavioral outcomes used for primary impact analyses research questions.

Outcome name	Description of the outcome, and how it is operationalized.	Source of the measure	Timing of measure (e.g., 6 months after program ends)
i. Number of times tested for STI/HIV in past 3 months	Binary indicator for whether or not a participant has tested for an STI or HIV in the past 3 months. Yes/No response to “Have you been tested for STI in the past 3 months?”. “Yes” coded as “1” and “No” coded as “0”. “Have you been tested for HIV in the past 3 months?”. “Yes” to either question coded as “1” and “No” to both questions coded as “0”.		3 and 6 months following baseline
ii. Number of times participants report receptive condomless anal or vaginal intercourse at follow-up ^{a,b}	Count of number of times participants report receptive condomless anal or vaginal intercourse. “In the past 3 months, how many times have you had receptive vaginal or anal intercourse without you or your partner using a condom?”.		3 and 6 months following baseline

^a This outcome will be assigned a value of 0 if a respondent reported she has never had that type of sex or didn't have that type of sex in the past 3 months. This will allow for the full sample to be included in analytic models.

^b If an outcome assessing the number of times has a very skewed distribution, it may be collapsed into a dichotomous variable (0 times, 1 or more times), depending on the final distribution.

Table 2. Behavioral outcomes used for secondary impact analyses research questions.

Outcome name	Description of the outcome and how it is operationalized.	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)
i. Perceptions of social support	Average of 6 indicator variables. Responses ranged from “1 None of the time” to “5 All of the time”. Average was calculated if the		one-month, three-months,

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Outcome name	Description of the outcome and how it is operationalized.	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)
(based on mean score) at follow-up	participant answered 67% or more of the items.		and six-months post baseline
ii. Self-reported uptake of PrEP since last measurement period	The outcome is a response of “No, I have not used PrEP” or that the person has taken continuous PrEP or PrEP 2-1-1 or “don’t know/not sure.”		<u>one-month</u> , three-months, and six-months post baseline
iii. Self-efficacy in decisions around safer sex behavior (i.e., the HIV & Safer Sex: Self Efficacy Scale)	Responses range from 1 “not certain at all” to 8 “absolutely certain.” Self-efficacy scale was modified to ask about use of a “condom” rather than a barrier on an 8 item scale. Calculated if the participant reported 75% or more of the items in the scale.		<u>one-month</u> , three-months, and six-months post baseline
iv. Degree of comfort with external appearance as it relates to gender identity (i.e., the Transgender Congruence Scale, or TCS)	Average of 12-items on the TCS. Responses range from “1 strongly disagree” to “5 strongly agree” on a 12-item scale. Three questions are reverse coded: “The way my body currently looks does not represent my gender identity”; “I do not feel that my appearance reflects my gender identity” and “I am not proud of my gender identity.” Average scores were only calculated for participants who completed 75% or more of the scale items.		<u>one-month</u> , three-months, and six-months post baseline
v. Using a condom at last receptive anal intercourse or vaginal intercourse	Participants were asked “In the past 3 months, how many times have you had receptive vaginal or anal intercourse without you or a partner using a condom?”. To include the full sample participants who reported never having receptive sex were coded as “0”. Participants who reported using a condom the last time they had receptive sex were coded as “0”. Participants who reported not using a condom the last time they had receptive sex were coded as a “1”.		three- and six-months post baseline
vi. Self-reported number of visits to	Count of number of visits to a health care provider. “In the past 3 months, how many		three- and six-months

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Outcome name	Description of the outcome and how it is operationalized.	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)
a health care provider (of any type and by type)	times have you seen a health care provider for transition-related care?"; "In the past 3 months, how many times have you seen a psychiatrist/psychologist/social worker/MFT (marriage and family therapist) or other mental health care provider?" "In the past 3 months, how many times have you seen a doctor or other health care provider for any other reason (excluding mental health or transition-related care)?"		post baseline
vii. Self-reported number of contacts as/with a mentor/mentee for guidance or support	Combined count of total contacts as a mentor and/or as a mentee. "About how many times have you connected with those you mentored (your mentee or mentees) in the past month?". "About how many times have you connected with your mentor or mentors in the past month?"		three- and six-months post baseline
viii. What are participants' reactions to the full TWC app at immediate follow-up	TWC full app sub-group only per Clinical Trials.		One month post baseline
ix.			

^a If an outcome assessing the number of sexual partners has a very skewed distribution, it may be collapsed into a dichotomous variable (0 partners, 1 or more partners) or trichotomous variable (0 partners, 1 partner, 2 or more partners), depending on the final distribution.

a. Analytic sample

The analytic samples for both primary and secondary outcomes are dependent on the results of imputation of missing data. If we can successfully impute missing values (using multiple imputation) for data missing due to attrition at follow-up and item non-response, the samples will be comprised of all youth who completed a baseline survey. If this first approach is unsuccessful, we will only impute missing values due to item non-response, in which case the sample will be comprised of youth who completed both the baseline and 3-month post-program follow-up surveys.

b. Data cleaning

Missing data. We will use listwise deletion for all outcomes and only included complete cases.

