Reducing HIV Health Disparities Among African American Transgender Women: An mHealth Approach to Improving Prevention, Testing, and Treatment Outcomes

NCT: NCT05483686

Date of Document: 5/1/2023

Reducing HIV Health Disparities among African American Transgender Women:
An mHealth Approach to Improving Prevention, Testing, and Treatment Outcomes (R44MH117837)

PROTOCOL SUMMARY FOR NEW AND CONTINUING PROTOCOLS

1. Provide a brief (200-250 word) summary of the background or statement of the problem.

One in five transgender women (TGW) in the United States is infected with HIV. The burdens of the disease are particularly onerous for African Americans. While only 16% of TGW in the U.S. are Black, more than half of all new HIV cases in TGW between 2009 and 2014 were among African Americans. In response to this crisis, the 2015 update to the National HIV/AIDS Strategy highlighted African American TGW as a key population for whom cost-effective, scalable interventions should be prioritized.

African American TGW experience a complex interaction of racism, sexism, and transphobia that often leads to discrimination, social marginalization, and institutional invalidation (e.g., restricted economic opportunities, substance use, interpersonal and institutional violence, frequent incarceration, mental health issues, unstable housing). Because of these challenges, TGW exhibit health disparities across the entire spectrum of HIV-related outcomes, including frequency of risk behaviors, uptake of pre-exposure prophylaxis (PrEP), and at all points along the HIV care continuum (i.e., testing, linkage to and retention in care, ART prescription, viral suppression).

2. State purpose of study:

Despite the urgent need for effective HIV prevention and treatment resources, only one CDC-defined evidence-based intervention (EBI) for TGW currently exists and it is limited to only those TGW who are in primary relationship with a cisgender man, willing to participate in couples-based counseling, and able to attend 3 in-person sessions. It is also not tailored to the socio-cultural life context of Black TGW. EBIs help HIV prevention planners select the most effective interventions for their communities. Without this indispensable guidance, providers will often turn to the closest analog population, MSM, and deliver those interventions to TGW. This strategy undermines TGW's gender identity, provides incomplete or inaccurate information and skills, and has led scientists, medical professionals, and public health officials to call for the development of high-impact approaches to HIV prevention, testing, and treatment designed specifically for TGW.

We intend to meet this unfulfilled need by developing **Shine**, a mobile intervention designed specifically for African American TGW that is theory-based, individually-tailored, and empowering. Based on the IMB-model, users receive three types of personalized text messages: informational, motivational, and skill-building. Based on the Model of Gender Affirmation, additional messaging provides strategies for gaining intra- and interpersonal forms of gender affirmation. These text messages are supplemented by two types of web-based videos: unscripted peer narratives and educational instruction. Links to these videos are integrated into the messaging to enhance the trans-specific understanding of gender affirmation within our IMB framework.

We plan to test the effectiveness of **Shine** in a randomized controlled trial with 215 African American TGW. Participants will be randomly assigned to receive either the mobile **Shine** intervention or a YouTube playlist of CDC-developed videos about HIV for transgender adults. Before and at 6-months post-randomization, we will assess participants' risk for HIV transmission, practice of individual recommended behaviors based on HIV status (i.e., condomless anal sex, ART adherence, PrEP interest/uptake), barriers to those behaviors, gender affirmation, and social support.

3. Indicate the total number of subjects and the number of sites:

Number of subjects: 215

Number of sites: 1 (1 recruitment partner [Trans Women of Color Collective], with recruitment occurring in person and online throughout the United States)

4. Indicate the characteristics of study population:

(a) Gender: Males yes_____ no___X__

Trans Females yes__X__ no_____

(b) Age range: from__18__ to__no upper limit__

(c) Racial and Ethnic Groups:

Caucasian	yes_____	no__X___
Black	yes__X__	no_____
Hispanic	yes__X__	no_____
American Indian	yes_____	no___X__
Alaskan Native	yes_____	no___X__
Asian/Pacific Islander	yes_____	no___X__
Other (specify) _____		

(d) Justify any exclusion of specific gender, age, and racial or ethnic groups:

Shine, the proposed intervention program, is specifically aimed at TGW. Approximately 20% of TGW in the United States are infected with HIV. While Black TGW make up only 16% of the U.S. population of TGW, they account for over half of new HIV infections. Because of this burden, and the dearth of effective, broadly disseminated interventions targeting African American TGW, **Shine** is designed specifically to improve HIV outcomes and increase access to gender affirmation in an African American population. To provide a meaningful test of this program's efficacy, only African American participants will be included in the randomized controlled trial of **Shine**.

Children will not be included in the proposed randomized controlled trial. While children younger than 18 represent an important group for HIV prevention and treatment efforts, their developing physical, cognitive, and social-emotional skills and capacities require unique HIV planning separate from adults. As such, recruitment will be limited to adults.

5. State inclusion criteria for enrollment in study:

To be eligible, participants must: 1) identify as a Black transgender woman using the recommended 2-step method (Step 1: assigned male birth sex, Step 2: current gender identity is female); 2) be aged 18 or older; 3) report risk of HIV transmission in the past 3 months (i.e., condomless anal sex with a serodiscordant or risky male partner and either inconsistent ART adherence or inconsistent PrEP use); 4) own a smartphone; and 5) be able to read and speak English.

6. State exclusion criteria for enrollment in study:

The only exclusion criterion for this project is the failure to meet the inclusion criteria described above.

7. Will vulnerable subjects be enrolled in this study?	yes___X___	no____ ___
(a) Individuals with diminished mental capacity	yes_____	no___X_
(b) children	yes_____	no___X_
(c) pregnant women	yes_____	no___X_
(d) fetuses	yes_____	no___X_
(e) economically or educationally disadvantaged persons	yes___X____	no_____
(f) prisoners	yes_____	no__X___

8. If vulnerable subjects are to be enrolled, describe the special precautions that will be taken to ensure that consent is freely given and that the rights and welfare of the subjects are protected:

We are not specifically seeking to enroll participants with any of the characteristics described in Question 7. However, due to the disadvantages faced by many Black TGW in our target population, it is likely that we will enroll participants who are economically and/or educationally disadvantaged. To protect the rights and welfare of potentially vulnerable participants, informed consent will be required for study participation and participants will be encouraged to ask any questions they may have about the study procedures. In addition, the level of compensation for this study is consistent with what has been approved by this Board with similar

populations in previous studies. Finally, the level of compensation is also consistent with what is used in similar studies by other investigative teams.

9. If the study involves children, will a Certification of Assent form be used to document that assent was freely given without coercion? yes_____ no_____
   If no, indicate how assent will be documented:
   N/A

10. Indicate where and how research data will be stored to ensure confidentiality:

At the beginning of the study, all participants will be asked to provide the study coordinator with the mobile phone number they wish to use for the research project. To distinguish this number from other contact information, it will be called the "study phone number." The study phone number will be part of the data file containing baseline and follow-up survey responses. Phone numbers will be encrypted in this file. Participants will be linked by user ID to additional information contained in the Contact File. No names will be contained with survey responses in the data file and survey responses will not contain any descriptive text (i.e. the survey questions and response options will be stored in a separate codebook).

The study phone number will also be used to send the text messages that provide participants with access to their randomly assigned materials For participants assigned to the control condition, the study phone number is where the link to the playlist of CDC videos will be sent. This text will originate from the study coordinator's project phone. For participants assigned to receive the **Shine** intervention, their "join" text will launch a check of the originating number against the study phone numbers in the data file. A request from a phone number not in the data file will be denied. This will ensure that no one other than participants assigned to receive the **Shine** intervention can access it.