Inconsistencies. Because of forced skip patterns pre-programmed into the electronic data collection devices, we expect the sexual behavior outcome data to be relatively clean within time points. *Within time* consistencies will be checked on questions asking about the type of sex had in the last 3 months and the number of times respondents had the type of sex across all partners. *Across time* inconsistency will be checked on questions asking whether respondents have ever had vaginal or anal sex. The survey asks respondents to think about the different sexual partners they have had in the past 3 months and to answer questions about the number of times they had each type of sex (vaginal, oral, and anal) with each partner and the number of times they used condoms or other barrier methods; these data are person specific, which may help recall.

Extreme values. For questions asking about the number of times a behavior occurred we will examine extreme values in the context of other responses and apply a consistent decision rule.

c. Assessment of baseline equivalence

In addition to the baseline measures of the outcomes, the following variables will be used to assess equivalence of the intervention and control groups at baseline: age, race, ethnicity, sexual orientation, and baseline measurements of the primary outcome variables. To assess equivalence between groups on each of these variables, we used regression analyses with the variable of interest as the dependent variable and the intervention indicator as the independent variable. The groups are considered not equivalent on a given variable if the *p*-value for the intervention indicator's regression coefficient is < 0.05 using the Wald test.

d. Condition crossover and contamination

An intent to treat model will be used in the analysis so that participants will be analyzed as randomized to treatment or control and followed up regardless of whether they interact with women in the other condition. The survey asks respondents if they shared the app with anyone else; we will report summary statistics on this indicator. We do not have names who they shared the app with so we cannot assess contamination.

e. Analytic approach for primary research questions

i. Model specification:

SPSS will be used to conduct the descriptive and bivariate analyses; Stata will be used to conduct the multivariable analyses. Statistical significance levels will be set at $p < .05$ unless otherwise noted.

Separate data analyses will be performed on each outcome variable named above and will progress through the following stages:

First, *descriptive analyses* will be used to explore the data on all model variables at baseline and each follow up for distributional assumptions and

unanticipated patterns that might affect subsequent analyses. For example, as noted in the outcomes table, some outcomes may need to be dichotomized if the distribution is too skewed towards 0.

Second, *bivariate analyses* will be used (1) to compare the baseline demographic and background characteristics of the intervention and control groups and (2) to test for relationships between the outcome variable and potential covariates (confounders) being measured. A potential covariate will be included in the model if: (1) the variable is associated with the condition indicator at $p < 0.15$; and (2) the variable is associated with the outcome at $p < 0.15$ in ***individual bivariate analyses***. Our plan for covariate screening is derived from those suggested in Altman (1991) and Hosmer and Lemeshow (1989). In the latter, it is suggested that $p < .25$ as a screening criterion may be more appropriate than $p < .05$ because the latter often fails to identify variables that may be important to control. We have traditionally “split the difference” and selected a $p < .15$ to preserve degrees of freedom of the model. We routinely include the baseline value of the outcome regardless of screening criteria (Pocock et al, 2002). Below, we clarify which covariates will be included regardless of these screening criteria. (4) Bivariate analyses will also be conducted to assess baseline equivalence for the final primary analytic samples.

Third, *multivariable analyses* will be conducted using regression analyses (linear or logistic) to evaluate the research questions as definitively as possible.

Each model will include an indicator variable denoting (1) intervention group, (2) the baseline outcome variable, (3) the number of days between the baseline and follow-up survey (if there is a large range), (4) the standard demographics of age at baseline and race/ethnicity at baseline, and (5) a set of *a priori* demographics and outcome-related covariates that screened positively as candidates for inclusion in the bivariate screening step.

Covariates

Covariates to be forced into all models on an *a priori* basis:

1. Baseline value of outcome
2. Adjustments for imbalances across conditions in baseline equivalence on demographic variables for those differences reaching statistical significance.

A priori covariates to be screened into the models:

1. Sexual orientation
2. Relationship status
3. Race/ethnicity
4. Age
5. Work status
6. Rural location

NOTE: if there is high correlation ($r>.5$) between some of these indicators we will not include them all.

ii. Sample attrition

Attrition analyses will be conducted to examine the rate of attrition by condition, and what characteristics might be related to attrition. Results from the attrition analyses will help evaluate the need to temper interpretations of outcome results.

iii. Adjustments for multiple comparisons (if applicable)

Adjustments for multiple comparisons will be conducted for primary outcomes using the Benjamini-Hochberg correction as outlined in the WWC Procedures Handbook v4.1.

f. Analytic approach for secondary research questions

Analyses for secondary research questions will proceed using the same steps as described for the primary research questions.

5) Additional planned analyses

Additional exploratory analyses of the impact evaluation data may include the following.

- a. Subgroup analyses based on participants in each condition who downloaded their respective apps will be completed for the primary outcome variables.
- b. Subgroup analyses by various subsets of the sample, such as those defined by race/ethnicity variables, age group, or HIV and PrEP status (e.g., PrEP uptake on those who were HIV negative and not using PrEP at baseline) may be performed similarly to those described for the main analyses.