To ensure the security of this personal information, all **Shine** study phone numbers will be encrypted and stored on a secure server, behind a firewall. Further, texts and active web links will be sent through a secure communication protocol HTTPS to the SMS text messaging gateway, and then on to participants' phones. This protocol protects against malicious third parties attempting to access the phone number data while information is being transferred from the SMS software application to participants' phones. All participant phone numbers will be deleted from the secure server upon completion of the field test (experimental participants) or post-study **Shine** access (control participants). Experimental group participants will complete assessment items and receive personalized feedback as part of the **Shine** intervention. A database hosted on separate server from the web application will contain a list of SMS-based replies for each response option from the assessment. Receipt of one of those response options will trigger a tailored SMS response.

While the **Shine** intervention includes sensitive information about HIV and a user's HIV status and behaviors, it is only accessible on a participant's personal mobile phone. Before engaging with the intervention, experimental participants will have the opportunity to learn how to erase the **Shine** text messages from their phones if they choose. In addition, all participants must opt-in to receiving intervention messages by sending a text message to a study-provided number. Participants will be told that they may choose to opt-out of the intervention and messages at any time. Further, our strict security strategy will include transmitting data to participants from a secure server, which reads telephone numbers and then transmits data to a personal phone through a secure communication protocol HTTPS to a SMS text messaging gateway. HTTPS will provide authentication of the third-party SMS text messaging service that the program will use to transmit the text messages, ensuring that no data (e.g., phone numbers) are intercepted by a third party.

Finally, encrypted study phone numbers will be deleted from the program files as soon as a participant's study participation is complete. For experimental participants, the study phone number will be deleted as soon as the participant completes the follow-up research survey. Control participants will be offered access to the **Shine** intervention (which requires the study phone number) after completing the follow-up research survey. These participants will have 30 days to begin interaction with the **Shine** program. If the participant has not sent the "join" text message to begin using **Shine** within that time frame, program access will close, and the study phone number will be deleted. For control participants who do engage with the **Shine** program within 30 days,

program access will close 120 days after completion of the follow-up research survey and the study phone number will be deleted.

11. Will data (e.g. records, samples, specimens, databases, surveys, etc.) be obtained with identifiers that can be directly or indirectly linked back to the subjects?

yes__X___ no__ _____

12. Indicate who will have access to information about the subjects that is identifiable:

Consent forms will be signed electronically. A password-protected excel spreadsheet (called the Contact File) will contain participants' contact information (i.e., first and last names, study phone number, secondary phone number, email address and/or mailing address based on payment preference) and a log of the time, date, and content of all interactions with participants. Further, a single linkage file will be maintained that links participant names to user ID numbers. No names will be included on the survey and only the ISA Principal Investigator and the study coordinator will have access to the linkage file. The linkage file will be stored separately from the survey data on a password-protected computer, in a password protected Excel file. Importantly, staff at TWOCC will not have access to the research survey data. In addition, no one outside the research team will have access to any information with personal identifiers and ISA will not report any data with personal identifiers.

13. Indicate how potential subjects will be identified and recruited for participation in the study:

Given the size and hard to reach nature of our target population, multiple strategies will be used to recruit participants. All recruitment will be conducted by the Trans Women of Color Collective (TWOCC). TWOCC is a national organization designed to "uplift the narratives, leadership, and lived experiences of trans people of color." A key component of these efforts is hosting and participating in events throughout the country that are designed to offer support and empowerment to African American trans women. These events include happy hours, networking and leadership seminars and retreats, art showings, activism, national and international speakers, fashion shows, and dance parties. TWOCC also uses social media to reach and connect with trans women of color throughout the country. All recruitment will be passive, with the two main recruitment strategies being in-person and online.

First, TWOCC's leadership and administrative teams will assist with recruitment during all community-based events that occur during the recruitment period. TWOCC's team members will distribute flyers describing the study at such events (see Appendix A: Study Flyer). The flyer will instruct interested women to contact the ISA study coordinator for more information and to complete eligibility screening. Similarly, if a potential participant asks a TWOCC associate for more information on the study, that associate will direct her to the contact information on the flyer. Second, TWOCC will disseminate the study flyer via the official TWOCC Facebook and Twitter profiles. The flyer will be posted on both social media channels weekly during the study recruitment period. The digital flyer will be identical to the paper flyer. Potential participants who comment on the social media posts will be instructed to contact the ISA study coordinator for more information.

14. Indicate when and where consent will be obtained:

When a potential participant has had the study described to her, meets eligibility criteria (see Appendix B: Eligibility Form), and expresses interest in enrolling in the study, the study coordinator will trigger a text to be sent to that person's study phone number. The text will include a link to an online version of the informed consent form presented on a secure webpage (i.e., communication between the phone's browser and webpage are encrypted; see Appendix C: Informed Consent Form). The study coordinator will remain on the phone during the consent process. Interested women can have the consent form read to them if they prefer. Women who agree to participate will acknowledge their consent by pressing a button at the bottom of the online consent form that reads "*ACCEPT*." Women who choose not to participate after reading the informed consent form will press a button that reads "*DECLINE*." These women will be thanked for their time and all contact will cease. All consenting participants will be sent a copy of the consent form via their preferred communication medium (e.g., text, mail, email). The consent form will detail in writing what was described by the study coordinator. In

addition, the consent form will have the name and toll-free telephone number of the Principal Investigator and the IRB Chairperson if participants have any questions.

15. Indicate how you will determine whether the subjects (or their surrogates) understand the information that was provided in the consent document:

All participants will be given the opportunity to ask questions after the study coordinator has explained the study and before they receive the informed consent text message. In addition, after reviewing the informed consent, participants will be asked again if they have any questions or want more information on any aspect of the study. Finally, all participants will be provided with the names and phone numbers of the study PI and the ISA IRB. They will be instructed to call the PI or ISA if they have questions related to requirements of participation or for questions related to the nature of the study.

16. Summarize in a narrative what actually will be done to the subjects during their participation in the study.

(A) a clear description of what is being done for research purposes and what is being done as part of standard clinical care;

All described procedures, including the completion of research surveys, the **Shine** program, and the control videos, are part of the research process. The study procedures will take place over a 6-month period. First, all consented participants will complete the baseline research survey via telephone (see Appendix D: Research Surveys), be randomized to the experimental or control condition, and review their assigned materials (either the **Shine** program or a YouTube playlist of CDC-developed videos on HIV prevention and treatment among transgender adults). While the **Shine** intervention is designed to be completed in 1-2 months, participants will have up to 3 months to complete the intervention. Three months after sending the "join" text, experimental participants' access to **Shine** will be terminated. Six months after the first research appointment, all participants will again be contacted by phone to complete the follow-up survey. After completing the follow-up survey, participants in the control condition will have access to the **Shine** program. Please see Appendix E: Study Protocol for more information on these procedures. In addition, please see Appendix F: Reminder Protocol and Appendix G: Retention Protocol for details on additional contact with participants.

(B) a list of tests and procedures that will be performed for research purposes (e.g. blood tests, urine tests, cultures, interviews, questionnaires, surgical procedures, cardiac catheterization, pulmonary function tests, X-rays, scans, etc.);

Please see Appendix D: Research Surveys for all research items.

(C) a brief description of the analyses that will be performed on the biologic or non-biologic (i.e. questionnaires) samples collected

The data will derive from a randomized controlled trial (RCT) with random assignment of individual participants to one of two study conditions (intervention vs. control). Data will be collected at baseline and at 6 months post-baseline. The primary outcome measure is a binary composite HIV transmission risk score. This dichotomous metric is calculated by measuring whether a participant or her partner consistently used at least one effective method for reducing HIV transmission risk (i.e., adherence to biomedical [ART or PrEP] and behavioral [condoms, serosorting] strategies) during each instance of anal sex over the past month. Every anal sex act must be protected by one of these methods to receive an overall composite score of 0. The individual behavioral components of the composite score (i.e., percentage of condomless anal sex, serosorting, PrEP or ART adherence) will serve as secondary measures. In addition, specific outcomes by HIV status will include HIV medical care utilization and adherence, HIV testing, and PrEP knowledge, interest, and uptake. Finally, further secondary measures will assess gender affirmation, well-being, social support, and sexual communication. All measures are self-report and assessed using established scales that have evidence of reliability and validity.

Binomial logistic regression will be the main analytic technique for the primary outcome (composite HIV transmission risk score) and other non-continuous measures. For continuous measures, hierarchical linear modeling (HLM) will be used. All models will control for any demographic covariate (e.g., age) that varies at the .2 significance level due to randomization failure at baseline.

(D) a list of investigational devices that will be used, indicate if they are classified as significant risk (SR) or non-significant risk (NSR) devices and whether there is an IDE or there is an application to the FDA for an IDE if the device is SR;

N/A

(E) a statement that defines who will be financially responsible for the costs associated with participation in the study (e.g. examinations, procedures, drugs, devices, etc.) and a statement that defines what will be provided without cost to the subjects;

ISA will be responsible for all costs. Participants will be provided access to the **Shine** program and up to $175 in cash incentives.

(F) your assessment of whether the research involves any physical, psychological, social and/or economic risk(s) and the magnitude of the risk(s);

We believe that the potential risks of collecting the survey data are small. It is possible that as a result of completing the research survey questions, a participant may learn that her behavior puts her at risk for negative HIV-related outcomes (i.e., contracting HIV or worsening disease, depending on status). This realization may be accompanied by distress. If this should occur during survey administration, participants will be encouraged to discuss their concerns with a health care provider. They will also be provided with a list of resources in the informed consent that can provide information about HIV. Further, a participant may become uncomfortable when responding to questions regarding her health history. To minimize this risk, the questions will be phrased in ways to minimize any potential discomfort and participants will be free to skip any question they do not wish to answer. Further, the research team is using survey items that have been successfully used in past research with similar populations. Finally, users will complete the surveys via telephone call and their names will never be associated with their survey responses. These confidentiality measures should also serve to reduce any potential risk to participants.

We also believe that the potential risks of going through either the experimental or control conditions are small. It is possible that, as a result of reviewing either the **Shine** or control materials, a participant may learn that her behavior (e.g., inconsistent adherence to ART; condomless anal sex) may put her at risk of poorer HIV-related outcomes. These realizations may be accompanied by distress. If this should occur, participants will be encouraged to discuss their concerns with a health care provider. The informed consent will also provide information on alternative methods for receiving the type of information available in the **Shine** intervention and control materials.

(G) your assessment of the risk/benefit ratio of the research;

There are several benefits to participating in the proposed research to both the research participants and others. The first is the development of a state-of-the-art mobile intervention that can provide participants with valuable tailored information about HIV within a gender-affirming and empowering context. Because the intervention is mobile, the information can be accessed at a time and place of the user's choosing. This information should not only be of interest to participants but also help them understand the importance of biomedical and behavioral strategies in protecting their health. This research also has the potential to benefit many other Black TGW, as ISA will use participant input to make changes in the design of the **Shine** intervention to better meet the needs of the larger community of African American TGW. Given that the potential risks are very small, the risk to participants seems quite reasonable in relation to the benefits.

NOTE:

a) Data and patient safety monitoring: if required, a Data and Safety Monitoring Board (DSMB), which must be convened by the PI, can be made up of internal and/or external members who have the appropriate expertise and are totally independent of and unaffiliated with the study. The composition of the DSMB should be commensurate with the complexity of the proposed study and will be reviewed by the IRB. Approval of the DSMB by the IRB is required prior to initiating the clinical trial.

A Data and Safety Monitoring Board is not necessary for the proposed research because it does not meet the definition of a Phase III Clinical Trial and poses no more than minimal risk.